
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): February 24, 2016

ASSEMBLY BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35005
(Commission
File Number)

20-8729264
(IRS 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)

N/A
(Former name or former address, if changed since last report)

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 (see General Instructions A.2. below):

- 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

Assembly Biosciences, Inc. (the “Company”) is furnishing an investor presentation, attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company intends to use from time to time in meetings with investors and others beginning on February 24, 2016. The investor presentation will also be available on the Company’s website at <http://investor.assemblybio.com/index.cfm>.

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:

The following exhibit relating to Item 7.01 shall be deemed furnished, and not filed:

99.1 Assembly Biosciences, Inc. Investor Presentation February 2016.

SIGNATURES

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

Assembly Biosciences, Inc.

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

February 24, 2016

EXHIBIT INDEX

Exhibit No.

Description

99.1

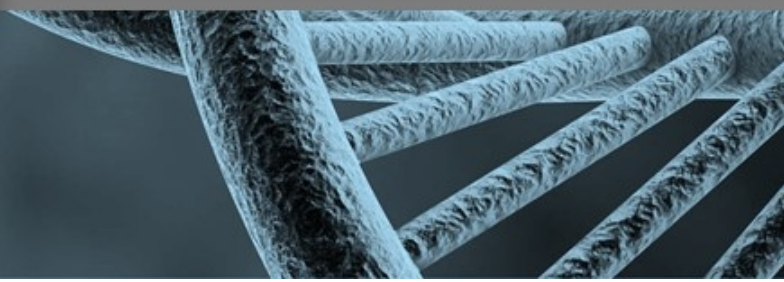
Assembly Biosciences, Inc. Investor Presentation February 2016.



Assembly Biosciences
Nasdaq: ASMB

February 2016

RBC Capital Markets
2016 Healthcare Conference



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

Focus on infectious diseases

- ◆ Developing best-in-class small molecules for the treatment of chronic **hepatitis B (HBV)**
- ◆ Platform for developing drug-like oral **microbiotic (MB) therapeutics**

World class team

- ◆ Proven leadership team producing successful companies & drugs for the past 30+ years
- ◆ 50 employees and 35 FTEs across research and development

Proprietary technologies

- ◆ Novel targets with proprietary chemistry/screening platforms (HBV)
- ◆ Differentiated discovery & development platform leveraging bacterial strain *inventory* and Gemicel™ oral capsule delivery (MB)

Strong financials

- ◆ Funded through inflection points; rapid, capital efficient development
- ◆ Partnership opportunities in non-infectious disease indications

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

	Derek A. Small President & CEO		Richard Colonno, PhD Chief Science Officer		Uri Lopatin, MD CMO & VP R&D
	Thomas Rollins Chief Development Officer Head of Microbiome		David Barrett CFO & COO		Lee Arnold, PhD 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); Targeva®; Sivestro®; Zerbaxa®; Lunesta®; Fosamax®, many others

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



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HBV-Cure Program

HBV Opportunity: More Patients Diagnosed/Treated



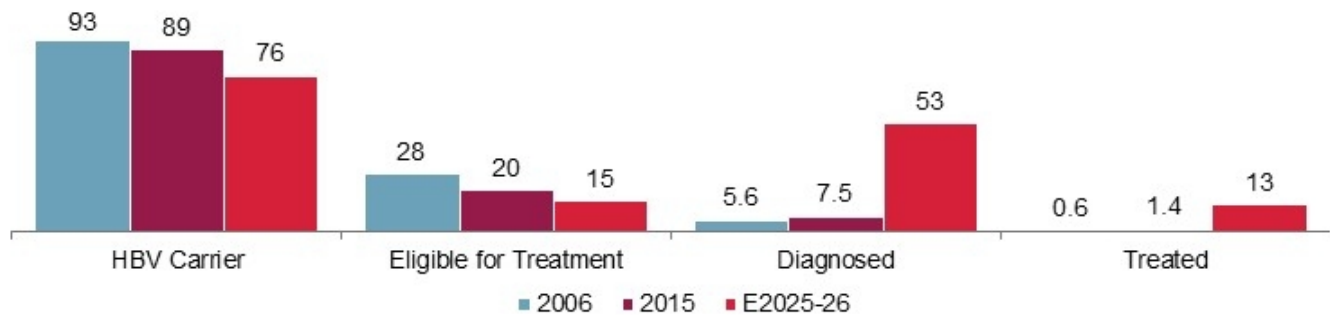
◆ ~240M chronically infected globally

- 90M in China (top 5 health priority for sFDA); >10M EU; ~ 2M in USA⁽¹⁾
- 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)



