The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and they are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale thereof is not permitted.

# PROSPECTUS SUPPLEMENT (To the Prospectus dated January 15, 2015)

Subject to completion dated March 18, 2015

### **Shares**



# Assembly Biosciences, Inc. Common Stock

Assembly Biosciences, Inc. is offering shares of common stock.

Our common stock is listed on The NASDAQ Capital Market under the symbol "ASMB". The last reported sale price of our common stock on The NASDAQ Capital Market on March 17, 2015, was \$13.70 per share.

To the extent that the underwriters sell more than shares of common stock, the underwriters have the option for a period of 30 days from the date of this prospectus to purchase up to an additional shares from us at the public offering price less the underwriting discount.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page S-7 of this prospectus supplement and on page 7 of the accompanying prospectus for a discussion of information that should be considered in connection with an investment in our securities.

	Price to Public	Underwriting Discounts and Commissions <sup>(1)</sup>	Proceeds to Assembly Biosciences
Per Share	\$	\$	\$
Total	\$	\$	\$

(1) We have agreed to reimburse the underwriters for certain expenses. See "Underwriting."

The underwriters expect to deliver the shares of common stock to investors on or about March , 2015.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

**Credit Suisse** 

William Blair

The date of this prospectus supplement is March , 2015.

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### ABOUT THIS PROSPECTUS SUPPLEMENT

On November 26, 2014, we filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-3 (File No. 333-200612) utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement, as amended, was declared effective on January 15, 2015.

This prospectus supplement describes the specific terms of an offering of our securities and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part, the accompanying prospectus, provides more general information. If the information in this prospectus supplement is inconsistent with the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement.

In making your investment decision, you should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus and any relevant free writing prospectus. We have not authorized anyone to provide you with any other information. If you receive any information not authorized by us, you should not rely on it. We are not making an offer to sell the securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained or incorporated by reference in this prospectus supplement or the accompanying prospectus or any relevant free writing prospectus is accurate as of any date other than its respective date.

It is important for you to read and consider all of the information contained in this prospectus supplement and the accompanying prospectus in making your investment decision. We include cross-references in this prospectus supplement and the accompanying prospectus to captions in these materials where you can find additional related discussions. The table of contents in this prospectus supplement provides the pages on which these captions are located. You should read both this prospectus supplement and the accompanying prospectus, together with the additional information described in the sections entitled "Where You Can Find More Information" and "Incorporation of Certain Information by Reference" of this prospectus supplement, before investing in our securities.

We are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the securities in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This prospectus supplement, the accompanying prospectus and the documents we have filed with the SEC that are incorporated herein and therein by reference contain such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.

Words such as "may," "might," "should," "anticipate," "estimate," "expect," "projects," "intends," "plans," "believes" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management's current judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to:

- our expectations regarding preclinical studies and clinical trials, the timing of preclinical and clinical results, development timelines and regulatory filings and submissions for our product candidates;
- · our liquidity and our expectations regarding our needs for and ability to raise additional capital; and
- the amount, and our expected uses, of the net proceeds of this offering.

Please also see the discussion of risks and uncertainties under "Risk Factors" beginning on page S-Z of this prospectus supplement and page Z of the accompanying prospectus, and in our most recent Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC and which is incorporated herein by reference.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus supplement or the accompanying prospectus or in any document incorporated herein or therein by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus supplement or the accompanying prospectus or the date of the document incorporated by reference herein or therein. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

### PROSPECTUS SUPPLEMENT SUMMARY

The following summary is qualified in its entirety by, and should be read together with, the more detailed information and financial statements and related notes thereto appearing elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. Before you decide to invest in our securities, you should read the entire prospectus supplement and the accompanying prospectus carefully, including the risk factors and the financial statements and related notes included or incorporated by reference in this prospectus supplement and the accompanying prospectus.

### **Business Overview**

We are a biopharmaceutical company committed to developing novel oral therapies for the cure of intractable infectious diseases, focusing on hepatitis B virus (HBV) and C. difficile-associated infections (CDAD). On July 11, 2014, Assembly Biosciences was formed by the merger of private company Assembly Pharmaceuticals, Inc. and Nasdaq-listed Ventrus Biosciences, Inc. The merger resulted in a shift in strategic focus, the addition of a new lead drug development program for the company, and changes in personnel.

Assembly Pharmaceuticals was founded in 2012. The cure for HBV is based on the research and intellectual property of Indiana University professor Adam Zlotnick, PhD. Dr. Zlotnick is a pioneer in the biophysics of viral capsid assembly and in elucidating the role of core protein in HBV. His decades of research and development of novel screening technologies led to the discovery of multiple families of small molecule CpAMs. Other founders of Assembly include Chief Medical Officer and Vice President of Research & Development Uri Lopatin, MD, who previously led the HBV programs at Gilead Sciences and Roche Pharmaceuticals. We believe Assembly is well positioned to develop its two lead programs, with a senior scientific team that has over 30 years of combined experience working on HBV and a proven track record of innovation using deep science.

The team has collectively discovered more than 20 clinical candidates and 10 marketed drugs.

The target of our lead program is a clinical cure for HBV, a pathogen that infects 350 million people worldwide and is associated with an estimated 650,000 deaths each year. Assembly has discovered and is developing a series of new compounds, known as core protein allosteric modulators, or CpAMs, with the potential to modulate the HBV core protein—a polyfunctional essential viral protein—at multiple complementary points in the viral lifecycle. These core proteins are involved in several steps of the HBV lifecycle and are essential for HBV's continued regeneration and survival. Modulation of these core proteins with Assembly's CpAMs has demonstrated preclinical proof of principle and multiple cell-based models have shown that CpAMs can selectively reduce the production of viral antigens—viral proteins responsible for common symptoms related to HBV—as well as reduce viral load—the amount of infectious viral particles circulating in the bloodstream. Our CpAMs have multiple differentiated mechanisms and molecules, giving us a potential pipeline of differentiated early-stage products. This enables us to pursue both mono and combination therapies that have differentiated mechanisms, potentially facilitating the achievement of improved cure rates. Our goal is to develop single agents and combinations of anti-HBV therapeutics that will permanently eradicate the HBV infection

Our microbiome program, which we are pursuing as a treatment for CDAD, is based on the targeted delivery of novel microbiome-based therapies in a proprietary oral formulation, 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 several types of beneficial bacteria, in novel "synthetic formats", to the gastrointestinal, or GI, tract. The technology builds upon experience reported in the literature of successfully treating CDAD with fecal material transplant, or FMT, and seeks to provide a potentially curative therapy using a targeted and specific microbiome therapy delivered in an oral capsule.

We currently have administrative offices in New York City and research facilities in 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 Pharmaceuticals co-founder and head of our HBV Scientific Advisory Board, working closely with a local contingent of Assembly employees focused on rapidly and efficiently translating pharmaceuticals scientific advances into drug discovery approaches.

## **Business Strategy**

Assembly Biosciences is committed to 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 certain intractable conditions. This commitment drives our efforts to develop novel approaches to treating HBV and CDAD. Assembly is forging a new and different path to treating these conditions, inspired by the needs of millions of affected patients and by our belief that our novel science may have the potential to overcome the limitations of conventional approaches. We have two promising proprietary technology platforms, and a portfolio of novel, potentially curative drugs for HBV and CDAD infections, both of which currently are intractable. We intend to progress these program portfolios using a variety of strategic arrangements, including potential collaborations, licenses, partnerships and other types of business arrangements. These may provide non-dilutive resources for drug development, as well as clinical development and commercial expertise.

### **HBV-Cure Program**

Our HBV-Cure research team is working on discovering and developing multiple core protein allosteric modifiers (CpAMs) with the potential to modulate the HBV core protein—a polyfunctional essential viral protein—at multiple complementary points in the viral lifecycle. 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 and is a leading cause of chronic liver disease and liver transplants worldwide. HBV is an underappreciated global epidemic—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 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 mortality and morbidity rate than hepatitis C virus and HIV infections combined. An estimated 650,000 people die every year from HBV-related causes. While many patients currently receive treatment for their HBV infections, the majority do not, partly as a byproduct of the lack of effective treatments. The cure rate with current therapies is estimated at only 3–5%. Despite the low rate of diagnosis and drug 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 launched.

