## SCHEDULE 14A INFORMATION

#### Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

- Preliminary Proxy Statement
- □ Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

X

- □ Definitive Proxy Statement
- Definitive Additional Materials
- □ Soliciting Material Pursuant to § 240.14a-12

## ASSEMBLY BIOSCIENCES, INC.

(Name of Registrant as Specified In Its Charter)

Payment of Filing Fee (Check the appropriate box)

- ☑ No fee required.□ Fee computed or
  - Fee computed on table below per Exchange Act Rules 14a-6(i)(4) and 0-11.
    - 1. Title of each class of securities to which transaction applies:
    - 2. Aggregate number of securities to which transaction applies:
    - 3. Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):
    - 4. Proposed maximum aggregate value of transaction:
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Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

- 1. Amount Previously Paid:
- 2. Form, Schedule or Registration Statement No.:
- 3. Filing Party:
- 4. Date Filed:



# ASSEMBLY BIOSCIENCES 2015 ANNUAL SHAREHOLDERS REPORT



# DEAR SHAREHOLDERS:



Derek A. Small, President and Chief Executive Officer

Just over a year and a half ago we formed Assembly Biosciences through a merger of a public and private company to focus on highly innovative programs aimed at achieving curative therapies.

We started with a small combined team of about 10 people and two separate programs addressing hepatitis B virus (HBV) infection and microbiome therapeutics.

Today we have advanced these programs significantly and established what we believe to be a world class team and focused company committed to achieving our ambitious goals of becoming an integrated biotechnology company discovering, developing and commercializing novel HBV and microbiome therapies

#### ESTABLISHING THE FOUNDATION WITH A WORLD CLASS TEAM

In January this year we announced several new additions to our senior management team. The team now includes deeply experienced drug-hunters and drug developers who have collectively discovered and brought to market more than 10 commercially successful products in infectious disease (ID), gastroenterology (GI) disorders and various other disease indications.

We have built out our research and development teams in both our HBV and Microbiome programs and now number approximately 50 full-time employees and roughly 35 FTE chemistry and other specialist outsourced team members. The majority of our R&D is conducted in our research fadility in San Francisco and supplemented by focused teams in Indiana and New York. We are now leveraging these resources to advance our discovery and development programs towards dinical development & commercialization.

#### HBV-CURE PROGRAM – MOVING OUR FIRST DRUG CANDIDATE INTO THE CLINIC

More effective cures for HBV are clearly needed. Currently there are over 240 million people worldwide chronically infected with HBV; with over 90 million in China. Unlike hepatitis C virus infection (HCV), where cure rates are now nearing 99%, the current cure rates for HBV are less than 5%, and chronic HBV infection is associated with high rates of disability and early death from cancer and other liver diseases – globally over 500,000 deaths estimated annually.

This is not acceptable, and we believe our scientific and drug discovery insights represent an opportunity to address this deficiency.

Our HBV program began modestly in the lab of Dr. Adam Zlotnick at Indiana University based on his vision that modulating the multiple functions of the HBV core protein (HBc) might represent a new therapeutic modality with curative potential. We have now built our chemistry, biochemistry, and biology teams

## 2015 KEY ACHIEVEMENTS

- Completed +\$80 million capital raise providing funding to key inflection points
- Recruited R&D teams with record of success & world-class expertise
- ✓ Presented human clinical data demonstrating Gemicel<sup>™</sup> can target bolus delivery to lower GI tract
- Identified new CpAM class targeting HBV core protein with multiple potential leads



to a level of sophistication and novel R&D expertise that we believe rivals any in the HBV field. Our team has established distinct chemical series for the modulation of HBc and other targets relevant to achieving cures for this devastating disease, along with innovative assays and biomarkers to facilitate the R&D process.

In December we announced the selection of our first lead HBV candidate, which is now in INDenabling development. In addition, we have advanced a number of other molecules toward possible candidate selection in the near future and established a research engine to generate multiple molecules that are potential candidates for the combination regimens we believe will likely be required to cure HBV. We anticipate entering Phase 1 clinical trials with our first HBV candidate during the second half of 2016.

MICROBIOME PROGRAM – A FULLY-INTEGRATED PLATFORM FOR DISCOVERING, CGMP MANUFACTURING AND ORALLY DELIVERING TARGETED MICROBIOTIC DRUGS

We believe that we have the potential to become one of the leading microbiome companies in the world.

We understand this is a bold statement, but there are a number of reasons we believe this to be true.

The Assembly team has been working on our microbiome programs for over four years focusing diligently on research and development activities to increase our confidence in the program's three main elements: Bacterial Strain Selection We are building a fully synthetic microbiome product from the ground up. To succeed, we first set out to select human bacteria strains that would have both therapeutic properties and also be amenable to being produced as drugs. We have biologic successfully established our program for microbiome bacterial strain discovery and selection, both internally and in collaboration with some of the leading scientists academic and microbiome research companies in the field.