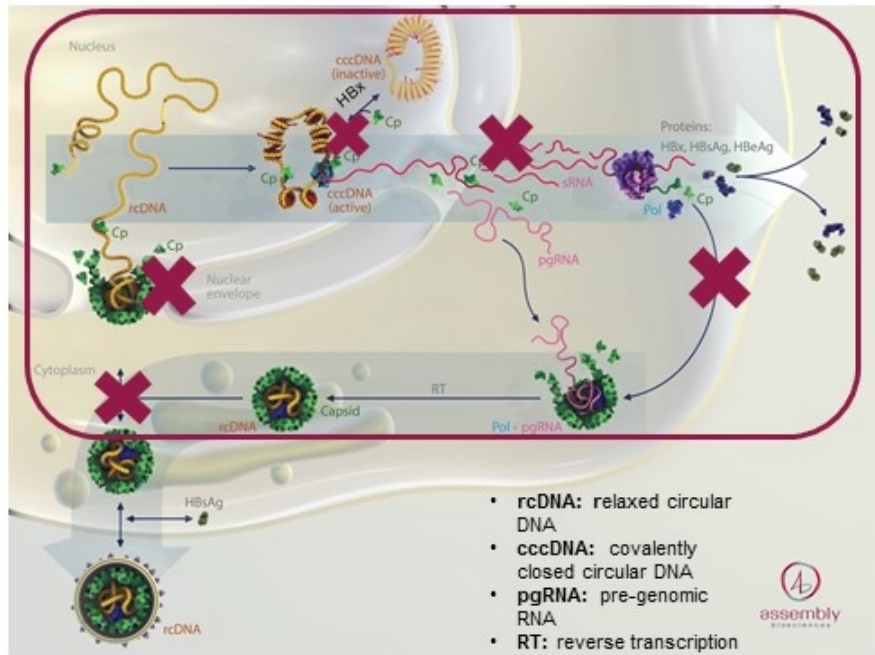
Number of patients entering treatment is increasing despite a decreasing population of new patients

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

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



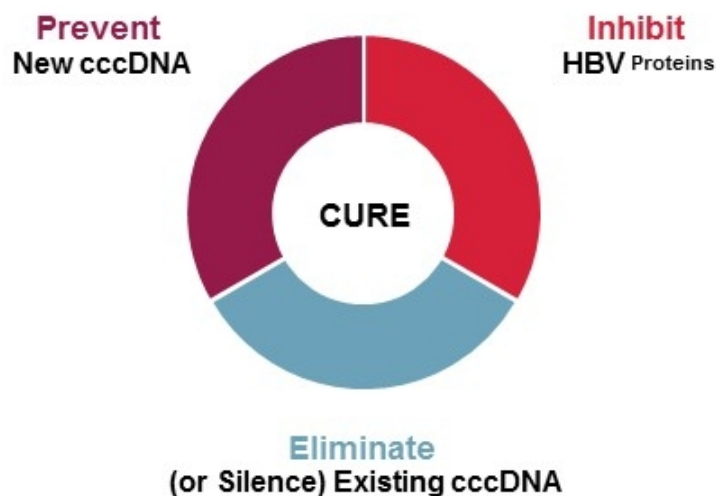
ASMB Goal: Curative Therapy for HBV



◆ 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 period¹
- 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