### **Current Treatments**

Current therapeutic options for HBV include:

- **Antiviral medications**. Several antiviral medications—including lamivudine (Epivir), adefovir (Hepsera), telbivudine (Tyzeka) and entecavir (Baraclude)—can help fight the virus and slow its ability to damage the liver.
- **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 get pregnant within a few years. It's given by injection. Side effects may include depression, difficulty breathing and chest tightness.
- **Liver transplant**. If the liver has been severely damaged, a liver transplant may be an option. During a liver transplant, the surgeon removes the damaged liver and replaces it with a healthy liver. Most transplanted livers come from deceased donors, though a small number come from living donors who donate a portion of their livers.

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

HBV is a DNA-virus that establishes an intra-nuclear reservoir of closed circular covalent DNA (cccDNA) that sustains infection in the liver through chronic and occult hepatitis B. No current oral therapies can target its activity directly, and thus molecules that can modulate cccDNA are highly sought in the HBV

field. The HBV Core (HBc) protein is a highly conserved viral 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—small molecules that directly target and allosterically modulate HBc functions. Assembly's HBV pipeline offers 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 diversity of approaches to HBc provides us a solid position to develop a foundation for a clinical cure of 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 anything targeting HBV from the point of capsid formation to release of viral particles from the cell for re-infection. Molecules that modulate core protein capsid alone present a downstream target approach and are unlikely to be curative on their own. We believe that our ability to develop multiple CpAms that target both the downstream and upstream aspects of the viral lifecycle will allow us to develop multiple combination regimens that will target "upstream" as well as "downstream" components of the HBV life cycle. Other core competencies and competitive advantages we bring to our lead program include our knowledge of HBV biology, our proprietary enabling assays, our world class chemistry and our relevant clinical expertise.

A clinically and preclinically accepted benchmark for therapeutic agents with an effect on cccDNA activity is thought to be expression of viral antigens. In this regard, Assembly's CpAMs have shown preclinical proof of principle. In a variety of cell culture molecules, CpAMs have demonstrated the ability to reduce viral antigens: HBV E antigen (HBeAg) and HBV S antigen (HBsAg). Sustained (off treatment) inhibition of HBsAg in patients is considered a functional cure, and is a key endpoint in clinical development.

Our clinical strategy encompasses testing CpAMs as monotherapy and in combination. Our access to multiple classes can allow us to explore the activity of CpAMs in combination both across CpAM classes and with other classes of HBV therapies. Our planned clinical program includes 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 nucleoside polymerase inhibitors. The Phase II studies will 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 select first generation lead molecules in the 2015-early 2016 timeframe and initiate clinical trials in 2016. Assembly's CpAM platform also offers a multi-generation pipeline and Assembly plans to advance second and third generation CpAMs into clinical development in 2016–2017. Assembly also has research programs looking at other novel targets for HBV that are complementary in nature to our core protein programs.

## Microbiome Platform (CDAD)

## **Background**

In recent years, there has been increasing interest in the 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 CDAD, the most common nosocomial, or hospital acquired, infection, which is a significant medical problem in hospitals and long-term care facilities as it becomes increasingly resistant to common antibiotics. CDAD is estimated to afflict more than 500,000 people each year in the US. 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 of the colon, 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 CDAD. Patients typically develop CDAD 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 and excretes spores into the hospital environment that can survive for months on dry surfaces in hospital rooms such as beds and doors. It also spreads when contamination from other patients is transmitted through the hands and clothing of healthcare workers.

### **Current Treatments**

Therapeutic options for CDAD 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., there are more than 800,000 treatments per year for CDAD.

### **Our CDAD Focus—Microbiome Therapeutics**

There has been considerable experience reported in the literature of successfully treating CDAD with fecal material transplants (FMT) from healthy individuals. FMT is believed to act by restoring a healthy balance of microbes in the gut. But use of FMT, because of the possibility of unknown and potentially damaging constituents, is problematic, and other options have been sought. Preliminary CDAD 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 CDAD 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 CDAD.

The concept has also been validated in animal studies. Several publications in recent years have demonstrated that administering even a few strains of bacteria may be sufficient to have a curative effect in mouse models of CDAD, 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 CDAD 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), might be effective in providing 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 CDAD patients who have failed antibiotic treatment at least three times.

However, we believe that the development of a 'synthetic' bacterial product for the treatment of CDAD, 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 CDAD patients receiving FMT, use of machine learning-derived predictive algorithms, culturing, and, screening of promising strains, and confirmation in an animal model of CDAD.

A second challenge is the effective and reliable oral delivery of billions of organisms to the colon using only a few capsules. To accomplish this, we in-licensed a delivery technology we call GemicelTM. Gemicel is a novel coating and encapsulation technology that allows controlled delivery of an oral formulation specifically targeted for pulsed release in the pH environment of selected portions of the GI system.

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 to represent conditions in each section of the GI tract lumen, the formulation can deliver its contents to the targeted sites. We are conducting a radiolabelled scintigraphy study in humans to further validate this technology and we expect results in mid-year 2015.

A third challenge is to be able to process, scale up, and reliably and economically manufacture for clinical trials and, ultimately, commercialization, the strains we select for use in CDAD. There is considerable experience in industrial scale production of bacteria under GMP, and there are several commercial scale vendors. 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 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 CDAD using selected, identified 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 CDAD patients who have relapsed after three or four standard antibiotic regimens. We will explore various regimens for further clinical development in these initial studies. We estimate that the first clinical trial will begin in the first half of 2016, with data available in late 2016 or early 2017

Our Gemicel technology also has the potential to deliver viral antigens to immune responsive tissue in gut, with the potential to improve existing oral vaccines or to allow oral delivery of vaccines that are currently limited to intra-nasal or systemic delivery. We will be conducting experiments in animal models to assess whether oral administration of certain vaccines using Gemicel creates effective immune responses. If the technology were successful in this indication, we plan to license this application to a major vaccine manufacturer. We expect results from this program in the first half of 2016.

Depending on the progress and success of our CDAD 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 illnesses.

### **Company History**

On July 11, 2014, we merged with Assembly Pharmaceuticals Inc. in a reverse triangular merger with our wholly owned subsidiary, which we refer to as the Assembly Merger. In connection with the Assembly Merger, on July 11, 2014, we changed our name from Ventrus Biosciences, Inc. to Assembly Biosciences, Inc. 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).

### **Corporate Information**

Our executive offices are at 99 Hudson Street in New York, NY, 10013, and our research facility is at 953 Indiana Street, in San Francisco, CA 94103. Our telephone number is (646) 706-5208, and our website address is www.assemblybio.com. The information contained on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus supplement.

As used in this prospectus supplement, unless the context otherwise requires, references to "Assembly," "we," "us," "our" and similar references refer to Assembly Biosciences, Inc. and our wholly owned subsidiary Assembly Pharmaceuticals, Inc.

## The Offering

Common stock offered by us shares of common stock.

**Option to purchase additional shares**We have granted the underwriters an option for a period of 30 days to purchase

up to an additional shares of common stock.

Common stock to be outstanding immediately after this offering

shares of common stock.

*Use of proceeds* We intend to use the net proceeds from this offering for general corporate

purposes, including funding our preclinical and clinical research and development activities and for working capital. See "Use of Proceeds" on page

S-<u>26</u>.

*Risk factors* See "Risk Factors" beginning on page S-7 of this prospectus supplement and

other information included or incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of factors you

should carefully consider before investing in our securities.

NASDAQ Capital Market Trading symbol

"ASMB"

The number of shares of our common stock to be outstanding immediately after this offering is based on 10,672,059 shares outstanding as of December 31, 2014, and does not include, as of that date:

- 3,249,651 shares of our common stock subject to outstanding options having a weighted average exercise price of \$6.26 per share; and
- 270,761 shares of our common stock issuable upon the exercise of outstanding warrants having a weighted average exercise price of \$24.34 per share.

Unless otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their option to purchase up to an additional shares of our common stock.

### RISK FACTORS

Investing in our common stock involves risk. Before deciding whether to invest in our common stock, you should consider carefully the risks and uncertainties described below. You should also consider the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K which is on file with the SEC and is incorporated herein by reference. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section above entitled "Cautionary Statement Regarding Forward-Looking Statements."

### **Risks Related to Our Business**

### We have no approved products and currently are dependent on the success of our HBV and microbiome therapies.

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.

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 and 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 us, 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 our product candidates, our HBV and microbiome therapies, both of which are in preclinical development. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, either of our current or any of our other product candidates.

Our HBV and microbiome therapies are our only current product candidates. Both are in pre-clinical development stages. 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 United States 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, 2014, the combined company had an accumulated deficit of \$139.7 million. Net cash outflows after the Assembly Merger was approximately \$7.5 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.