#### Delivery of Microbiota Selectively to the GI Tract

Early on, we realized the field was competitive with many entrants. A key opportunity was the hurdle of effectively and specifically delivering bacteria to relevant regions of the gastrointestinal (GI) tract. To address this, in 2013 we obtained an exclusive license to a novel delivery technology called Gemiœl™ that allows for bolus delivery of therapeutic bacteria to targeted regions of the colon. Earlier in 2015 we achieved a major human proof of concept milestone with Gemicel; human data confirming that Gemicel can

Preparing to advance our lead Microbiome & HBV programs into clinical trials in 2016 Capital efficient and funded through inflection points. Proprietary platforms offer multiple partnership opportunities

### 2016 PROJECTED MILESTONES

- Complete senior management expansion
- Present 1st human study data for GemiceI<sup>™</sup> oral colonic delivery technology √
- Advance 1<sup>st</sup> Microbiome program for CDI into IND-directed studies √
- Present data at 2016 EASL Congress on HBV-Cure clinical candidates √
- Submit IND for 1<sup>st</sup> Microbiome program -ABI–M101 for CDI
- Initiate ABI-M101 Phase Ib clinical study in recurrent CDI patients
- Initiate IND-directed studies on 2nd Microbiome program candidate
- Present data on HBV-Cure leads at AASLD 2016 scientific meeting
- Initiate Phase I clinical trial with 1st HBV-Cure molecule in healthy volunteers
- Select 2nd HBV-Cure program clinical candidate



successfully target bolus delivery to the ileum and colon were presented at a scientific meeting in January 2016.

#### cGMP Microbiota Manufacturing

To make microbiotic therapies into FDA-regulated biologic drugs, we needed to be able to reliably and consistently manufacture our selected individual bacteria strains under cGMP conditions and to scale the manufacturing simply and cost efficiently. In 2015, we built out a world-dass manufacturing team that can achieve scalable and costeffective cGMP manufacture.

We advanced these key components of our Microbiome program significantly in 2015, and are now in IND-directed development of our first biologic drug candidate, ABI-M101. We expect to initiate a Phase 1b clinical trial in patients with recalcitrant *C. difficile* infections (rCDI) during the second half of 2016, and in parallel advance our programs into other disease indications.

The potential opportunities for this fully integrated microbiotic therapy platform are many, and going forward we plan to develop programs both internally and potentially in collaboration with partners.

## COMMITMENT TO PATIENTS

In the midst of all this activity, it's important to emphasize that we do what we do to help patients - this drives each one of us in the company. In fact, it's core to our culture, and we intend to keep this part of our work practices every day as we continue to develop and advance our innovative therapies for the benefit of patients. We look forward to reporting on our progress over the course of this year, and welcome your questions and comments, which can be sent via the Contact section on the Investor Relations page at the Assembly website.

In closing, I would like to sincerely thank you for your trust and support over this past year. I'd also like to thank our employees for their commitment to excellence and productivity in science and drug development, and certainly want to acknowledge the invaluable input and strategic guidance of our Board of Directors.

Sincerely,

Derek A. Small President and CEO Assembly Biosciences





# MICROBIOME PLATFORM: DEVELOPING DRUG-LIKE **ORAL BIOLOGICS**

# PLATFORM FACILITATES THERAPEUTIC AREA & INDICATION EXPANSION

## **KEY ADVANTAGES:**

- Microbiota strain selection methods
- Scalable process development & GMP manufacturing
- Gemicel<sup>™</sup> oral-targeted delivery technology





# HBV-CURE PROGRAM: ADVANCING TOWARDS CLINICAL TRIALS

# R&D ENGINE PRODUCING PROMISING 2ND & 3RD GENERATION CPAMS WITH VARIED PROFILES & ACTIVITY

# HBV: Millions Affected with Major Unmet Need

- >240 million worldwide have chronic HBV
- >90% currently are NOT cured
- Results in liver disease/death for >500,000 annually

## Preclinical Studies Show Clinical Potential of New CpAM Series

- Potent, pan-genotypic activity across multiple viral genotypes
- Favorable drug characteristics & PK profiles
- Multiple other series under evaluation 2<sup>nd</sup> & 3<sup>rd</sup> generation with varied anti-viral activities
- Lead candidate advancing towards clinical trials in 2H 2016

# TO ACHIEVE CLINICAL CURES, HBV THERAPY MUST:







## CORPORATE INFORMATION

## Directors

Anthony E. Altig Chief Financial Officer, Biotix Holdings, Inc.

Mark Auerbach Director, RCS Capital Corporation

Richard DiMarchi, PhD Cox Distinguished Professor of Biochemistry and Gill Chair in Biomolecular Sciences

Myron Z. Holubiak President, Leonard +Meron Biosciences, Inc.

Alan J. Lewis, PhD Chief Executive Officer, DiaVacs, Inc.

William Ringo Director Sangamo BioSciences, Inc. Mirati Therapeutics, Immune Design Corp., Dermira and Five Prime Therapeutics

Derek A. Small President and Chief Executive Officer, Assembly Biosciences, Inc.

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Website www.assemblybio.com

### Stock Listing

Assembly Biosciences, Inc. common stock is listed on the Nasdaq Capital Market and quoted under the symbol "ASMB"

#### Officers

Derek A. Small President and Chief Executive Officer

David J. Barrett, C.P.A. Chief Financial Officer and Chief Operating Officer

Uri Lopatin, M.D. Chief Medical Officer and Vice President of Research and Development

Lee D. Arnold, M.D. *Chief Discovery Officer* 

Richard Colonno, PhD Chief Scientific Officer

Thomas E. Rollins Chief Development Officer and Head of Microbiome Program

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