Lead Candidate: AB-101 to Prevent cccDNA



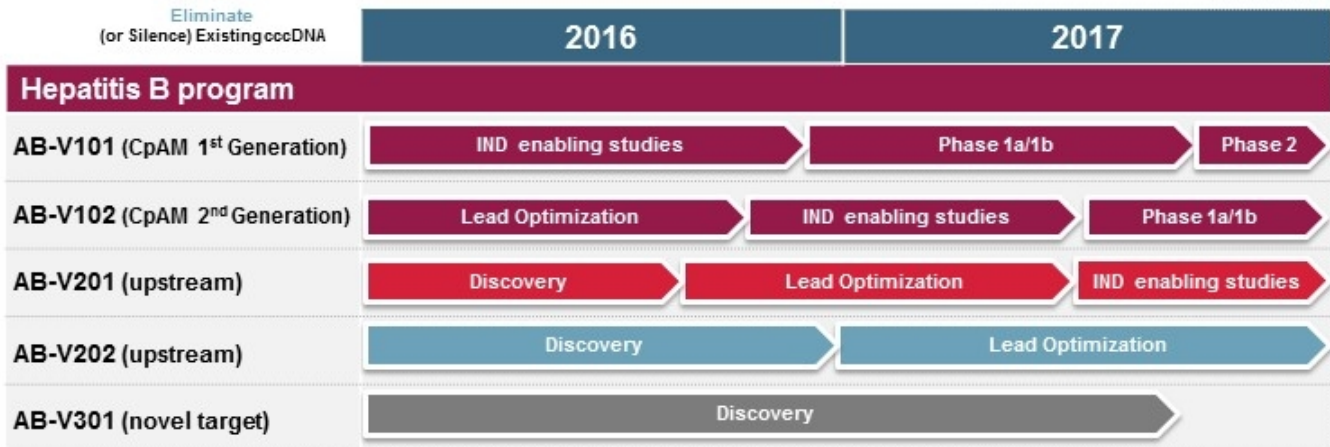
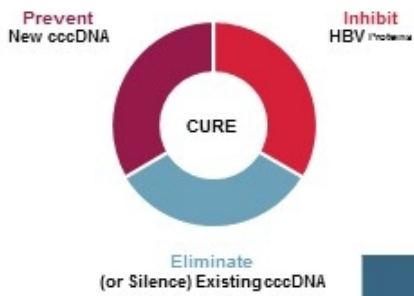
Significant progress in 2015 – selected first lead candidate & building R&D engine

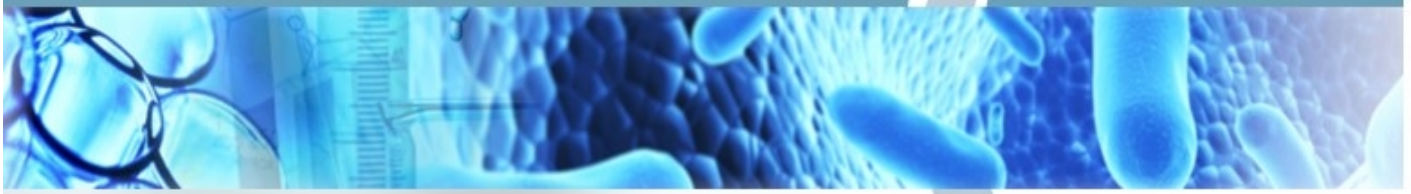
- ◆ **Strong patent position on CpAMs (Core protein Allosteric Modifiers) compositions and uses for HBV**
- ◆ **Potent lead series**
 - Alters Cp oligomer conformation
 - Reduces pgRNA packaging
 - Inhibits rcDNA formation
 - Reduces rcDNA delivery to nucleus
 - **Prevents synthesis of new cccDNA**
- ◆ **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
- ◆ **Additionally, pursuing multiple series of CpAMs for 2nd & 3rd Generations**
 - Optimizing SAR for upstream-acting compounds
 - Multiple active series under evaluation