## Pre-clinical testing and clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

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. 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. 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. These same risks apply to our planned development of our current and any other product candidates.

### 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 early stages of 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.

# The results of both ongoing and future studies and trials for any of our product candidates might not be predictive of the results in any future studies or trials.

The results of any earlier study or trial for any of our product candidates may not be predictive of the results for any future studies or trials. Further, 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. In addition, unforeseen safety issues could emerge in any future study or trial, which could severely hamper the likelihood of FDA or other regulatory approval of any product candidate. If any of these events were to occur, the development of any product candidate could be significantly delayed and 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.

## 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 program 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 second quarter of 2016. 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, 2014 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 therapy is advantageous. If that collaboration is not maintained, we may not be able to capitalize on the market potential of our HBV therapy.

Dr. Adam Zlotnick is the founder of our HBV therapy. We have entered into a three-year consulting agreement with Dr. Zlotnick 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 three-year term expires 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.

### 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

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.

## 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. We have not yet tested our HBV therapy or our microbiome therapy in clinical trials and safety issues could arise during that planned testing or testing of any other product candidates. If a product is approved, any limitation on use that might be necessary 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 are reliant on the services of these third parties to conduct studies on our behalf. If we are unable to continue with or retain 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. 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 might not 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 CDAD 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, CDAD 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 an 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.

### Physicians and patients might not accept and use our drugs.

Even if the FDA approves one of our product candidates, physicians and patients might not accept and use it. Acceptance and use of our products will depend upon a number of factors, including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our product;
- cost-effectiveness of our product relative to competing products or therapies;
- availability of reimbursement for our product from government or other healthcare payors; and
- effective marketing and distribution efforts by us and our licensees and distributors, if any.

If our current product candidates are approved, we expect sales to generate substantially all of our revenues for the foreseeable future, and as a result, the failure of these products to find market acceptance would harm our business and would require us to seek additional financing.

# 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 United States, 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 United States. 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 United States. 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.

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. Lee D. Arnold, and our Chief Financial Officer and Chief Operating Officer, David J. Barrett. Our employment agreements with Mr. Small, Dr. Lopatin, Dr. Arnold 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 cannot enforce non-compete and confidentiality provisions applicable to our employees and consultants, our business might materially suffer.

We include a non-compete provision in any employment agreement we enter into with an employee, including those for Messrs. Small, Barrett, Lopatin and Arnold, that runs during the term of the agreement and for a period of time after termination, depending on the individual.

We include a confidentiality provision in any employment or consulting agreement we enter into with an employee or a consultant. The confidentiality provision runs during the term of the agreement and thereafter without limit.

For future employees with whom we do not enter into an employment agreement, we will enter into a confidentiality agreement with the same provisions described above.

To be able to enforce these non-compete and confidentiality provisions we would need to know of any 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 non-compete and confidentiality provisions could have an adverse effect on our business.

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

As of February 28, 2015, we had 21 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, government regulation, 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 must 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 of 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. For example, the FDA proposed that we include an additional treatment arm in our pivotal Phase III trial for our former product candidate iferanserin, which increased the cost of that trial.

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.

### 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' drugs 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. A successful product liability claim 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 United States and abroad related to our novel technologies and medicines 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 medicines 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.

We might be involved from time to time in litigation to determine the enforceability, scope and validity of our proprietary rights. Any such litigation could result in substantial cost and divert management's attention from our operations.

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 we infringe the rights of third parties we might have to forgo selling our future products, pay damages, or defend against litigation.

If our product candidates, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we might have to:

- obtain licenses, which might not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate;

- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- · pay damages; and/or
- defend litigation or administrative proceedings which might be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Any of these events could substantially harm our earnings, financial condition and operations.

### **Risks Related to Our Common Stock**

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

Our common stock is listed on The NASDAQ Capital Market under the symbol "ASMB." We might not be able to maintain the listing standards of that exchange. If we fail to maintain the listing requirements, our common stock might trade on the OTC Bulletin Board or in the "pink sheets" maintained by 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 17, 2015, 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 you from being able to sell your shares of our common stock at or above the price you 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 17, 2015, our executive officers, directors and one of our founders beneficially owned approximately 28% of our outstanding voting common stock. Therefore, these stockholders have the ability to influence us through their ownership position. These stockholders may be able to determine the outcome of all 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.

## **Risks Related to This Offering**

Our management will have broad discretion over the use of the net proceeds from this offering and we may use the net proceeds in ways with which you disagree or which do not produce beneficial results.

We currently intend to use the net proceeds from this offering for general corporate purposes, including funding our preclinical research and clinical research and development activities and working capital. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us or our stockholders. The failure of our management to use such funds effectively could have a material adverse effect on our business, prospects, financial condition, and results of operation.

Following this offering, our executive officers, directors and principal stockholders will continue to own a significant percentage of our stock and may be able to control matters submitted to stockholders for approval.

Upon completion of this offering, our executive officers, directors and a founder will continue to own a significant percentage of our outstanding common stock, which percentage could increase upon the exercise of options held by some of these individuals. As a result, if these stockholders were to choose to act together, they could exert significant influence on our management and affairs as well as matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that you may desire.

# A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act. In addition, as of December 31, 2014, 2,898,760 shares of our common stock are issuable upon exercise of outstanding options and warrants.

### You will experience immediate dilution in the book value per share of the securities you purchase in this offering.

Because the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on a public offering price of \$ per share, and a net tangible book value per share of our common stock of \$1.58 as of December 31, 2014, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$ per share in the net tangible book value of the common stock you purchase. See "Dilution" for a more detailed discussion of the dilution you will incur if you purchase our securities in this offering.

# If you purchase the securities sold in this offering, you may experience dilution if we issue additional equity securities in future fundraising transactions.

If we issue additional common stock, or securities convertible into or exchangeable or exercisable for common stock, our stockholders, including investors who purchase shares in this offering, will experience dilution, and any such issuances may result in downward pressure on the price of our common stock.

### USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of common stock we are offering will be approximately \$ million (or approximately \$ million if the underwriters exercise in full their option to purchase additional shares of common stock), after deducting the estimated underwriting discounts and commissions and estimated offering costs payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations. We expect to use the net proceeds of this offering to fund our preclinical and clinical research and development activities, working capital and general corporate and administrative expenses.

The amounts and timing of our use of the net proceeds from this offering will depend on a number of factors, such as the timing and progress of our research and development. As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. Accordingly, our management will have broad discretion in the timing and application of these proceeds. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short-term, interest-bearing instruments.

## DIVIDEND POLICY

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. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors our board deems relevant.

### **DILUTION**

If you purchase shares in this offering, your interest will be diluted to the extent of the difference between the offering price per share of our common stock and the net tangible book value per share of our common stock after this offering. Our net tangible book value as of December 31, 2014, was \$16.8 million, or \$1.58 per share of common stock. "Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares of common stock outstanding.

After giving effect to the sale by us of shares of our common stock offered in this offering at an offering price of \$ per share, and after deducting the underwriting fees and \$125,000 of estimated offering expenses that we will pay, our net tangible book value as of December 31, 2014, would have been approximately \$ million, or \$ per share of common stock. This amount represents an immediate increase in net tangible book value of \$ per share to existing stockholders and an immediate dilution of \$ per share to purchasers in this offering.

The following table illustrates dilution:

Offering price per share	\$
Net tangible book value per share as of December 31, 2014	\$ 1.58
Increase in net tangible book value per share after this offering	\$
Pro forma net tangible book value per share after this offering	\$
Dilution per share to new investors in this offering	\$

The above table is based on 10,672,059 shares outstanding as of December 31, 2014 and excludes, as of that date:

- 3,249,651 shares of our common stock subject to outstanding options having a weighted average exercise price of \$6.26 per share; and
- 270,761 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$24.34 per share.

To the extent that any outstanding options or warrants are exercised, new options are issued under our 2014 Stock Incentive Plan, or we otherwise issue additional shares of common stock in the future, at a price less than the public offering price, there will be further dilution to new investors.

If the underwriters exercise their option to purchase additional shares of our common stock or if any additional shares are issued in connection with outstanding options or warrants, there will be additional dilution.

## **DESCRIPTION OF SECURITIES**

In this offering, we are offering — shares of common stock. The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption "Description of Common Stock" starting on page <u>27</u> of the accompanying prospectus.

