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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **January 11, 2016**

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**ASSEMBLY BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation)

**001-35005**  
(Commission  
File Number)

**20-8729264**  
(I.R.S. Employer  
Identification No.)

**101 Sixth Avenue, Ninth Floor**  
**New York, NY 10013**  
(Address of principal executive offices, including zip code)

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

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 7.01 Regulation FD Disclosure.**

On January 11, 2016, Assembly Biosciences, Inc. (the “Company”) announced that beginning on January 12, 2016, the slide presentation attached as Exhibit 99.1 will be presented by the Company’s management in various investor meetings. Information in this presentation may also be used by management of the Company in future meetings regarding the Company.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Slide presentation, dated January 2016

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 11, 2016

**Assembly Biosciences, Inc.**

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

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Slide presentation, dated January 2016

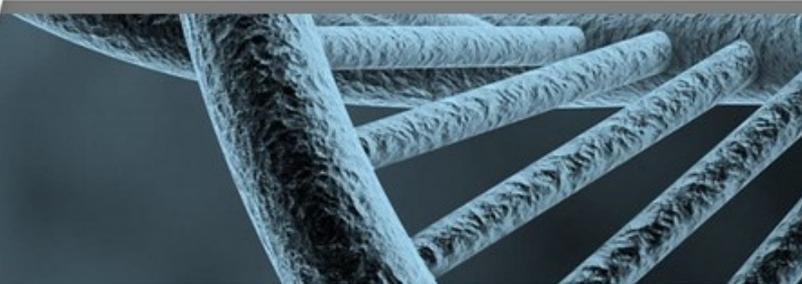
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**Assembly Biosciences**  
**Nasdaq: ASMB**

**January 2016**



## Cautionary Note Regarding Forward-Looking Statements



*The information in this presentation contains estimates and other forward-looking statements regarding future events, including statements about the therapeutic potential of our HBV and CDI programs, timing of the initiation of our planned clinical trials in each of these programs, plans, strategies, and intentions related to our programs, and projections regarding capital. Certain forward looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as “developing”, “potential,” “projected,” “anticipated”, “positioned,” “strategy,” “should” or “may.” Such forward-looking statements, which we intend to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: our ability to retain necessary employees and to staff our operations appropriately; the components, timing, cost and results of clinical trials and other development activities involving our product candidates; the unpredictability of the preclinical and clinical development of our product candidates and of the duration and results of regulatory review of those candidates by the FDA and foreign regulatory authorities; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014, and other reports filed with the Securities and Exchange Commission. It is not possible for Assembly management to predict all risks nor can Assembly assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements Assembly may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.*

# Investment Highlights



## An integrated infectious disease company

<b>Focus on infectious diseases</b>	<ul style="list-style-type: none"><li>◆ Developing best-in-class small molecules for the treatment of chronic hepatitis B (HBV)</li><li>◆ Developing drug-like oral microbiotic (MB) therapeutics for the prevention of recurrent <i>C. difficile</i> infection (rCDI)</li></ul>
<b>World class team</b>	<ul style="list-style-type: none"><li>◆ Experienced team with 50 employees and 35 FTEs / chemists / consultants</li><li>◆ MB and HBV program developed with leading scientific experts in discovery, development, manufacturing and delivery</li></ul>
<b>Proprietary technologies</b>	<ul style="list-style-type: none"><li>◆ Novel targets with proprietary chemistry/screening platforms (HBV)</li><li>◆ Differentiated discovery platform leveraging bacterial strain library and GEMICEL™ oral capsule delivery (MB)</li></ul>
<b>Strong financials</b>	<ul style="list-style-type: none"><li>◆ Funded through inflection points; rapid, capital efficient development</li><li>◆ Partnership opportunities in non-infectious disease indications</li></ul>

**Our goal: Create a functional cure for chronic HBV and create a new class of medicines using our proprietary microbiome therapy technologies**

# Experienced Scientific & Leadership Team



*Proven leadership team producing successful companies & drugs for the past 30+ years*

	<b>Derek A. Small</b> President & CEO		<b>Richard Colonno, PhD</b> Chief Science Officer		<b>Uri Lopatin, MD</b> CMO & VP R&D
	<b>Thomas Rollins</b> Chief Development Officer Head of Microbiome		<b>David Barrett</b> CFO & COO		<b>Lee Arnold, PhD</b> Chief Discovery Officer