ASMB Hepatitis B Pipeline



Lead CpAM program projected to enter Phase 1 in 2H 2016





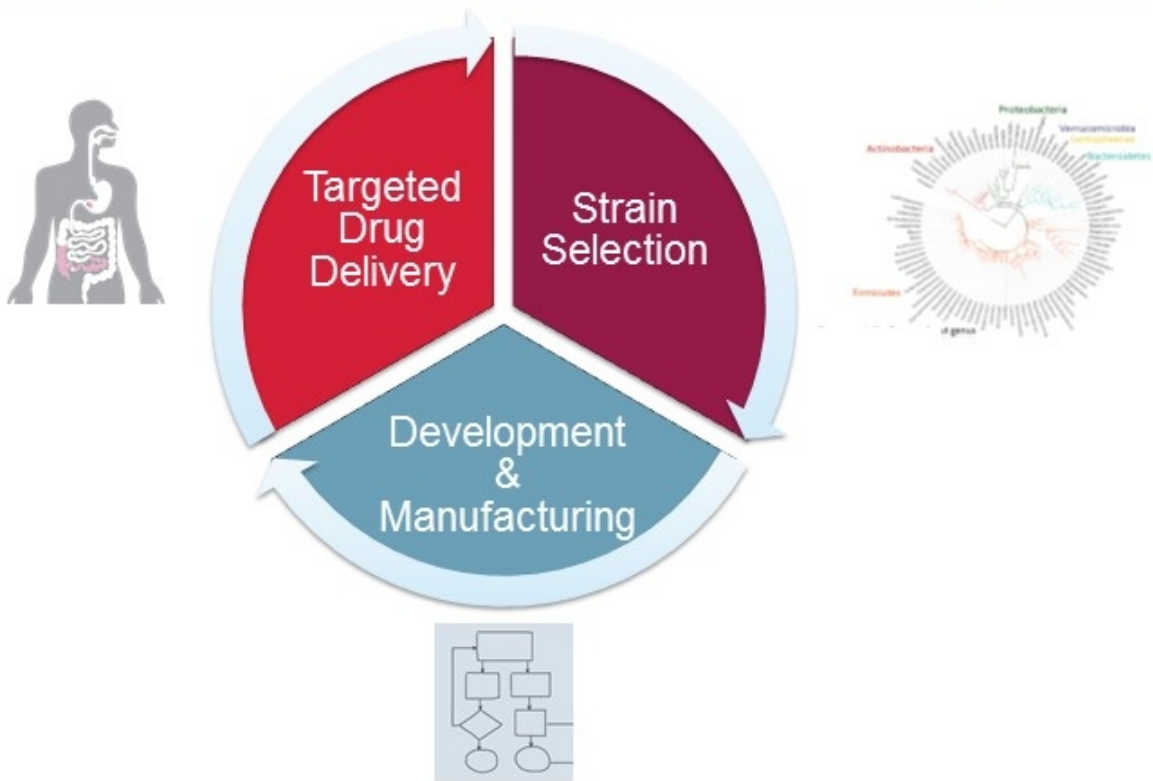
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Microbiome Program

Our Microbiome Program Vision



Best-in-class microbiome program with a fully-integrated platform to deliver drug products across multiple indications and therapeutic categories



The ASMB Approach: 'Druggable' Microbes



- ◆ **Problem:** FMT is a procedure not a product
- ◆ **Solution:** Replace FMT with oral microbiotic therapy comprised of GMP mono-cultured bacteria

Gemisel™ platform technology enables targeted delivery to the colon of select strains of vegetative bacteria

- Spores and
- Non-spores



Proprietary & scientifically rigorous strain selection methodologies, including:

- Human FMT studies
- Sequencing and analysis protocols
- *in vitro* and *in vivo* models

- Isolation
- Development of appropriate culture media & cultivation conditions

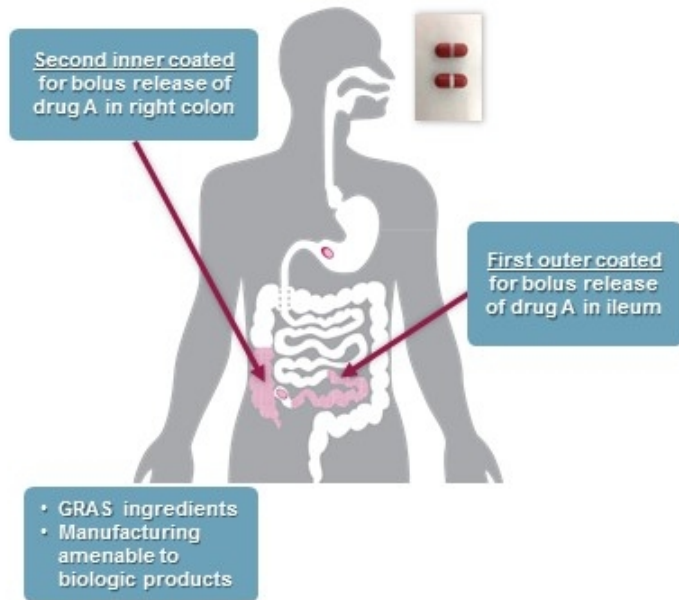
- GMP cell banking of pure strains
- GMP production of bulk material
- Scale up

