# 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): November 9, 2016**

# ASSEMBLY BIOSCIENCES, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-35005** | **20-8729264** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**11711 N. Meridian Street, Suite 310**
**Carmel, Indiana 46032**
(Address of principal executive offices, including zip code)

**(317) 210-9311**
(Registrant's telephone number, including area code)

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))

**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 November 9, 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. Corporate Presentation November 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.**

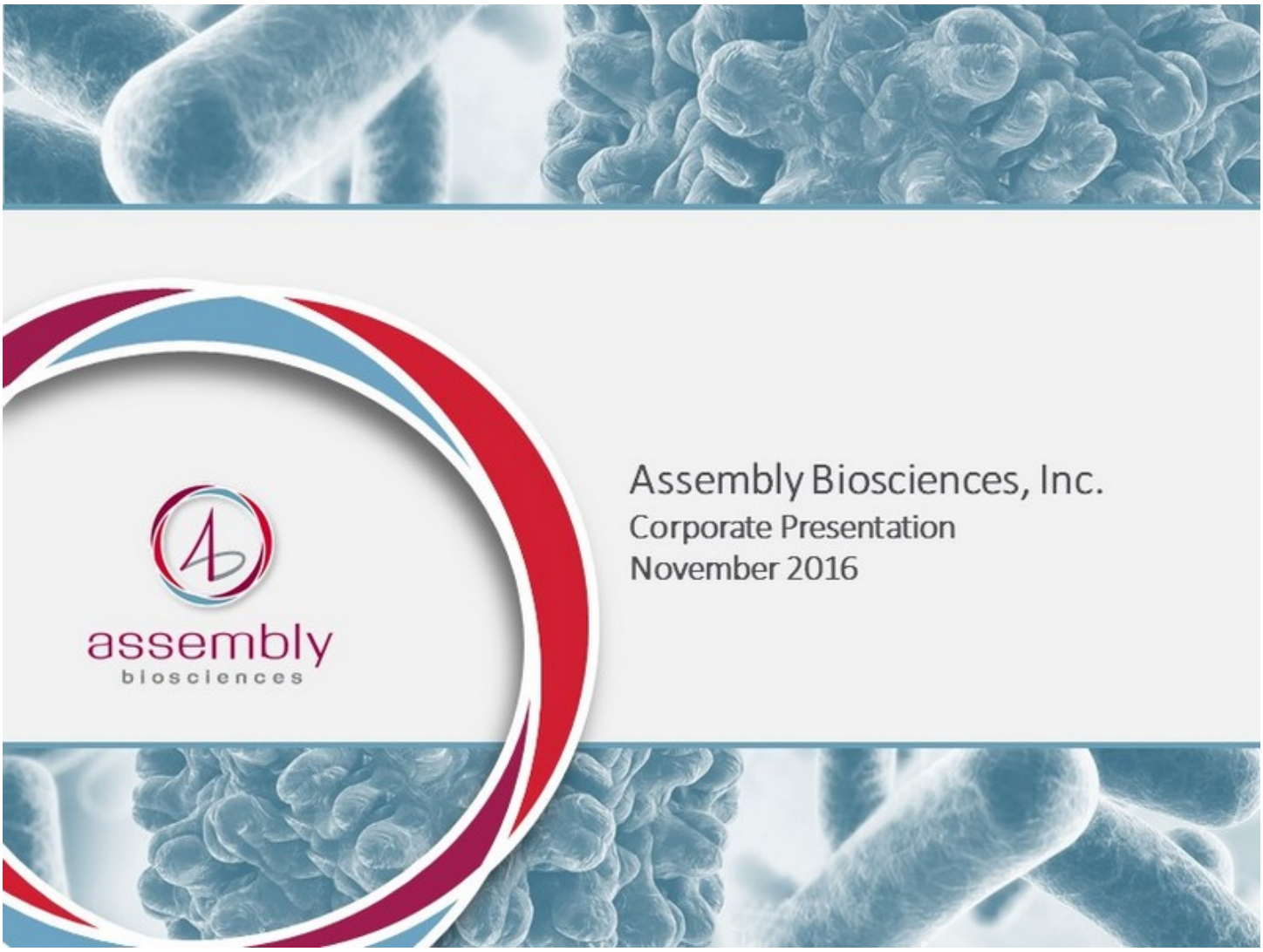
By: /s/ Derek Small
Derek Small
President and Chief Executive Officer