### UNDERWRITING

Under the terms and subject to the conditions contained in an underwriting agreement dated March , 2015, we have agreed to sell to the underwriters named below, for whom Credit Suisse Securities (USA) LLC and William Blair & Company, L.L.C. are acting as representatives, the following respective numbers of shares of common stock:

Underwriter	Shares
Credit Suisse Securities (USA) LLC	
William Blair & Company, L.L.C.	
Total	

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock in the offering if any are purchased, other than those shares covered by the over-allotment option described below. The underwriting agreement also provides that if an underwriter defaults the purchase commitments of non-defaulting underwriters may be increased or the offering of common stock may be terminated.

We have granted the underwriters a 30-day option to purchase up to additional shares of common stock from us at the initial public offering price, less the underwriting discounts and commissions. The option may be exercised only to cover any overallotments of common stock.

The underwriters propose to offer the shares of common stock initially at the public offering price on the cover page of this prospectus supplement and to selling group members at that price less a selling concession of up to \$ per share. After the initial public offering, the public offering price and selling concession may be changed by the representatives.

The following table summarizes the compensation and estimated expenses we will pay.

	Per	Per Share		Total	
	Without Over-allotment	With Over-allotment	Without Over-allotment	With Over-allotment	
Underwriting Discounts and					
Commissions paid by us	\$	\$	\$	\$	
Expenses payable by us	\$	\$	\$	\$	

We have agreed to reimburse the underwriters for all expenses and fees related to the review by the Financial Industry Regulatory Authority up to \$ .

We have agreed that we will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act of 1933 (the "Securities Act") relating to, any of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, without the prior written consent of the representatives for a period of 90 days after the date of this prospectus, subject to certain customary exceptions. However, in the event that either (1) during the last 17 days of the "lock-up" period, we release earnings results or material news or a material event relating to us occurs or (2) prior to the expiration of the "lock-up" period, we announce that we will release earnings results during the 16-day period beginning on the last day of the "lock-up" period, then in either case the expiration of the "lock-up" will be extended until the expiration of the 18-day period beginning on the date of the release of the earnings results or the occurrence of the material news or event, as applicable, unless the representatives waive, in writing, such an extension.

Our officers and directors have agreed that they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, enter into a transaction which would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any of these transactions are to be settled by delivery of our common stock or such other securities, in cash or otherwise, or publicly disclose the

intention to make any such offer, sale, pledge or disposition, or to enter into any swap, hedge or other arrangement, without, in each case, the prior written consent of the representatives for a period of 90 days after the date of this prospectus, subject to certain customary exceptions. However, in the event that either (1) during the last 17 days of the "lock-up" period, we release earnings results or material news or a material event relating to us occurs or (2) prior to the expiration of the "lock-up" period, we announce that we will release earnings results during the 16-day period beginning on the last day of the "lock-up" period, then in either case the expiration of the "lock-up" will be extended until the expiration of the 18-day period beginning on the date of the release of the earnings results or the occurrence of the material news or event, as applicable, unless the representatives waive, in writing, such and extension.

We have agreed to indemnify the underwriters against liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in that respect.

Our common stock is listed on the NASDAQ Global Select Market, under the symbol "ASMB".

In connection with the offering the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions, and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934 (the "Exchange Act").

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by either exercising their over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, that position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock
  originally sold by such syndicate member are purchased in a stabilizing transaction or a syndicate covering transaction to
  cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock. As a result the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The Nasdaq National Market and, if commenced, may be discontinued at any time.

A prospectus in electronic format may be made available on the web sites maintained by one or more of the underwriters, or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations.

### Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates may in the future provide a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

## Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area that has implemented the Prospectus Directive, each, a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in such Relevant Member State, or the Relevant Implementation Date, shares of our common stock will not be offered to the public in that Relevant Member State prior to the publication of a prospectus in relation to the common stock that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of common stock may be made to the public in that Relevant Member State at any time:

- (a) to any legal entity that is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the manager for any such offer; or
- (c) in any other circumstances that do not require the publication by us of a prospectus pursuant to Article 3(2) of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of common stock to the public" in relation to any common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common stock to be offered so as to enable an investor to decide to purchase or subscribe the common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

### Notice to Prospective Investors in the United Kingdom

Our common stock may not be offered or sold and will not be offered or sold to any persons in the United Kingdom other than persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or as agent) for the purposes of their businesses and in compliance with all applicable provisions of the Financial Services and Markets Act 2000, or FSMA, with respect to anything done in relation to our common stock in, from or otherwise involving the United Kingdom.

In addition, each underwriter:

- (a) has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) to persons who have professional experience in matters relating to investments falling with Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which section 21 of FSMA does not apply to us; and
- (b) has complied with, and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the shares of common stock in, from or otherwise involving the United Kingdom.

### Notice to Prospective Investors in Switzerland

This document is not intended to constitute an offer or solicitation to purchase or invest in the shares described herein. The shares may not be publicly offered, sold or advertised, directly or indirectly, in, into or from Switzerland and will not be listed on the SIX Swiss Exchange or on any other exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares constitutes a prospectus as such term is understood pursuant to article 652a or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any other regulated trading facility in Switzerland, and neither this document nor any other offering or marketing material relating to the shares may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, nor the Company nor the shares have been or will be filed with or approved by any Swiss regulatory authority. The shares are not subject to the supervision by any Swiss regulatory authority, e.g., the Swiss Financial Markets Supervisory Authority FINMA (FINMA), and investors in the shares will not benefit from protection or supervision by such authority.

## **LEGAL MATTERS**

The validity of the securities being offered hereby will be passed upon by Wyrick Robbins Yates & Ponton LLP, Raleigh, North Carolina. Goodwin Procter LLP, New York, New York, is acting as counsel for the underwriters in connection with this offering.

## **EXPERTS**

The balance sheets of Assembly Biosciences, Inc. as of December 31, 2014 and 2013 and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2014, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference, which report expressed an unqualified opinion on the financial statements. Such financial statements have been incorporated herein by reference in reliance on the report of EisnerAmper LLP given upon their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC's web site at http://www.sec.gov. Our common stock is listed on The NASDAQ Capital Market, and you can read and inspect our filings at the offices of the Financial Industry Regulatory Authority, Inc. at 1735 K Street, Washington, D.C. 20006.

This prospectus supplement is only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act of 1933, as amended, and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus supplement, and the accompanying prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

### INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus supplement, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act of 1933, as amended, with the SEC with respect to the securities being offered pursuant to this prospectus supplement. This prospectus supplement omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities being offered pursuant to this prospectus supplement. Statements in this prospectus supplement regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in "Where You Can Find More Information." The documents we are incorporating by reference are:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 12, 2014;
- our Amendment No. 1 to our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2014, filed with the SEC on March 16, 2015; and
- our Current Reports on Form 8-K filed with the SEC on February 17 and February 24, 2015 (other than information in Item 2.02 thereof).

In addition, all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed in such forms that are related to such items unless such Form 8-K expressly provides to the contrary) subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, before the date our offering is terminated or completed are deemed to be incorporated by reference into, and to be a part of, this prospectus supplement.

Any statement contained in this prospectus supplement or in a document incorporated or deemed to be incorporated by reference into this prospectus supplement will be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus supplement modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Assembly Biosciences, Inc., 99 Hudson Street, 5<sup>th</sup> Floor, New York, NY, 10013, (646) 706-5208.

You should rely only on information contained in, or incorporated by reference into, this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference in this prospectus supplement or the accompanying prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

## **Prospectus**



\$120,000,000 of Common Stock, Preferred Stock, Warrants, Debt Securities and/or Units

From time to time, we may offer up to \$120,000,000 of any combination of the securities described in this prospectus, either individually or in units, in one or more offerings in amounts, at prices and on the terms that we will determine at the time of offering. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. We will specify in any accompanying prospectus supplement the terms of any offering. You should read this prospectus and the applicable prospectus supplement, as well as any documents incorporated by reference in this prospectus and any prospectus supplement, carefully before you invest in any securities. This prospectus may not be used by us to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

We will sell these securities directly to our stockholders or to other purchasers or through agents on our behalf or through underwriters or dealers as designated from time to time. If any agents or underwriters are involved in the sale of any of these securities, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions or discounts.

Our common stock trades on the NASDAQ Capital Market under the trading symbol "ASMB." On November 25, 2014, the reported closing price of our common stock was \$8.60 per share. We recommend that you obtain current market quotations for our common stock prior to making an investment decision.