Gemicel™: Providing Direct Delivery to Colon



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



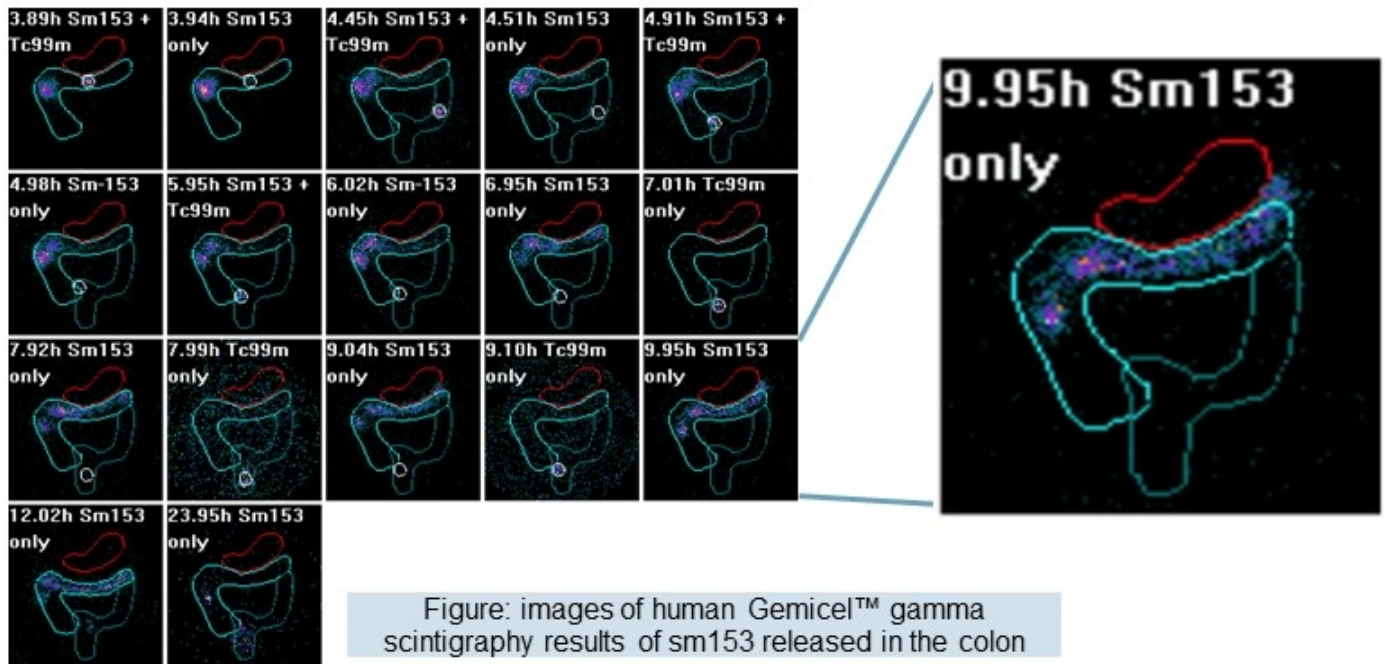
Despite challenges, the colon is an attractive site for drug delivery and especially for microbiotic delivery IF it can be reliably delivered