November 9, 2016

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Assembly Biosciences, Inc. Corporate Presentation November 2016. |

**Exhibit 99.1**


assembly
biosciences
Assembly Biosciences, Inc.
Corporate Presentation
November 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-Cure and Microbiome programs, timing of the initiation of and availability of data from our ongoing and planned clinical trials in each of these programs, plans, strategies, milestones, 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," "anticipated", "positioned," "believe" 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: preclinical models may not be representative of disease behavior in clinical studies, 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, 2015, 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.

# Company Highlights

## Clinical-stage company focused on two key areas of drug development

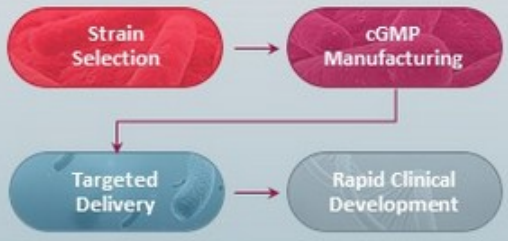
### HBV-Cure Program

- A potent series of direct acting **oral antivirals** that selectively target HBV to increase the current low cure rate
- ASMB lead series of CpAMs target HBV Core Protein and inhibit steps involved in cccDNA formation and viral replication

Core Protein Allosteric Modulator (CpAM)


### Microbiome Program

- Oral **live biotherapeutics** designed to address diseases associated with the human microbiome
- Capability to rapidly advance therapies to clinical trials




### Proprietary Technologies

- HBV: Chemically differentiated patent estate
- MB: GEMICEL® a targeted patented pending delivery technology and inventory of synthetic bacteria

### Experienced Team

- Proven leadership team producing successful companies & drugs
- 65 employees and 31 dedicated chemists