Previous companies	Drugs discovered/significant contributions to devel.
Gilead, Merck, BMS, Roche, Pfizer, JNJ, Cubist, Vertex, Presidio, Naurex, OSI, BASF, Deloitte, Overture, others	entecavir/Baraclude™ (HBV); ravidasvir (HCV); Incivek™ (HCV); atazanavir/Reyataz™ (HIV); Crixivan® (HIV); Tarceva®; Sivestro®; Zerbaxa®; Lunesta®; Fosamax®, many others

Additional team members	
<b>Elizabeth Lacy</b> , GC, VP Legal Operations	<b>Micah Mackison</b> , VP Corp Devel. & Strategy
<b>Eric Ruby</b> , VP Regulatory & Quality Assurance	<b>Wayne Herber, PhD</b> VP Biologics Mfg. & Quality
<b>Hongmei Huang, PhD</b> VP of Informatics	<b>Mohan Kabadi, PhD</b> VP Mfg. & Process Devel.
<b>Leping Li, PhD</b> VP of Discovery	<b>Adam Zlotnick, PhD</b> HBV Chief Science Adv.



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## HBV Opportunity

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# HBV Opportunity: More Patients Diagnosed/Treated



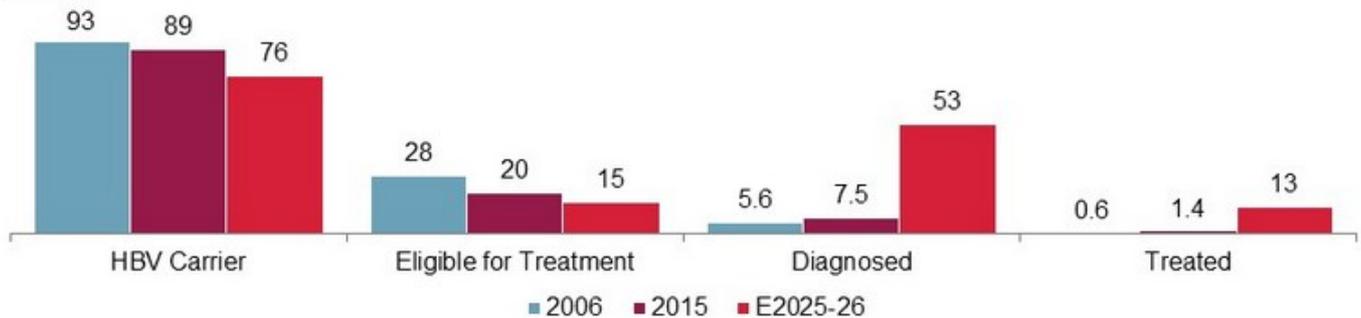
## ◆ ~240M chronically infected globally

- 90M in China (top 5 health priority for sFDA); >10M EU; ~ 2M in USA<sup>(1)</sup>
- Current standard of care is **not curative** in >90% of patients, yet represents >\$1B/year market globally and is expected to grow significantly

## ◆ Improvements in diagnostics, greater access to care and heightened awareness are driving increasing number of patients to start therapy

### HBV in China

(in millions)



**Number of patients entering treatment is increasing despite a decreasing population of new patients**

(1) Kowdley K, Hepatology 2011; 56:422.