You should carefully read this prospectus, the prospectus supplement relating to any specific offering of securities and all information incorporated by reference herein and therein.

Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under "Risk Factors" beginning on page  $\overline{2}$  and in the documents incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 15, 2015.

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### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this shelf registration process, we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of \$120,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering.

This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. Prospectus supplements may also add, update or change information contained or incorporated by reference in this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus, includes all material information relating to this offering. You should carefully read this prospectus, the applicable prospectus supplement, the information and documents incorporated herein by reference and the additional information under the heading "Where You Can Find More Information" before making an investment decision.

You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated herein by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

This prospectus may not be used to consummate sales of our securities, unless it is accompanied by a prospectus supplement.

Unless the context otherwise requires, "Assembly," the "company," "we," "us," "our" and similar names refer to Assembly Biosciences, Inc.

# PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read together with, the more detailed information and financial statements and related notes thereto appearing elsewhere or incorporated by reference in this prospectus and any prospectus supplement. Before you decide to invest in our securities, you should read the entire prospectus and the prospectus supplement carefully, including the risk factors and the financial statements and related notes included or incorporated by reference in this prospectus and the prospectus supplement.

## **Business Overview**

We are a biopharmaceutical company that aspires to scientific leadership in the field of infectious diseases by:

- · discovering treatments for patients with Hepatitis B virus, or HBV; and
- addressing diseases associated with the disruption of normal gut flora, such as clostridium difficile associated diarrhea or CDAD.

We are developing two proprietary platforms to achieve our goals: (i) an HBV-cure platform focused on oral drugs with novel direct-acting mechanisms, and (ii) an orally-delivered microbiome therapeutics platform for treating CDAD, which we refer to as our microbiome program.

# The HBV-Cure Platform

HBV is an underappreciated global epidemic with twice as many people infected (over 350 million globally) and a higher mortality and morbidity rate than Hepatitis C and HIV, combined—over 600,000 people die every year from HBV-related causes. Less than 5% are diagnosed and treated today, and there is a low cure rate with current chronic therapies.

The current therapies for HBV, such as the reverse transcriptase inhibitors entecavir or tenofovir, potently suppress virus production (commonly referred to as "viral load"), but they continue to allow for a living virus and production of viral proteins and specifically viral antigens such as HBsAg. Current therapies must therefore be taken chronically, submitting patients to their associated significant and treatment limiting side effects.

By comparison, modulation of key aspects of the viral replication reservoir in other viruses, such as the new therapies for Hepatitis C for instance, has shown to be key for increasing the rates of curing patients. The viral reservoir for HBV is the intranuclear covalently closed circular DNA, or cccDNA. We believe that a "functional cure" is possible by developing drugs that target multiple aspects of the viral life cycle, and specifically the HBV viral reservoir.

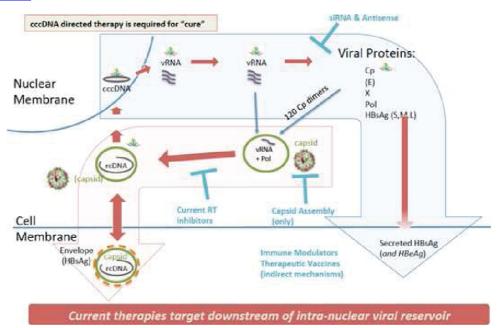
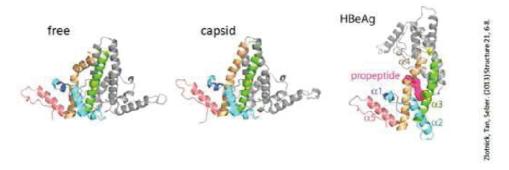


Figure 1—The HBV life cycle with emphasis on the role of core protein and cccDNA relative to existing other approaches.

Other HBV treatments in development include immunomodulatory approaches, such as the TLR (Toll-like receptors: a class of proteins that play a key role in the innate immune system) programs and therapeutic vaccine programs that rely on the body's immune system to clear virus; and siRNA (small interfering Ribo Nucleic Acid: a class of double-stranded RNA) approaches that target and rely on the degradation of the viral RNA, reducing RNA-to-protein translation, and also rely on the body's immune system to potentially clear the virus. While these approaches are differentiated from the current standard of care therapies, they do not directly target the viral reservoir (see Figure 1).

We have discovered a series of new compounds based on the seminal research of our co-founder Dr. Adam Zlotnick focusing on HBV core protein—a unique viral protein that is required for HBV lifecycle, and has no human homologue, meaning the HBV core protein is unique from any human protein. Our molecules, known as Core protein Allosteric Modulators, or CpAMs, are capable of targeting and altering certain key proteins of HBV. The HBV core protein is a pleiotropic protein, or it is a protein that has more than one effect, and it flexes into multiple conformations required for several steps of the HBV lifecycle including interaction with the HBV intra-nuclear reservoir: cccDNA (see Figures 1 and 2).



# Deep understanding of core protein is a differentiating advantage for Assembly

**Figure 2**—HBV core protein is pleiotropic, which allows it to have multiple function in the HBV life cycle, including being required for cccDNA activity.

Modulation of these specific forms of HBV core proteins with our CpAMs has demonstrated preclinical proof of principle. We have shown in multiple cell models that our CpAMs can selectively reduce the production of viral antigens such as HBsAg and HBeAg—viral proteins which reflect the activity of cccDNA—and can reduce viral load. We believe that our CpAMs are the first of this novel class of molecules to show such effects in preclinical models.

We believe the key advantages of our approach will be:

- **Convenience**—we plan to offer a convenient oral pill formulation;
- **Combination therapy**—we believe our product candidate may be used as either a single agent or in combination with existing therapies;
- Immune response—our product candidate should not require an immune response, but may still benefit from this if reducing viral antigen and pre-genomic RNA supports anti HBV immunity;
- Efficacy—since our CpAMs could target multiple aspects of the viral life cycle they may demonstrate an efficacy advantage over other approaches; and
- **Safety**—since HBV core protein is a unique viral protein with no human homologue, there could be safety advantages due to a potentially reduced risk of off target activity.

We are planning to select in mid-2015 a first generation lead molecule for development, and to initiate clinical trials in the first half of 2016. Our CpAM platform offers a multi-generation pipeline and we plan to advance second and third generation HBV-targeted molecules into clinical development rapidly behind the first program.

Our in-licensed intellectual property portfolio includes multiple patents filed in generally two categories: (i) platform patent applications, which include multiple applications filed and others in process that cover mechanisms of action, methods of treatment, and assays among other platform-related claims; and (ii) composition of matter applications for our several chemical series.

## The CDAD Microbiome Platform

Our second program is based on a novel coating and encapsulation technology that allows for targeted delivery of complex agents to select regions of the gastrointestinal, or GI, tract.

We are currently focusing our technology on delivering beneficial specific bacteria to treat CDAD. CDAD is a major health problem with more than a five-fold increase in CDAD-associated deaths between 1999 and 2007, and CDAD is the leading cause of death associated with gastroenteritis in the U.S. This translates to an estimated 14,000 Americans that die from causes linked to CDAD each year.

There has been considerable experience reported in the literature of treating CDAD with fecal material transplant, or FMT. In addition, there are preliminary studies using selected bacterial strains and of bacterial spores from processed FMT. These reports have demonstrated a significant and growing precedent of successful cures in patients, and provide an excellent path for potentially curative therapy using a targeted and specific microbiome therapy.

We believe that by providing the benefits found in FMT therapy, in an oral capsule that contains specific bacteria rather than whole or processed feces, clinical adoption could be increased.

Our current research plan includes collaborations with key leaders in the microbiome field, while diligently developing the chemistry, manufacturing, and controls systems for supporting U.S. Food and Drug Administration regulated clinical trials and eventual commercial supply. We anticipate a clinical proof of principle for the delivery technology in the second quarter of 2015. Additionally, we expect to select our specific microbiome strain leads for development in mid-2015 and to initiate clinical trials in early 2016.

## **Our Strategy**

We plan to build a multi-product company, based on our expertise in HBV and microbiome therapeutics, that discovers, develops, and commercializes first-in-class medicines to treat HBV, CDAD, and potentially other viruses and infectious diseases. Key elements of our strategy include:

- Aggressively pursuing the development of novel medicines to increase the cure rates in HBV, CDAD, and other infectious diseases of high unmet medical need;
- Maintaining our leadership and competitive advantage in the fields of direct-acting HBV therapies and orally deliverable microbiome therapies for CDAD;
- Continuing to build a multi-product platform for HBV, CDAD and other infectious diseases to generate medicines to increase cure rates; and
- Maintaining a commitment to the advancement of innovative science in drug development.