### Financial Position

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

# Experienced Leadership Team

Proven leadership team producing successful companies and drugs

**Derek A. Small**
President & CEO

**David Barrett**
CFO & COO

**Uri Lopatin, MD**
Chief Medical Officer

**Richard Colonno, PhD**
Chief Science Officer, HBV

**Miguel Barbosa, PhD**
Chief Scientific Officer, Microbiome

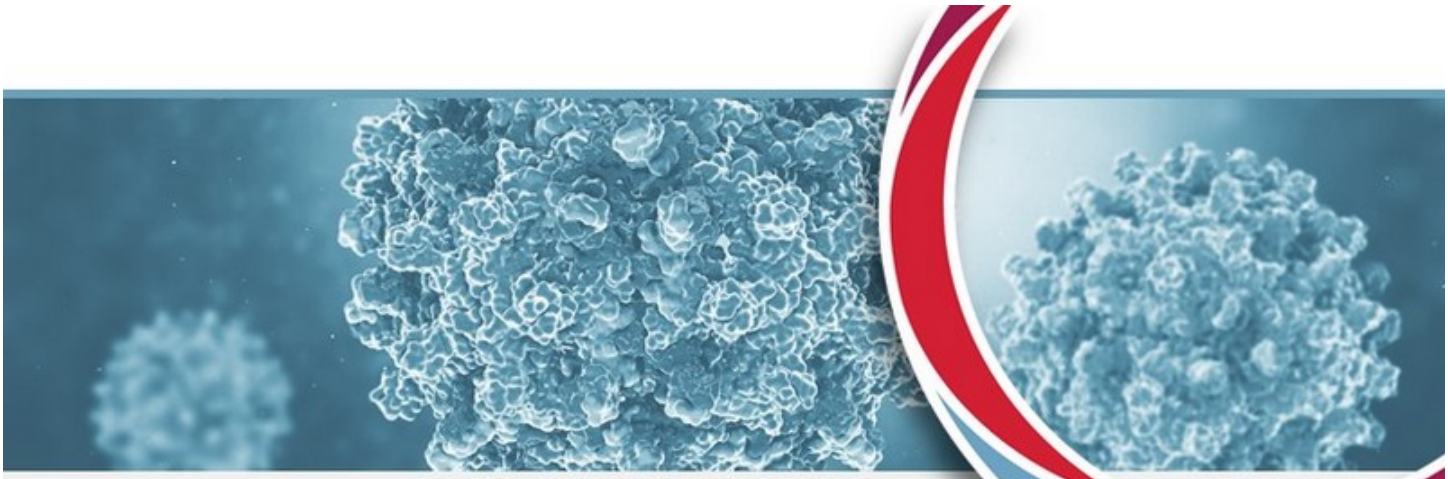
**Previous companies**


**Drugs discovered, developed, commercialized**

# Development Pipeline

| HBV Program | Discovery/Research | Lead Selection/ Optimization | IND Enabling | Clinical Trials | Near Term Milestones |
|---|---|---|---|---|---|
| ABI-H0731 (CpAM 1st Generation) | | | | | Q4 16: Initiated Ph 1 |
| CpAM 2nd Generation | | | | | H1 17: Preclinical profile |
| CpAM 3rd Generation | | | | | H2 17: Preclinical profile |
| HBV Novel Target | | | | | |

| Microbiome Program | Discovery/Research | Lead Selection/ Optimization | IND Enabling | Clinical Trials | Near Term Milestones |
|---|---|---|---|---|---|
| ABI-M101 (Recurrent *C.diff.*) | | | | | Q1 17: File IND |
| ABI-M201 (undisclosed indication) | | | | | Q2 17: IND enabling manufacturing |
| ABI-M301 (undisclosed indication) | | | | | Q2 17: IND enabling manufacturing |
| Other Indications | | | | | |



# *Hepatitis B – Cure Program*

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# Significant need for curative therapies for Hepatitis B

Market Opportunity ~240 million patients worldwide, ~90 million in China, >1 million in US

## Current therapies are inadequate

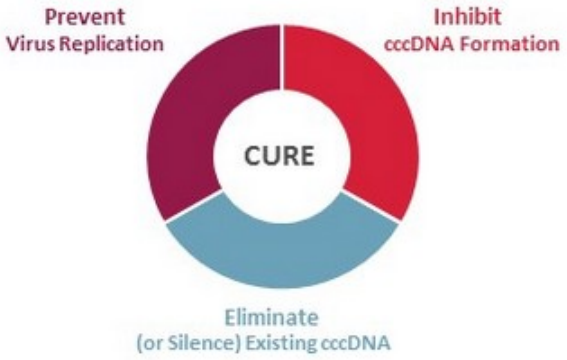
Limited to nucleos(t)ide analoges (Nucs) [entecavir, tenofovir] or pegylated-interferon-alpha (PegIFN-α)
Nucs suppress and maintain viral load at undetectable levels for years, allow for 1x/day dosing, well tolerated, and have a high barrier to resistance, BUT:

- *Less than 10% of patients achieve a sustained response off therapy*
- *NOT curative because they have limited effect on cccDNA*