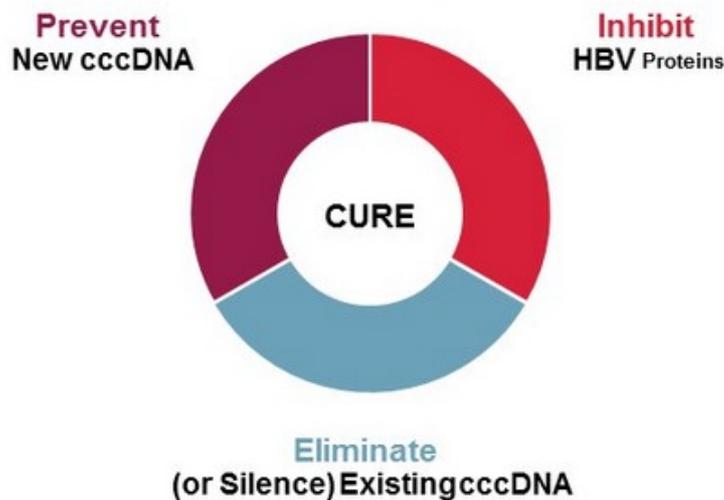
# ASMB Goal: Curative Therapy for HBV



## ◆ Current therapies are inadequate

- Interferons have poor tolerability, efficacy and are not an option for many patients
- Polymerase inhibitors are highly effective in inhibiting viral replication and driving viral loads to undetectable levels, but low level viral replication often persists for an extended period<sup>1</sup>
- Polymerase inhibitors have no effect on cccDNA levels (key target to eliminate infection)
- Multiple year therapy leads to very low cure rates (<10%)

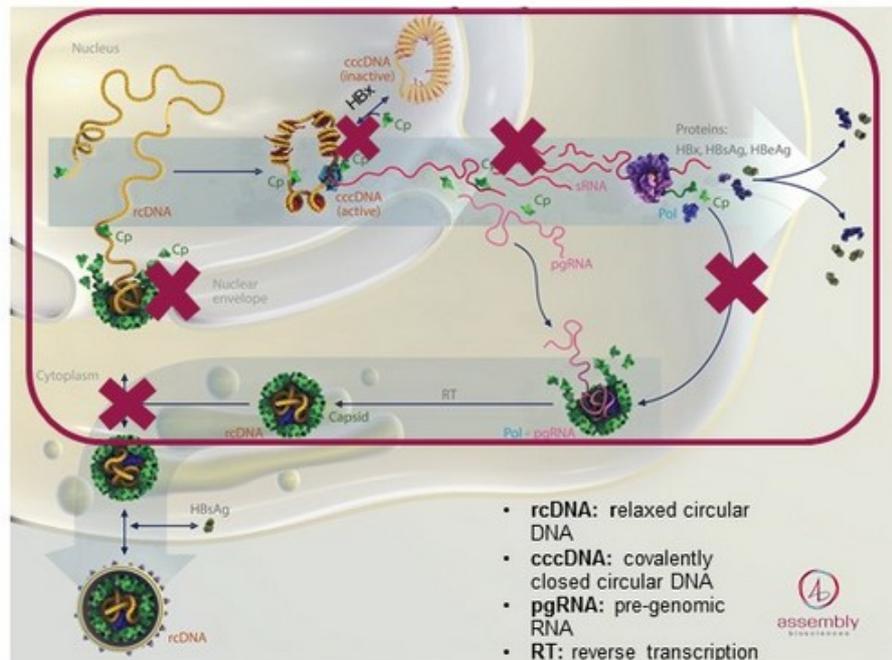
## ◆ To achieve clinical cure, therapy must **Prevent** new cccDNA, **Inhibit** HBV proteins and **Eliminate** (or silence) existing cccDNA



# HBV Core Protein: Required Throughout Lifecycle



- ◆ **HBV Core protein (Cp)** is a non-enzymatic viral protein with no human homologue and is involved in entire HBV viral lifecycle (upstream & downstream)
  - Believed to play a critical role in the generation and maintenance of cccDNA
  - Required for creating new rcDNA from pgRNA
  - Implicated in regulating host immune response