Human Scintigraphy Study: Gemice1™ POC



ASMB presented the bolus release demonstrated in ileum and colon in Jan 2016

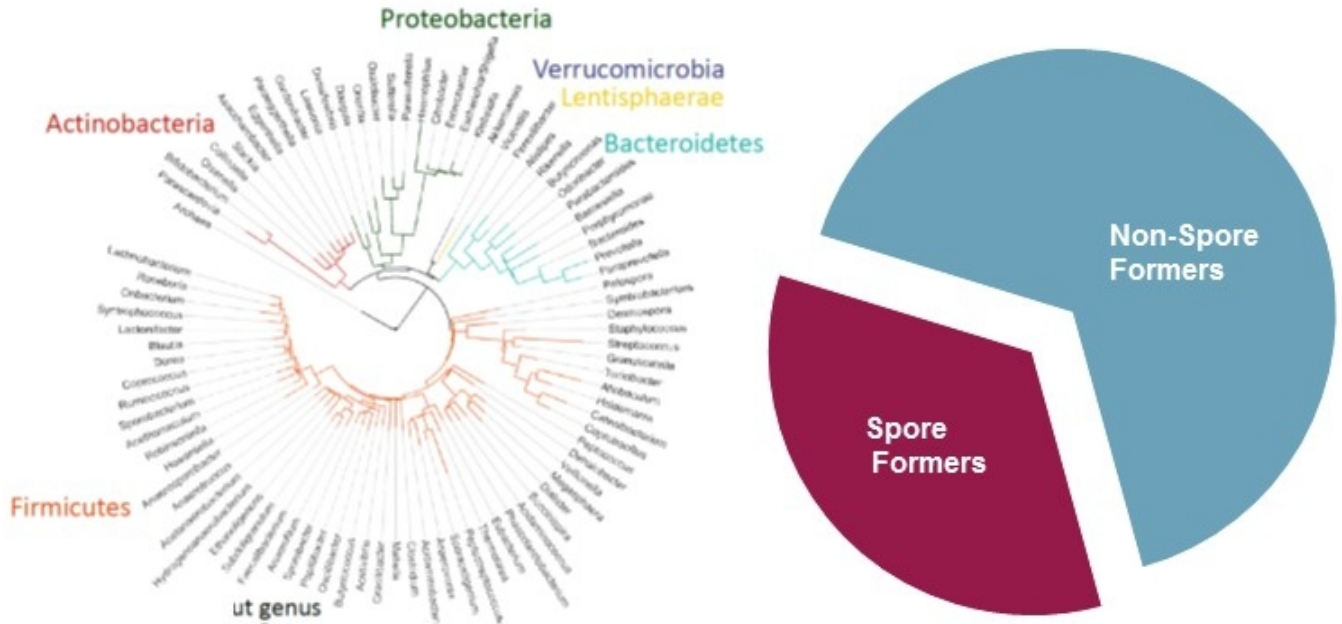
Patient Representative data: Sm-153



ASMB Strain Selection: Any Relevant Phyla



Our discovery and manufacturing engine, combined with Gemcel™ allows ASMB to use multiple phyla to optimize microbiotic therapeutics