• IFN's are poorly tolerated, compliance is challenging, and cure rates are low

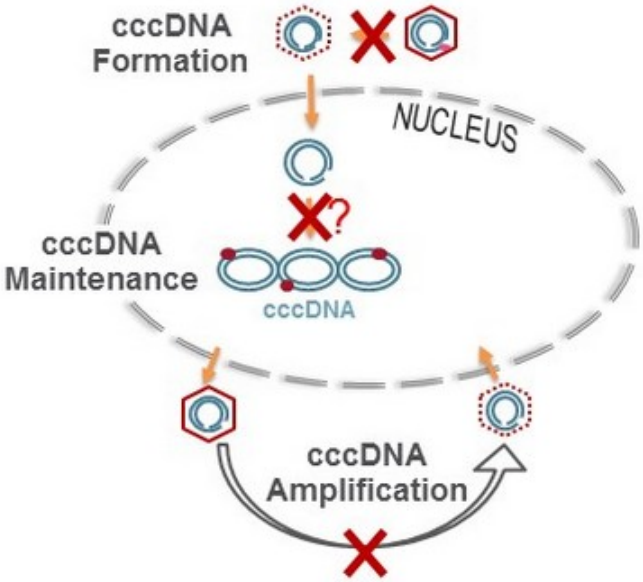
## ASMB believes a cure is possible

Decreasing/silencing cccDNA levels likely required to increase cure rates



# ASMB Goal: Curative Therapy for HBV

- HBV lifecycle is a complex process
- Nucs only inhibit reverse transcription
- HBV Cure requires inhibiting the formation of new cccDNA and/or silencing of existing cccDNA
- HBV core protein is believed to be involved in the amplification, formation and maintenance of cccDNA and pgRNA encapsidation

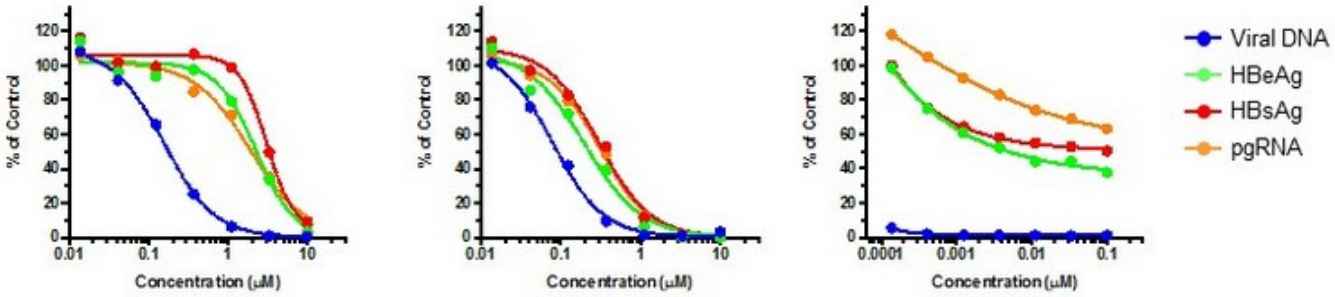



*ASMB has identified and developed a series of potent CpAMs that inhibit at least two of the three critical steps involved in cccDNA*

# CpAMs inhibit cccDNA formation in PHH cells

## Viral DNA, pgRNA, HBeAg and HBsAg in Primary Human Hepatocytes

**CpAM - ABI-H0731** | **CpAM - ABI-H0808** | **Nuc - Entecavir**




| | $EC_{50}$ (nM) | | | |
|---|---|---|---|---|
| **Compound** | **Viral DNA** | **HBeAg** | **HBsAg** | **pgRNA** |
| ABI-H0731 | 154 | 2,210 | 3,000 | 1,840 |
| ABI-H0808 | 80 | 196 | 310 | 305 |
| ETV | <0.1 | Incomplete | Incomplete | Incomplete |

- CpAMs reduced viral HBV DNA levels and known surrogate markers for cccDNA (HBeAg, HBsAg and pgRNA)
- ETV was highly effective at inhibiting HBV DNA levels, but exhibited limited effect on cccDNA surrogates

# CpAMs block cccDNA formation in HBV infected cells

**Monitoring of HBV cccDNA Levels**

To directly show inhibition of cccDNA levels

↓

Infection of HepG2-NTCP and PHH

↓

Extraction of extrachromosomal DNA

↓

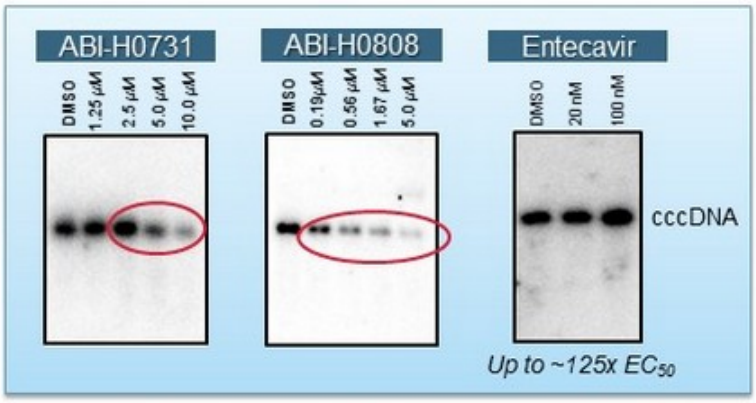
Sequential digestion with T5 exonuclease and EcoRI endonuclease