# **Our Guiding Principles**

We and our employees are committed to increasing cure rates for patients with serious infections. This commitment drives our efforts for applying cutting edge science toward the development and commercialization of novel approaches to treating HBV and CDAD. We pledge to:

- Follow the science and do what is right for patients;
- Maintain a culture of open communication and decision-making based on a deep understanding of our science and an appropriate allocation of resources;
- · Leverage strategic relationships with academic and corporate partners where and when appropriate; and
- · Execute relentlessly.

# **Company History**

On July 11, 2014, we merged with Assembly Pharmaceuticals Inc. in a reverse triangular merger with our wholly owned subsidiary, which we refer to as the Assembly Merger. In connection with the Assembly Merger, on July 11, 2014, we changed our name from Ventrus Biosciences, Inc. to Assembly Biosciences, Inc. 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).

## **Corporate Information**

Our executive offices are at 99 Hudson Street in New York, NY, 10013, and our research facility is at 953 Indiana Street, in San Francisco, CA 94103. Our telephone number is (646) 706-5208, and our website address is www.assemblybio.com. The information contained on our website is not a part of, and should not be construed as being incorporated by reference into, this prospectus supplement.

As used in this prospectus supplement, unless the context otherwise requires, references to "Assembly," "we," "us," "our" and similar references refer to Assembly Biosciences, Inc. and our wholly owned subsidiary Assembly Pharmaceuticals, Inc.

# **Offerings Under This Prospectus**

We may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, with a total value of up to \$120,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of any offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

The prospectus supplement also may add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

# This prospectus may not be used to consummate a sale of any securities unless it is accompanied by a prospectus supplement.

We may sell the securities directly to investors or to or through agents, underwriters or dealers. We, and our agents or underwriters, reserve the right to accept or reject all or part of any proposed purchase of securities. If we offer securities through agents or underwriters, we will include in the applicable prospectus supplement:

- the names of those agents or underwriters;
- · applicable fees, discounts and commissions to be paid to them;
- · details regarding over-allotment options, if any; and
- the net proceeds to us.

## Common Stock

We may issue shares of our common stock from time to time. The holders of common stock are entitled to one vote per share on all matters to be voted upon by stockholders. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably any dividends that may be declared from time to time by our board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of any preferred stock then outstanding.

## Preferred Stock

We may issue shares of our preferred stock from time to time, in one or more series. Our board of directors will determine the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by stockholders. Convertible preferred stock will be convertible into our common stock or exchangeable for our other securities. Conversion may be mandatory or at your option or both and would be at prescribed conversion rates.

If we sell any series of preferred stock under this prospectus and applicable prospectus supplements, we will fix the rights, preferences, privileges and restrictions of the preferred stock of such series in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the applicable prospectus supplement related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

### **Warrants**

We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from these securities. We will evidence each series of warrants by warrant certificates that we will issue under a separate agreement. We may enter into warrant agreements with a bank or trust company that we select to be our warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the applicable prospectus supplement related to the particular series of warrants being offered, as well as the warrant agreements and warrant certificates that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant agreement or warrant certificate containing the terms of the warrants we are offering before the issuance of the warrants.

# **Debt Securities**

We may offer debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. The senior debt securities will rank equally with any other unsecured and unsubordinated debt. The subordinated debt securities will be subordinate and junior in right of payment, to the extent and in the manner described in the instrument governing the debt, to all of our senior indebtedness. Convertible debt securities will be convertible into or exchangeable for our common stock or our other securities. Conversion may be mandatory or at your option or both and would be at prescribed conversion rates.

With respect to any debt securities that we issue, we will issue such debt securities under an indenture, which we would enter into with the trustee named in the indenture. Any indenture would be qualified under the Trust Indenture Act of 1939.

## **Units**

We may issue units consisting of common stock, preferred stock, debt securities and/or warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. In this prospectus, we have summarized certain general features of the units. We urge you, however, to read the applicable prospectus supplement related to the series of units being offered, as well as the unit agreements that contain the terms of the units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference reports that we file with the SEC, the form of unit agreement and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

### RISK FACTORS

Investing in our common stock involves risk. Before deciding whether to invest in our common stock, you should consider carefully the risks and uncertainties described below. You should also consider the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K which is on file with the SEC and is incorporated herein by reference, and which has been and may be amended, supplemented or superseded from time to time by other reports we have filed and may file with the SEC in the future. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section above entitled "Cautionary Statement Regarding Forward-Looking Statements."

## **Risks Related to Our Business**

## We have no approved products and currently are dependent on the success of our HBV and microbiome therapies.

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 U.S. Food and Drug Administration, or 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.

# 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 have generated losses since we began operations and, as of September 30, 2014, we had an accumulated deficit of \$129.3 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.

# Pre-clinical testing and clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

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. 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. For example, in late June 2012, we reported that our 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 second Phase III clinical trial for the treatment of anal fissures diltiazem demonstrated no significant improvement compared to placebo despite favorable results in a prior Phase III trial. These same risks apply to our planned development of our current and any other product candidates.

# 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.

# The results of earlier studies and trials for any of our product candidates might not be predictive of the results in any future studies or trials.

The results of any earlier study or trial for any of our product candidates may not be predictive of the results for any future studies or trials. Further, 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. In addition, unforeseen safety issues could emerge in any future study or trial, which could severely hamper the likelihood of FDA or other regulatory approval of any product candidate. If any of these events were to occur, the development of any product candidate could be significantly delayed and 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.

# We may 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 program 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 second quarter of 2016. 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.

# 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 September 30, 2014 is \$825,000. We also are obligated to pay IURTC royalty payments based on net sales of the licensed technology, which increase if we sublicense our rights to a non-affiliate third party. 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.

# We depend on our collaboration with Adam Zlotnick, the scientific founder of our HBV therapy. If that collaboration is not maintained, we may not be able to capitalize on the market potential of our HBV therapy.

Dr. Adam Zlotnick is the founder of our HBV therapy. We have entered into a three-year consulting agreement with Dr. Zlotnick 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 three-year term expires 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.

# Failure to integrate Assembly Pharmaceutical, Inc. into our operations successfully could adversely affect our business.

On July 11, 2014, we effected the Assembly Merger whereby Assembly Pharmaceuticals, Inc. became our wholly owned subsidiary. Our integration of the operations and personnel of Assembly may require significant efforts, including significant amounts of management's time, and result in additional expenses. Factors that will affect the success of the merger include the strength of our combined technology, our ability to execute our business strategy, our ability to adequately fund research and development and retain key employees, and results of clinical trials, regulatory approvals and reimbursement levels of any approved product. Our failure to successfully manage the Assembly Merger could have a material adverse impact on our business. In addition, we cannot be certain that Assembly Pharmaceuticals' technology will be successfully developed or, if approved, become profitable or remain so.

# 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 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.

## 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. We have not yet tested our HBV therapy or our microbiome therapy and safety issues could arise during that planned testing or testing of any other product candidates. If a product is approved, any limitation on use that might be necessary 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 are reliant on the services of these third parties to conduct studies on our behalf. If we are unable to continue with or retain 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, regulatory and scientific requirements and 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, nonclinical 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. 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 might not 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 CDAD 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, CDAD 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 an 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.

# Physicians and patients might not accept and use our drugs.

Even if the FDA approves one of our product candidates, physicians and patients might not accept and use it. Acceptance and use of our products will depend upon a number of factors, including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our product;
- cost-effectiveness of our product relative to competing products or therapies;
- · availability of reimbursement for our product from government or other healthcare payors; and
- · effective marketing and distribution efforts by us and our licensees and distributors, if any.

If our current product candidates are approved, we expect sales to generate substantially all of our revenues for the foreseeable future, and as a result, the failure of these products to find market acceptance would harm our business and would require us to seek additional financing.

# Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our product candidates, if approved, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- · private health maintenance organizations and health insurers; and
- other healthcare payors.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage might not be available, and reimbursement levels might be inadequate, to cover our products. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for our products, once approved, market acceptance of such products could be reduced.