# ASMB Progress: AB-101 to Prevent cccDNA



*Significant progress in 2015 – building R&D engine*

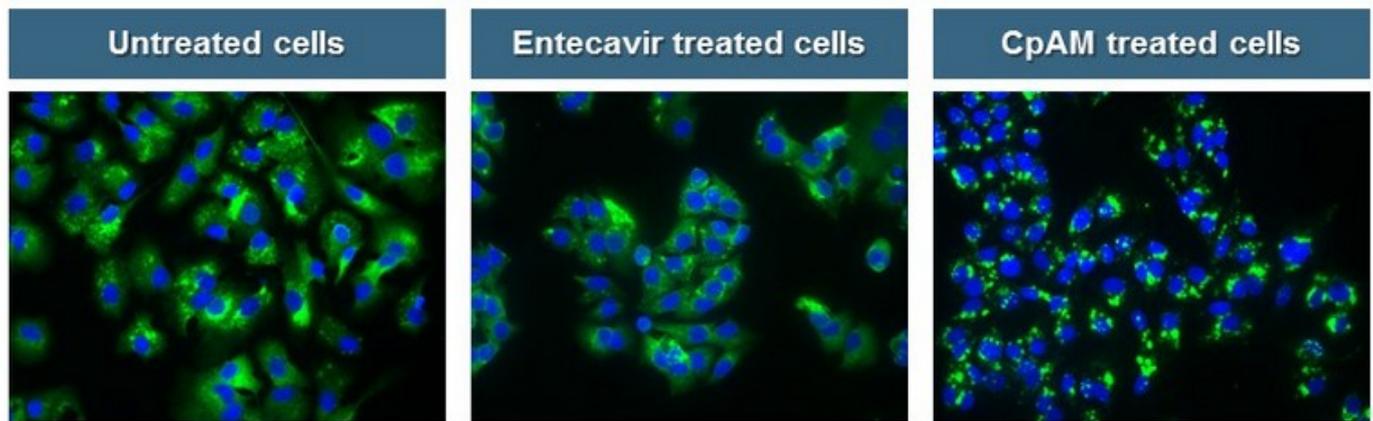
- ◆ **Strong patent position on CpAMs (Core protein Allosteric Modifiers) compositions and uses for HBV**
- ◆ **Potent lead series**
  - Alters Cp oligomer conformation
    - Reduces pgRNA packaging
    - Inhibits rcDNA formation
    - Reduces rcDNA delivery to nucleus
  - **Prevents synthesis of new cccDNA**
- ◆ **Profile of first candidates**
  - Potent, pan-genotypic activity ( $EC_{50}$  20-200nM) across multiple viral genotypes (A-D)
  - Highly favorable drug characteristics and PK profile in multiple species
  - IND-enabling studies underway
- ◆ **Pursuing multiple series of CpAMs to exploit distinct Cp functions**
  - Optimizing SAR for upstream-acting compounds
  - Multiple active series under evaluation

# Ongoing Programs: Inhibit HBV Proteins



*CpAMs effect cytoplasmic and nuclear localization as well as intrinsic functions of Cp*

Effect on Cp in HBV infected cells following treatment with CpAM vs ETV



## ◆ Mechanisms by which altered CpAM localization can contribute to HBV cure

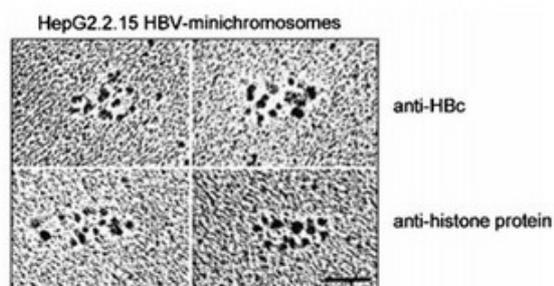
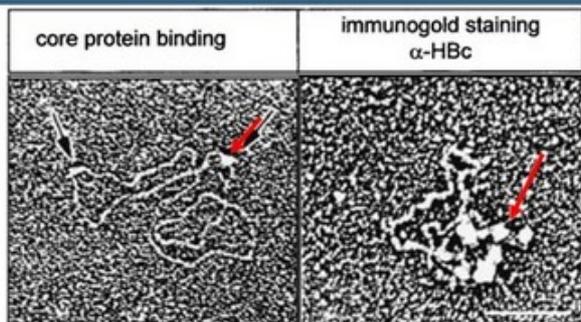
- Potential to alter antigen presentation
- Potential to drive immune mediated cell clearance
- Potential to modify Cp nuclear and cytoplasmic functions
- Potential to prevent Cp mediated regulation of immune responses



## Eliminate (or Silence) Existing cccDNA

- ◆ Persistent active cccDNA requires both host and viral proteins
- ◆ Only two viral proteins are associated with active cccDNA: Cp and HBx
- ◆ ASMB has initiated internal and external research to explore HBx and host related targets in addition to Cp