↓

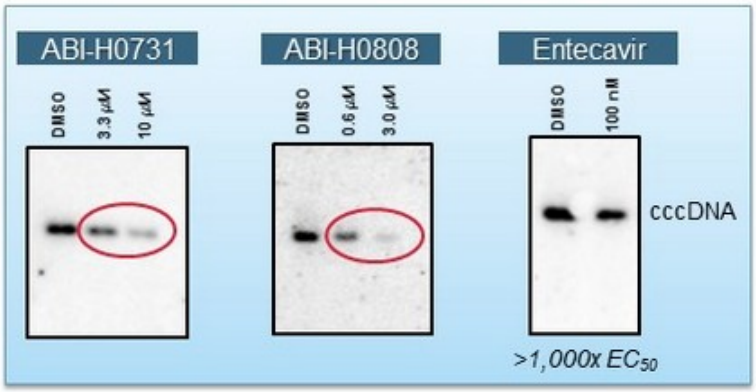
Southern Blot

- Only CpAMs reduced cccDNA formation in HepG2-NTCP and PHH
- ETV (125-1000x $EC_{50}$) had minimal effect on cccDNA levels!

**HepG2-NTCP**




**Primary Human Hepatocytes (PHH)**



# Lead Candidate ABI-H0731 and HBV Pipeline

- **Unique mechanism(s) that target core protein and affect cccDNA**
  - Not seen with current SOC
- **Favorable drug characteristics and PK profile in multiple species**
  - Balances potent antiviral effect with favorable drug properties
- **Initiated Phase 1 trial in Q4 2016**
  - Safety and PK
- **Additional candidates to be selected and optimized from proprietary CpAM series**

assembly biosciences

# *Microbiome Program*

# The Microbiome: Realizing the Promise

Modulating the gut microbiome has the potential to revolutionize the management of a broad range of therapy areas

- Infectious diseases
- GI disorders
- Oncology
- Metabolic diseases
- Neurosciences/CNS

PoC data has demonstrated that fecal microbiota transplants (FMT) will restore a dysbiotic microbiome to health

But, FMT is inadequate as a therapy:

lack of consistency, not scalable, not controlled, unreliable, poor route of administration

safety risk

**Assembly's goal:**
Develop new class of targeted, unique, safe and convenient live biotherapeutic (LBT) by applying rigorous pharmaceutical principles of drug development

# Strain selection guided by pathophysiological mechanism

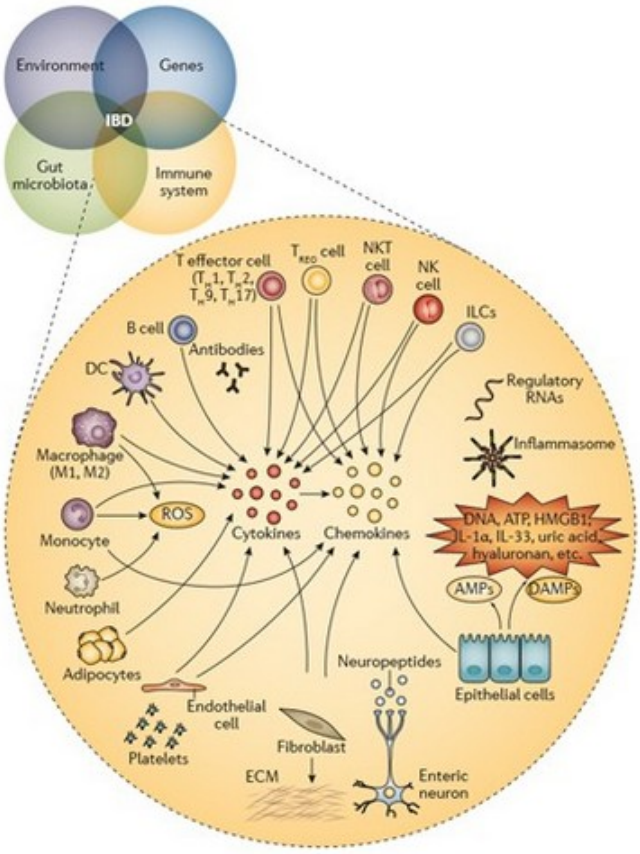
Mechanisms of disease pathology must be considered in context with environment, genome and microbiota