Proposals to modify the current health care system in the U.S. to improve access to health care and control its costs are continually being considered by the federal and state governments. In March 2010, the

U.S. Congress passed landmark healthcare reform legislation, of which the coverage and reimbursement provisions went into effect in late 2013. We cannot predict what impact on federal reimbursement policies and regulatory compliance landscape this legislation will have in general or on our business specifically. We expect continued judicial and legislative review and assessment of this legislation and possibly alternative health care reform proposals. We cannot predict judicial results or whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

Health administration authorities in countries other than the U.S. may not provide reimbursement for our product candidates at rates sufficient for us to achieve profitability, or at all. Like the U.S., these countries could adopt health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates.

Any reduction in reimbursement rates under Medicare or private insurers or foreign health care programs could negatively affect the pricing of our product candidates. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

# 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 Chairman and Chief Executive Officer, Dr. Russell H. Ellison, our President and Chief Operating Officer, Derek Small, our Chief Medical Officer and Vice President of Research and Development, Dr. Uri Lopatin, our Chief Scientific Officer, Dr. Lee D. Arnold, and our Chief Financial Officer, David J. Barrett. Our employment agreements with Dr. Ellison, Mr. Small, Dr. Lopatin, Dr. Arnold 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.

# If we cannot enforce non-compete and confidentiality provisions applicable to our employees and consultants, our business might materially suffer.

We include a non-compete provision in any employment agreement we enter into with an employee, including those for Messrs. Small and Barrett and Drs. Ellison and Arnold, that runs during the term of the agreement and for a period of time after termination, depending on the individual.

We include a confidentiality provision in any employment or consulting agreement we enter into with an employee or a consultant. The confidentiality provision runs during the term of the agreement and thereafter without limit.

For future employees with whom we do not enter into an employment agreement, we will enter into a confidentiality agreement with the same provisions described above.

To be able to enforce these non-compete and confidentiality provisions we would need to know of any 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 non-compete and confidentiality provisions could have an adverse effect on our business.

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

At October 31, 2014, we had 18 employees, 10 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, government regulation, 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 must 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 standards; 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 of 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 or licenses; 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. For example, the FDA proposed that we include an additional treatment arm in our pivotal Phase III trial for our former product candidate iferanserin, which increased the cost of that trial.

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. 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. Application holders must obtain FDA approval for product, manufacturing, and labeling changes, depending on the nature of the change. 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.

# 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' drugs 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. A successful product liability claim 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 United States and abroad related to our novel technologies and medicines 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 medicines 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.

We might be involved from time to time in litigation to determine the enforceability, scope and validity of our proprietary rights. Any such litigation could result in substantial cost and divert management's attention from our operations.

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 we infringe the rights of third parties we might have to forgo selling our future products, pay damages, or defend against litigation.

If our product candidates, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we might have to:

- obtain licenses, which might not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; and/or
- defend litigation or administrative proceedings which might be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Any of these events could substantially harm our earnings, financial condition and operations.

# **Risks Related to Our Common Stock**

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

Our common stock is listed on The NASDAQ Capital Market under the symbol "ASMB." We might not be able to maintain the listing standards of that exchange. If we fail to maintain the listing requirements, our common stock might trade on the OTC Bulletin Board or in the "pink sheets" maintained by 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 November 25, 2014, the closing price of our common stock has fluctuated between \$5.35 and \$85.75 (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 iferanserin failed to meet the endpoints of our Phase III trial, and after we announced in February 2014 that diltiazem demonstrated no significant improvement compared to placebo. Continued volatility in the market price of our common stock might prevent you from being able to sell your shares of our common stock at or above the price you 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.

# 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 adds 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 include:

- "blank check" preferred stock;
- 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;
- 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; and
- the ability of our board of directors to increase its size and fill vacancies.

# 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.

Substantial future sales of our common stock in the public market may depress our stock price and make it difficult for you to recover the full value of your investment in our shares of securities.

As of November 24, 2014, we had 10,647,059 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. The market price of our common stock may decline if our common stockholders sell a large number of shares of our common stock in the public market, or the market perceives that such sales may occur. In addition, at November 24, 2014, we had outstanding options and warrants to purchase an aggregate of 3,267,651 shares and 271,501 shares, respectively, of our common stock. If these options or warrants are exercised and the shares issued upon exercise are sold, the market price of our securities may also decline. These factors also could impair our ability to raise needed capital by depressing the price at which we could sell our securities.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This prospectus and the documents we have filed with the SEC that are incorporated herein by reference contain such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.

Words such as "may," "might," "should," "anticipate," "estimate," "expect," "projects," "intends," "plans," "believes" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, identify forward-looking statements. Forward-looking statements represent management's current judgment regarding future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks include, but are not limited to: risks related to costs, timing, regulatory review and results of our pre-clinical studies and clinical trials; our ability to obtain FDA and foreign 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 product candidates; our need to obtain additional funding and our ability to obtain future funding on acceptable terms, or at all; 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; and the future trading prices of our common stock and the impact of securities analysts' reports on these prices. Please also see the discussion of risks and uncertainties under "Risk Factors" above and contained in any supplements to this prospectus, and in our most recent annual report on Form 10-K, as revised or supplemented by our most recent quarterly report on Form 10-Q, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus or in any document incorporated herein by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

### USE OF PROCEEDS

We cannot assure you that we will receive any proceeds in connection with securities offered by us pursuant to this prospectus. Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of our securities by us under this prospectus for general corporate purposes, including preclinical and clinical trials, research and development expenses, and general and administrative expenses. We will set forth in the applicable prospectus supplement our intended use for the net proceeds received from the sale of any securities by us. Pending the application of the net proceeds, we intend to invest the net proceeds generally in high quality, short-term, interest-bearing securities.

## PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through underwriters or dealers, through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

A prospectus supplement or supplements (and any related free writing prospectus that we may authorize to be provided to you) will describe the terms of the offering of the securities, including, to the extent applicable:

- the name or names of the underwriters, if any;
- the purchase price of the securities or other consideration therefor, and the proceeds, if any, we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- · any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;
- · any public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

All securities we may offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate-covering or other short-covering transactions involve purchases of the securities, either through exercise of the over-allotment option or in the open market after the distribution is completed, to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Any underwriters that are qualified market makers on the NASDAQ Capital Market may engage in passive market making transactions in the common stock on the NASDAQ Capital Market in accordance with Regulation M under the Exchange Act, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

### DESCRIPTION OF COMMON STOCK

Pursuant to our certificate of incorporation, we are authorized to issue 50,000,000 shares of common stock, \$0.001 par value per share. As of November 24, 2014, we had 10,647,059 shares of common stock outstanding and 122 stockholders of record.

The following summary of certain provisions of our common stock does not purport to be complete. You should refer to our certificate of incorporation and our bylaws, both of which are included as exhibits to the registration statement we have filed with the SEC in connection with this offering. The summary below is also qualified by provisions of applicable law.

#### General

The holders of our common stock are entitled to one vote per share on all matters to be voted on by the stockholders, and there are no cumulative voting rights. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of common stock present in person or represented by proxy, subject to any voting rights granted to holders of any preferred stock.

The holders of common stock are entitled to receive ratable dividends, if any, payable in cash, in stock or otherwise if, as and when declared from time to time by our board of directors out of funds legally available for the payment of dividends, subject to any preferential rights that may be applicable to any outstanding preferred stock. In the event of a liquidation, dissolution, or winding up of our company, after payment in full of all outstanding debts and other liabilities, the holders of common stock are entitled to share ratably in all remaining assets, subject to prior distribution rights of preferred stock, if any, then outstanding. No shares of common stock have preemptive rights or other subscription rights to purchase additional shares of common stock. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable, and the shares of common stock included in this registration statement will be fully paid and nonassessable. The rights, preferences and privileges of holders of our common stock will be subject to, and might be adversely affected by, the rights of holders of any preferred stock that we may issue in the future. All shares of common stock that are acquired by us shall be available for reissuance by us at any time.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is VStock Transfer, LLC, Inc. The transfer agent's address is 18 Lafayette Place, Woodmere, New York 11598 and its telephone number is (212) 828-8436.

# **NASDAQ Capital Market**

Our common stock is listed for quotation on the NASDAQ Capital Market under the symbol "ASMB." On November 25, 2014, the reported closing price of our common stock was \$8.60 per share.

### DESCRIPTION OF PREFERRED STOCK

Our board of directors has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by our stockholders. As of the date of this prospectus, no shares of preferred stock were outstanding. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation and could have the effect of delaying, deferring or preventing a change in control of our company.

We will fix the rights, preferences, privileges and restrictions of the preferred stock of each series in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. This description will include any or all of the following, as required:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- · the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be
  calculated, and the exchange period;
- voting rights, if any, of the preferred stock;
- preemptive rights, if any;
- $\bullet$  restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material or special United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;

- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

If we issue shares of preferred stock under this prospectus, the shares will be fully paid and non-assessable.