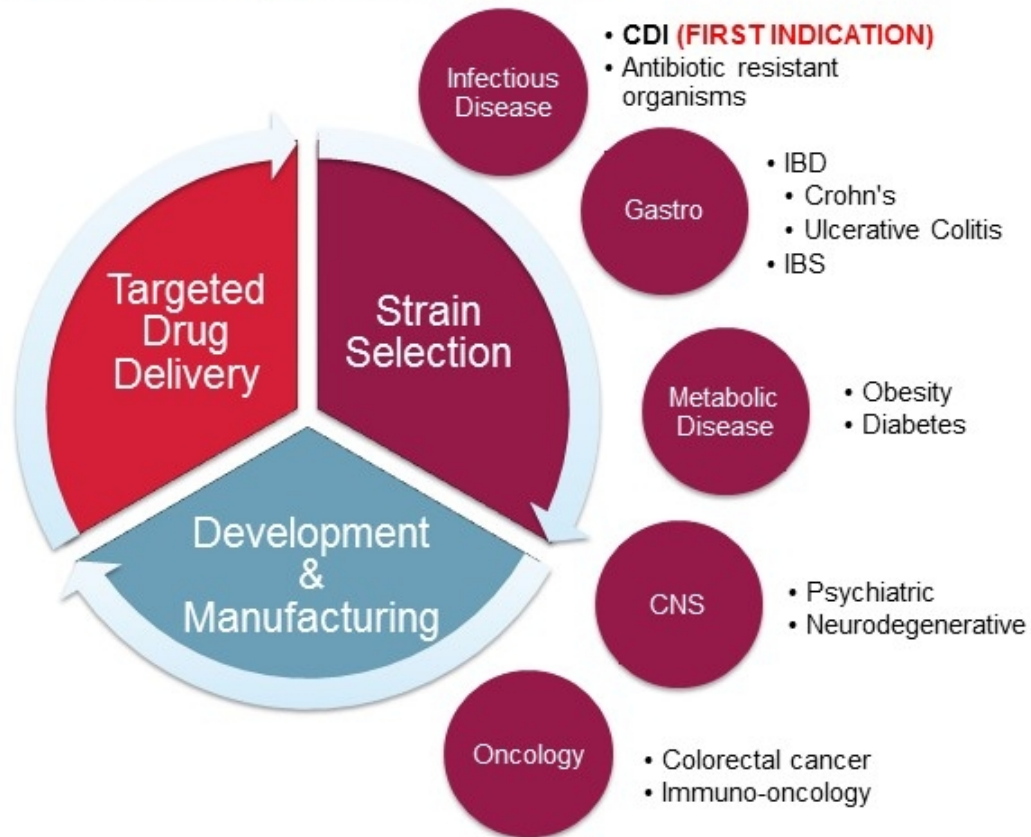


Broad capabilities provide more tools as options for complex diseases

Potential Microbiome Opportunities



ASMB platform built for therapeutic area expansion



C. Difficile: #1 Hospital Acquired Infection in US



Most common nosocomial infection in U.S

29,000

Deaths annually

\$4.9 Billion

Economic impact in US alone

\$18,000

Cost per episode for recurrent CDI patient

\$50,000

Amount saved per patient to break the recurrence cycle

NATIONAL ACTION PLAN FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA

TABLE 1: National Targets to Combat Antibiotic-Resistant Bacteria
By 2020, the United States will:
For CDC Recognized Urgent Threats:
Reduce by 50% the incidence of overall <i>Clostridium difficile</i> infection compared to estimates from 2011.
Reduce by 60% carbapenem-resistant Enterobacteriaceae infections acquired during hospitalization compared to estimates.
Maintain the prevalence of ceftriaxone-resistant <i>Neisseria gonorrhoeae</i> below 2% compared to estimates from 2013.

Dubberke 2012

Ghantoui 2010

National Action Plan for Combating Resistant Bacteria: March 2015

Leffler DA, Lamont JT. N Engl J Med 2015;372:1539-1548

AB-M101: Clinical Candidate for rCDI



Initial focus: 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:** Rapid regulatory/development path

- ◆ **Manufacturing:** cGMP manufacturing of individual strains; scalable, cost efficient, reliable and consistent

- ◆ **IP:** Gemichel™ is a patent pending delivery technology that allows for a unique IP position for all ASMB products in the microbiome program, including AB-M101

- ◆ **Patient Preference:** Oral treatment with dosing flexibility more acceptable to patients and may provide a better chance of efficacy/non-recurrence

ASMB Microbiome Pipeline



Lead program for recurrent rCDA projected to enter Phase 1b in 2H 2016

	2016	2017
Microbiome Program		
AB-M101 (Recurrent C.Diff)	IND enabling	Phase 1b, Phase 2/3
AB-M102 (new indication)	Lead Optimization	IND enabling studies, Phase 1b
AB-M103 (new indication)	Discovery	Lead Optimization, IND enabling
Gemicel™ (oral delivery)	Internal and partnered applications under consideration	
Strain Library & Inventory	Ongoing strain selection for library expansion of additional products	

Continued development of strain library and proprietary Gemicel™ delivery system provide potential to rapidly expand into other microbiome related conditions

- Primary CDI
- Irritable bowel syndrome (IBS)
- Additional infectious diseases
- Metabolic disease
- Inflammatory bowel disease (IBD)
- 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



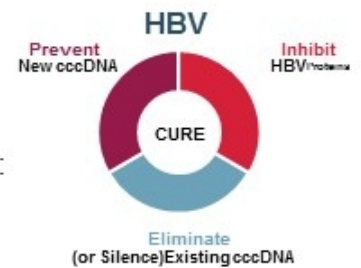
Investment Summary



◆ Experienced team with proven track record

◆ HBV platform: Developing oral small molecules for HBV cure

- Lead product anticipated to begin Phase 1 in 2H 2016
- Other molecules to follow
- Primary focus on modulating HBV Core Protein, provides an opportunity to:
 - **Prevent** new cccDNA formation
 - **Inhibit** function of existing proteins
 - **Eliminate** existing infected cells
- Clinical strategy to pursue combination therapy early in development



◆ Microbiome platform: Developing drug-like oral biologic products

- Lead product for recalcitrant CDI anticipated to begin Phase 1b in 2H 2016
- Follow success of FMT to expand into other indications
- Three differentiating elements to our MB program
 - **Strain selection** (vegetative and spore formers)
 - Process **development** and GMP **manufacturing**
 - **Targeted drug delivery** with Gemicel™



◆ Strong balance sheet with cash to inflection points