**Immune**

- Innate and adaptive immune
- Inflammatory mediators
- Oxidative stress

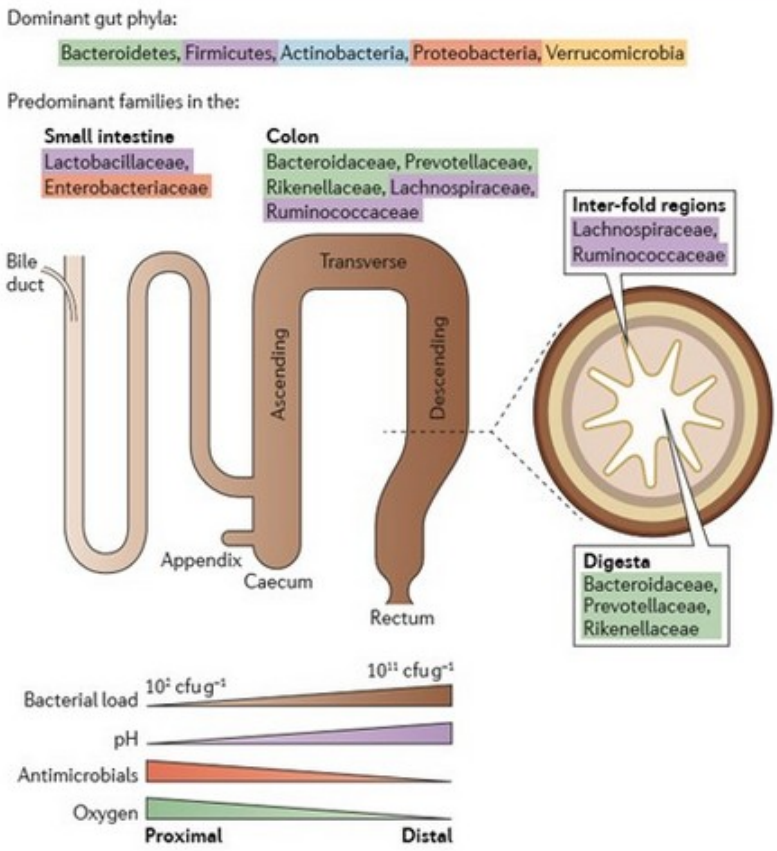
**Non-immune**

- Mucosal/epithelial barrier




Immunopathogenisis of IBD: current state of the art. 2015 Nature Reviews, & Hepatology, 13. Gastroenterology

# Unique microhabitats require targeted delivery




Gut biogeography of the bacterial microbiota. Donaldson et al. 2016 Nature Reviews Microbiology, 20.