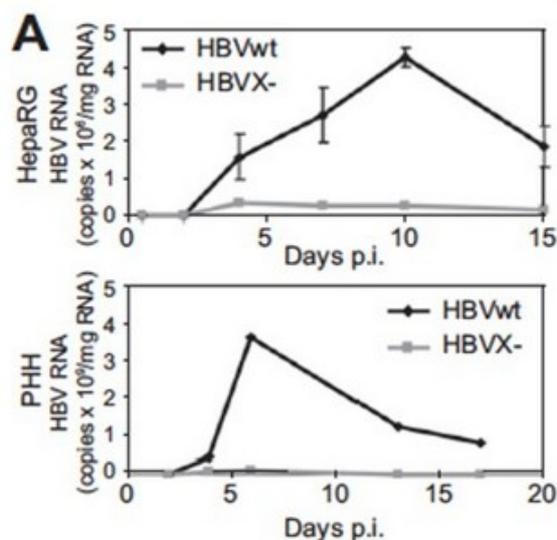
### Cp binds to cccDNA



Electron Microscopy

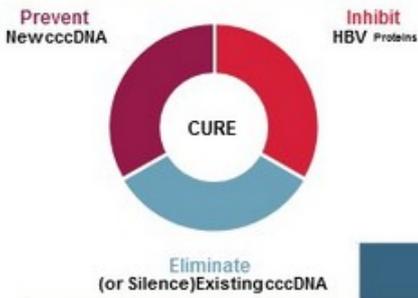
Source: Bock, Ct et al; JMB 307:183; (200).

### HBx regulation of cccDNA



Source: Riviere, L, et al. J Hepatology 63, 1093–1102 (2015).

# ASMB HBV Pipeline & Projected Timeline



	2015	2016	2017
<b>Therapeutics</b>			
<b>1st generation HBV CpAM</b>	Candidate selection	IND enabling studies	Ph 1a/1b Ph 2
<b>2nd generation HBV CpAM</b>	Research	Candidate selection	IND enabling studies Ph 1a/1b
<b>HBV upstream mechanism</b>	Research	Candidate selection	IND enabling
<b>HBV upstream mechanism</b>	Research	Candidate selection	
<b>Novel target(s)</b>		Research	



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## Microbiome Opportunity

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# Microbiome Opportunity: FMT as a Starting Point



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**EDITORIAL**  
**Fecal Microbiota Transplantation — An Old Therapy Comes of Age**  
Claran P. Kelly, M.D.  
N Engl J Med 2013; 369:474-475 | January 31, 2013 | DOI: 10.1056/NEJMe1214816

 **Journal of HOSPITAL MEDICINE** www.journalofhospitalmedicine.com

REVIEWS

**Fecal Microbiota Transplantation for the Treatment of *Clostridium difficile* Infection**  
Kishna Rao, MD<sup>1</sup>; Nasir Saeed, MD, PhD<sup>2</sup>

## Stool substitute transplant therapy for the eradication of *Clostridium difficile* infection: 'RePOOPulating' the gut

Elaine O Petrol<sup>1</sup>\*, Gregory B Gloor<sup>2</sup>, Stephen J Vanner<sup>3</sup>, Scott J Weese<sup>3</sup>, David Carter<sup>4</sup>, Michelle C Daigneault<sup>5</sup>, Eric M Brown<sup>6</sup>, Kathleen Schroeter<sup>6</sup> and Emma Allen-Vercoe<sup>6</sup>

## Administration of Spores of Nontoxigenic *Clostridium difficile* Strain M3 for Prevention of Recurrent *C difficile* Infection: A Randomized Clinical Trial

Dale N. Gerding, MD; Thomas Meyer, MD; Christine Lee, MD; Stuart H. Cohen, MD; Uma K. Murthy, MD; Andre Poirier, MD, MSc; Trevor C. Van Schooneveld, MD; Daniel S. Pard, MD, MS; Antonio Ramos, MD; Michelle A. Barron, MD; Hongyi Chen, PhD; Stephen Villano, MD

◆ ~500,000 cases of CDI yearly, 77% higher chance of being readmitted within 30 days, 55% longer hospital stay and 13% higher risk of mortality

### ◆ Dysbiotic microbiome linked to multiple diseases

- Primary CDI
- Irritable bowel syndrome (IBS)
- Other infectious diseases
- Metabolic disease
- Inflammatory bowel disease (IBD)
- Other indications (CNS; cancer)

# **Fecal Microbiota Transplant Works, But.....**



*Widespread adoption of fecal microbiota transplantation (FMT) is problematic*

- ◆ **FMT is a procedure not a product**
- ◆ **FMT is a true transplant of human-derived biological material**
- ◆ **Risks of infection transmission can't be fully resolved**
- ◆ **Poor patient and health care worker acceptance**
  - “...you want to put.... WHAT into me?”
- ◆ **Batch to batch inconsistency**