The General Corporation Law of the State of Delaware, the state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock.

### DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provision of any debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we may offer under a prospectus supplement may differ from the terms described below. For any debt securities that we may offer, an indenture (and any relevant supplemental indenture) will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement that includes this prospectus, or as an exhibit to reports that we file with the SEC and incorporated by reference in this prospectus.

With respect to any debt securities that we issue, we will issue such debt securities under an indenture, which we would enter into with the trustee named in the indenture. Any indenture would be qualified under the Trust Indenture Act of 1939.

With respect to any debt securities that we issue, we will describe in each prospectus supplement the following terms relating to a series of debt securities:

- the title:
- the principal amount being offered, and if a series, the total amount authorized and the total amount outstanding;
- any limit on the amount that may be issued;
- whether or not we will issue the series of debt securities in global form, and if so, the terms and who the depository will be;
- · the maturity date;
- the principal amount due at maturity;
- whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is
  not a United States person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional
  amounts;
- the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- whether or not the debt securities will be convertible into shares of our common stock or our preferred stock and, if so, the terms of such conversion;
- · whether or not the debt securities will be secured or unsecured by some or all of our assets, and the terms of any secured debt;
- the terms of the subordination of any series of subordinated debt;
- the place where payments will be payable;
- · restrictions on transfer, sale or other assignment, if any;
- · our right, if any, to defer payment or interest and the maximum length of any such deferral period;
- the date, if any, after which and the conditions upon which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemptions provisions;
- the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;

- whether the indenture will restrict our ability to pay dividends, or will require us to maintain any asset ratios or reserves;
- whether we will be restricted from incurring any additional indebtedness, issuing additional securities, or entering into a merger, consolidation or sale of our business;
- a discussion of any material or special United States federal income tax considerations applicable to the debt securities;
- · information describing any book-entry features;
- any provisions for payment of additional amounts for taxes;
- whether the debt securities are to be offered at a price such that they will be deemed to be offered at an "original issue discount" as defined in paragraph (a) of Section 1273 of the Internal Revenue Code of 1986, as amended;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- events of default;
- whether we and/or the debenture trustee may change an indenture without the consent of any holders;
- the form of debt security and how it may be exchanged and transferred;
- · description of the debenture trustee and paying agent, and the method of payments; and
- any other specified terms, preferences, rights or limitations of, or restrictions on, the debt securities and any terms that may be required by us or advisable under applicable laws or regulations.

### DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of any warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement may differ from the terms described below. With respect to any warrants that we offer, specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement that includes this prospectus or as an exhibit to reports that we file with the SEC and incorporated by reference in this prospectus:

- the specific designation and aggregate number of, and the price at which we will issue, the warrants;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- if applicable, the exercise price for shares of our common stock or preferred stock and the number of shares of common stock or preferred stock to be received upon exercise of the warrants;
- in the case of warrants to purchase debt securities, the principal amount of debt securities purchaselle upon exercise of one warrant and the price at, and currency in which, this principal amount of debt securities may be purchased upon such exercise;
- the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;
- whether the warrants will be issued in fully registered form or bearer form, in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;
- any applicable material U.S. federal income tax consequences;
- the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;
- the proposed listing, if any, of the warrants or the common stock issuable upon exercise of the warrants on any securities exchange;
- if applicable, the date from and after which the warrants and the common stock will be separately transferable;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- the anti-dilution provisions of the warrants, if any;
- any redemption or call provisions;
- · whether the warrants are to be sold separately or with other securities as parts of units; and
- any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

- in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on, the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture; or
- in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

# **Transfer Agent and Registrar**

The transfer agent and registrar for any warrants will be set forth in the applicable prospectus supplement.

## **DESCRIPTION OF UNITS**

We might issue units comprised of one or more debt securities, shares of common stock, shares of preferred stock and warrants in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of unit agreement, warrant and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

We may choose to evidence each series of units by unit certificates that we would issue under a separate agreement. If we choose to evidence the units by unit certificates, we will enter into the unit agreements with a unit agent and will indicate the name and address of the unit agent in the applicable prospectus supplement relating to the particular series of units.

# CERTAIN PROVISIONS OF DELAWARE LAW AND OF THE COMPANY'S CERTIFICATE OF INCORPORATION AND BYLAWS

Certain provisions of Delaware law and our certificate of incorporation and bylaws discussed below may have the effect of making more difficult or discouraging a tender offer, proxy contest or other takeover attempt. These provisions are expected to encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of increasing our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

### Delaware anti-takeover law

We are subject to Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date the person became an interested stockholder, unless:

- the board of directors approves the transaction in which the stockholder became an interested stockholder prior to the date the interested stockholder attained that status;
- when the stockholder became an interested stockholder, he or she owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers and certain shares owned by employee benefits plans; or
- on or subsequent to the date the business combination is approved by the board of directors, the business combination is authorized by the affirmative vote of at least 66 2/3% of the voting stock of the corporation at an annual or special meeting of stockholders.

Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or is an affiliate or associate of the corporation and within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock.

The existence of Section 203 of the Delaware General Corporation Law would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of our common stock.

## **Charter Documents**

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our company. First, the Bylaws provide that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing. Further, our bylaws limit who may call special meetings of the stockholders. Our certificate of incorporation does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. Our bylaws provide that the number of directors on our board, which may range from three to nine directors, shall be exclusively fixed by our board, which has set the number of directors at five. Newly created directorships resulting from any increase in our authorized number of directors and any vacancies in our board resulting from death, resignation, retirement, disqualification or other cause (including removal from office by a vote of the shareholders) will be filled by a majority of our board then in office. Finally, our bylaws establish procedures, including advance notice procedures, with regard to the nomination of candidates for election as directors and stockholder proposals. These and other provisions of our certificate of incorporation and bylaws and Delaware law could discourage potential acquisition proposals and could delay or prevent a change in control or management of our company.

## **LEGAL MATTERS**

The validity of the securities being offered hereby will be passed upon by Wyrick Robbins Yates & Ponton, LLP, Raleigh, North Carolina.

## **EXPERTS**

The balance sheets of Ventrus Biosciences, Inc., a development stage company (now Assembly Biosciences, Inc.) as of December 31, 2013 and 2012 and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2013 and 2012 and for the period from October 7, 2005 (inception) to December 31, 2013 have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference. Such financial statements have been incorporated herein by reference in reliance on the report of EisnerAmper LLP given upon their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC's web site at http://www.sec.gov. Our common stock is listed on the NASDAQ Capital Market, and you can read and inspect our filings at the offices of the National Association of Securities Dealers, Inc. at 1735 K Street, Washington, D.C. 20006.

This prospectus is only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act of 1933, as amended, and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

## INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act of 1933, as amended, with the SEC with respect to the securities being offered pursuant to this prospectus. This prospectus omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities being offered pursuant to this prospectus. Statements in this prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in "Where You Can Find More Information." The documents we are incorporating by reference are:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed with the SEC on March 31, 2014;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 filed with the SEC on May 5, 2014;
- our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, filed with the SEC on August 14, 2014;
- our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 filed with the SEC November 17, 2014;
- our Current Reports on Form 8-K filed with the SEC on January 8, January 16, February 12, April 4, May 19, July 11, July 14, July 30, August 13, September 17 (Form 8-K/A) and October 1, 2014;
- our definitive proxy solicitation materials filed with the SEC on June 9, 2014;
- the description of our common stock contained in our registration statement on Form 8-A (File No. 001-35005) filed with the SEC on December 10, 2010, including any amendment or report filed for the purpose of updating such description; and
- all of the filings pursuant to the Securities Exchange Act of 1934, as amended, after the date of the filing of the original registration statement and prior to the effectiveness of the registration statement.

In addition, all documents subsequently filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, before the date our offering is terminated or completed are deemed to be incorporated by reference into, and to be a part of, this prospectus.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Assembly Biosciences, Inc., Attention: David J. Barrett, 99 Hudson Street, 5<sup>th</sup> Floor, New York, New York 10013, (646) 706-5208.

You should rely only on information contained in, or incorporated by reference into, this prospectus and any prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference in this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.



**Shares of Common Stock** 

PROSPECTUS SUPPLEMENT

**Credit Suisse** 

William Blair

Prospectus Supplement dated March , 2015