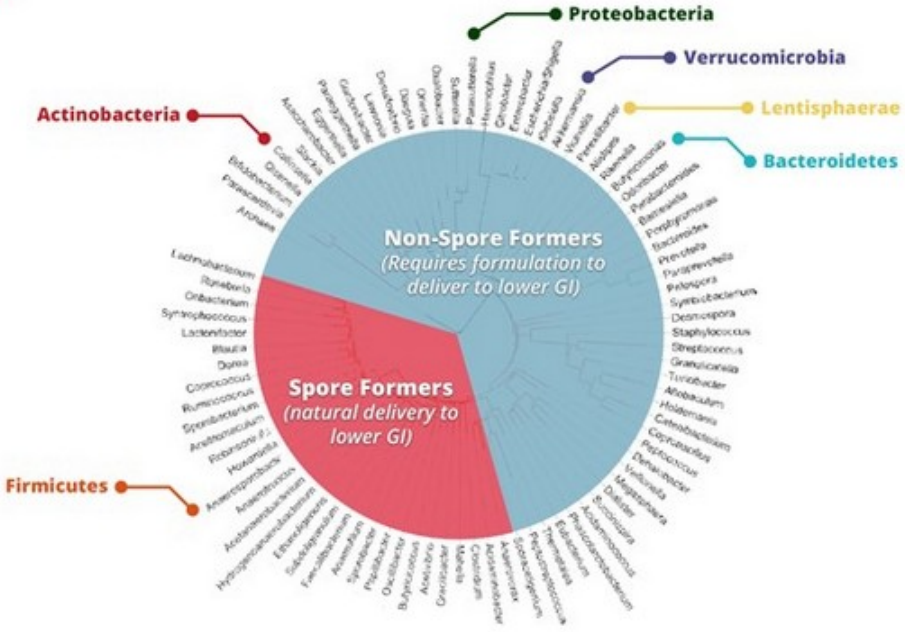
## Characteristics of Human Microbiota

- Adult intestinal microbiota is partially stable
  - ~ 40 bacterial species
- Consortia defined by
  - Founder effects
  - Immune system
  - Diet
- Bacteria microhabitats
  - pH
  - Oxygen
  - Antimicrobials
  - Nutrient availability

# Diverse phyla require unique drug formulation

Diversity is needed for optimal microbiotic therapeutics

## ASMB can deliver multiple phyla to optimize microbiotic therapeutics




Reference: SILVA. Available at: http://www.arb-silva.de/, rRNA gene database

# Solution: Our best-in-class microbiome platform

## Differentiated and fully-integrated platform to deliver live bio-therapeutics

**Strain Selection** › **cGMP Manufacturing** › **Targeted Drug Delivery** › **Rapid Clinical Development**

**Proprietary & scientifically rigorous, rational strain selection methodologies, including:**

- Human FMT studies
- Sequencing and analysis protocols
- Pathology-driven mechanisms
- In vitro and in vivo models

**Differentiated Manufacturing Approach**

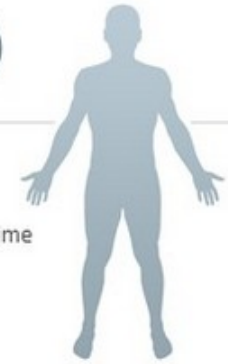
- Isolation
- Development of appropriate culture media & cultivation conditions
- Scale up
- GMP cell banking of pure strains and bulk drug substance

**Gemicel® delivery technology**

- Enables targeted delivery to specific regions of the colon
- Delivers select strains of vegetative bacteria
  - Spores
  - Non-spores

**Commensal organisms viewed as safe**

- Potentially shortens time to clinical trials
- Robust CMC data



# ABI-M101: Clinical Candidate Summary

## Best-in-class therapy for treatment of rCDI and Proof of Principle for Platform

**Efficacy:** ABI-M101 oral capsules incorporate select strains of vegetative bacteria to achieve similar efficacy and safety profile as FMT in the treatment of rCDI

- We believe that a therapy including both spore and non-spore forming vegetative 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 enabled by "bottom up" development path:

- Established product requirements consistent with prior FDA biologics experience
- No phase 1a or pre-clinical tox required

**IP:** Gemicel is a patent pending delivery technology that is used to formulate ABI-M101 and future microbiome programs