**A better approach is needed: Replace FMT with a product**

# ASMB's Proposed Solution: 'Druggable' Microbes



*Replace FMT with microbiotic therapy*

## ◆ What success in replacing FMT looks like

- An oral “biologic” pill
- Efficacy that meets or exceeds FMT response

## ◆ Assembly program plans to combine two differentiated components

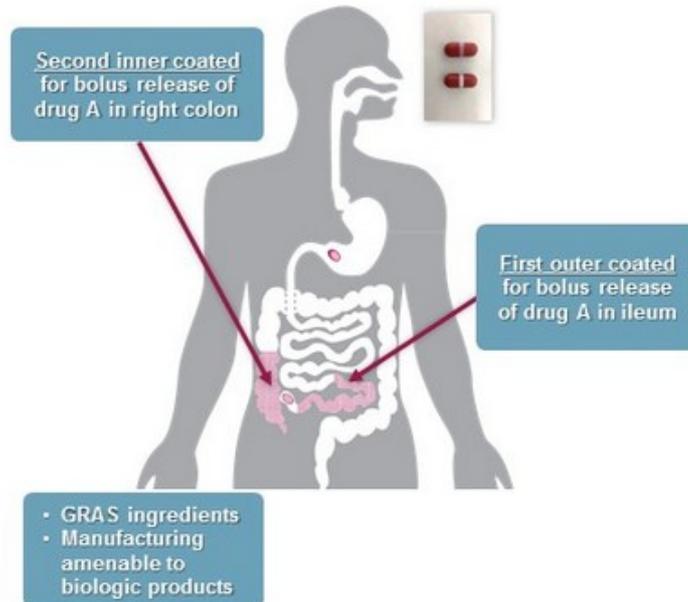
- cGMP production of systematically-selected strains of therapeutic bacteria should allow for consistent product
- GEMICEL™ platform technology; allows for targeted delivery of select strains of vegetative bacteria (both spore formers and non-spore formers) directly in the colon

# GEMICEL™ Formulation



Our proprietary targeted delivery technology enables direct treatment in the colon

## Controlled release platform



## Targeted delivery

*GI tract has number of defenses that make colonization challenging*

**6 meters**

Small intestine:  
complex pH and  
physiology



**1.5M**

Large intestine:  
complex flora



Despite challenges, the colon is an attractive site for drug delivery and especially for microbiotic delivery IF it can be reliably delivered

# Integrated Discovery & Manufacturing Engine



*Rigorous scientific development engine for bacterial therapy selection*

## Strain Selection

Proprietary selection methodologies

- ◆ Human FMT studies
- ◆ Scientifically rigorous sequencing and analysis including machine based algorithms
- ◆ *in vitro* and *in vivo* models

## Development / Manufacturing

Systems that assure proper design, monitoring and control of selected strains require

- ◆ Isolation
- ◆ Development of appropriate culture media & cultivation conditions
- ◆ GMP cell banking of pure strains
- ◆ GMP production of bulk material
- ◆ Scale up

## Targeted Delivery

**GEMICEL™** designed to enable reliable targeted delivery of otherwise “undeliverable” microbes while providing flexibility for single or multi-day regimens to optimize efficacy across multiple indications