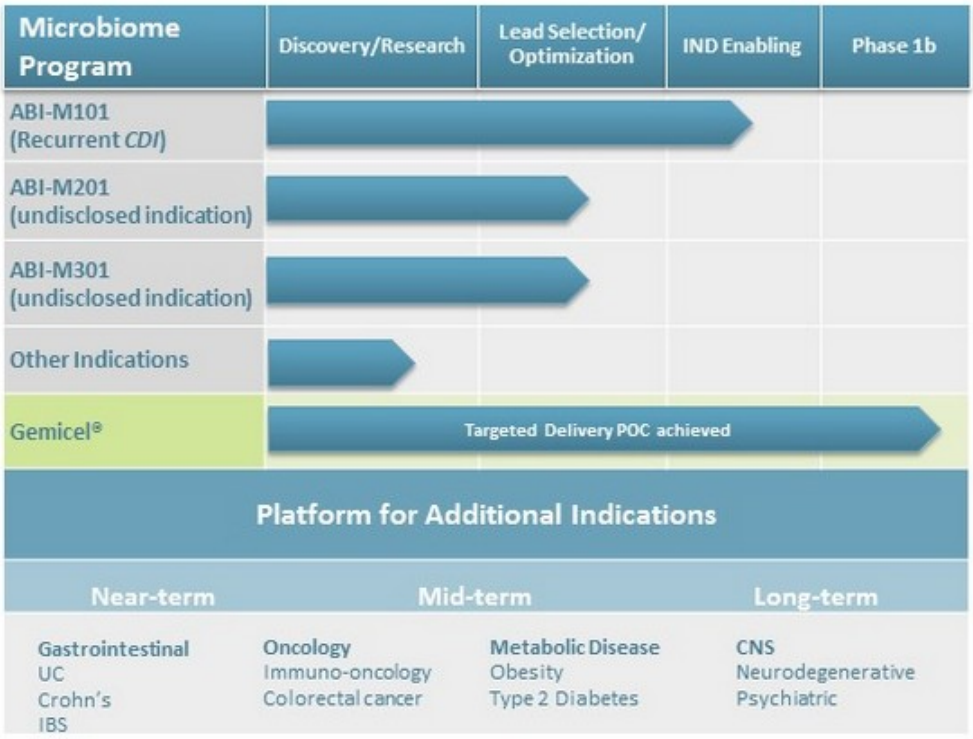
**Patient Preference:** Oral treatment with dosing flexibility more acceptable to patients

**Provide Proof of Principle** for microbiome platform

- Strain selection process
- Safe and targeted delivery of drug product

# Microbiome Pipeline and Platform

## Multiple Clinical POC Programs planned in 2016 & 2017



# 2016/2017 Milestones

- ✓ **Q3 2016 –** File CTA (IND equivalent) for ABI-H0731
- ✓ **Q4 2016** – Initiate ABI-H0731 Phase 1a/1b trial
- ❑ **Q1 2017** – File IND for ABI-M101
- ❑ **H1 2017** – Initiate ABI-M101 Phase 1 trial in *c.diff*
- ❑ **Q2 2017** – Initiate ABI-H0731 Phase 1b/2a trial
- ❑ **H2 2017** – ABI-H0731 Phase 1 safety profile and results

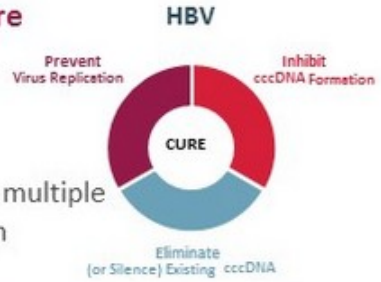
# Financial Summary

| | |
|---|---|
| **Nasdaq** | ASMB |
| **Cash, cash equivalents & marketable securities** | ~$75M as of June 30, 2016 |
| **Shares outstanding** | ~17.2M |
| **Fully diluted** | ~20.4M |

# Investment Summary

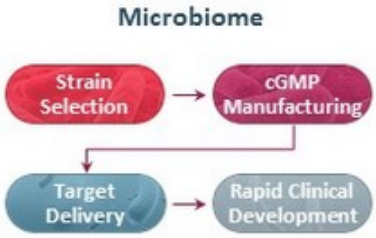
## HBV platform: Developing direct acting oral antivirals for HBV cure

- Lead product ABI-H0731 initiated Phase 1a study
- Next generation molecules to follow
- Primary focus on modulating HBV Core Protein, with affects on multiple parts of the viral cycle, including inhibition of cccDNA formation




## Microbiome platform: Developing drug-live oral live biotherapeutics

- Lead product for recurrent CDI anticipated to begin Phase 1b in H1 2017
- Build on 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®




## Experienced team with proven track record

## Strong balance sheet with cash to inflection points

Thank You

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