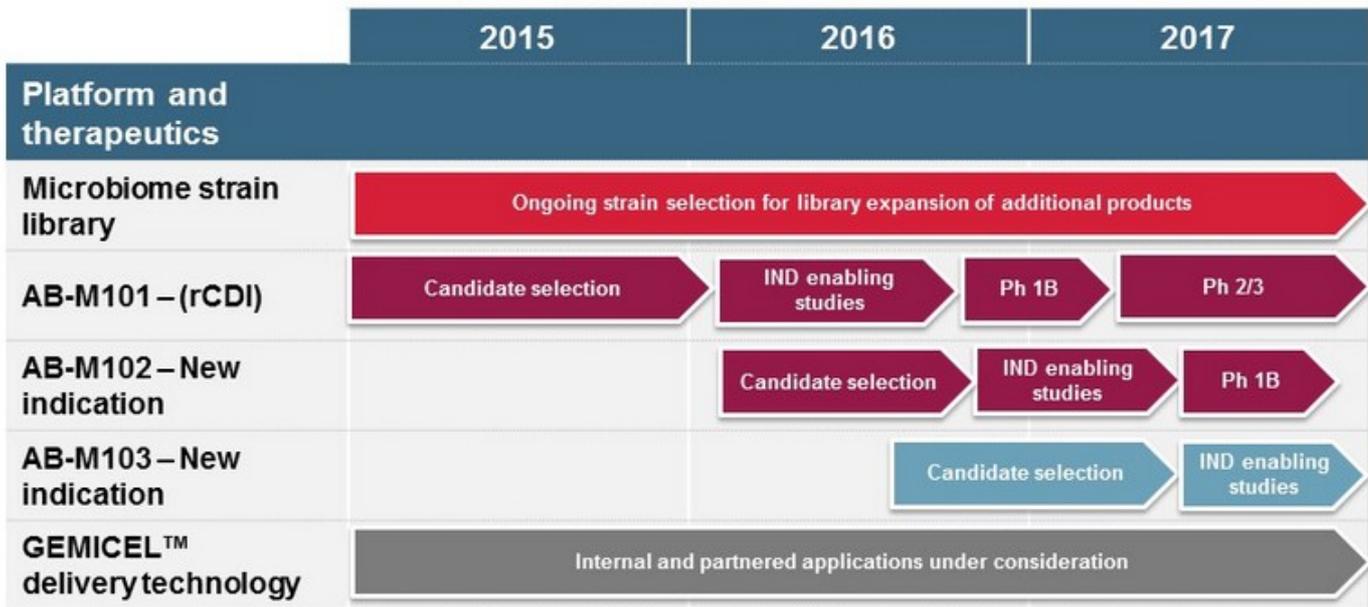
# MB Anticipated Clinical Candidate For rCDI



*Initial focus: AB-M101 as a best-in-class therapy for treatment of rCDI*

- ◆ **Efficacy:** AB-M101 oral capsules will incorporate select strains of vegetative bacteria to achieve similar efficacy and safety as FMT in the treatment of rCDI
  - We believe that a therapy including both spore and non-spore forming bacteria, delivered specifically to the lower GI tract, can be best in class for treatment of multiple types of intestinal dysbiosis
- ◆ **Regulatory/cGMP:** Anticipate that AB-M101 will be scalable, cost efficient, reliable and consistent
- ◆ **Patient Preference:** Oral treatment with dosing flexibility more acceptable to patients and may provide a better chance of efficacy/non-recurrence

# ASMB MB Pipeline & Projected Timelines



**Growing Strain library and proprietary Gemicel™ delivery system provide potential to rapidly expand into other microbiome related conditions**

- Primary CDI
- Other infectious diseases
- Inflammatory bowel disease (IBD)
- Irritable bowel syndrome (IBS)
- Metabolic disease
- Other indications (CNS; cancer)

# Financial Summary



Nasdaq	ASMB
Cash, cash equivalents & marketable securities	~\$97M as of September 30, 2015
Shares outstanding	~17.2M
Fully diluted	~20.4M

## Strong Base Of Biotech Investors



# Investment Summary

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- ◆ **Experienced team** with proven track record and deep industry experience
- ◆ **HBV platform:** Developing oral small molecules for HBV cure
  - Primary focus on Cp, as inhibitors have the potential to disrupt multiple aspects of viral life cycle
  - Continuing to explore other targets that may contribute to a cure
  - Phase 1 for lead product anticipated to begin 2H 2016 with other molecules to follow
  - Clinical strategy to pursue combination therapy early in development
- ◆ **Microbiome platform:** Developing drug-like oral biologic products
  - Initial focus rCDI to potentially restore dysbiotic microbiome from diseased to healthy state
  - Two differentiating elements to our MB program
    - A targeted delivery enables delivery of vegetative bacteria - both spore forming and non-spore forming bacteria
    - Proprietary integrated discovery and manufacturing engine with a growing library
  - Phase Ib for lead product for rCDI anticipated to begin 2H 2016; other indications to follow
  - Follow success of FMT to expand into other indications
- ◆ Achieved significant progress in 18 months and now advancing **two programs** towards the **clinic** in 2H 2016 with plans for more to follow
- ◆ **Strong balance sheet** with cash to inflection points