
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): January 9, 2017

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.)

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

(317) 975-2694
(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))
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Item 7.01. Regulation FD Disclosure

Assembly Biosciences, Inc. (the “Company”) is furnishing a corporate 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 January 9, 2017. The corporate 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, as amended (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, as amended, 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:

Exhibit No.	Description
99.1	Assembly Biosciences, Inc. Corporate Presentation January 2017.

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

Date: January 9, 2017

EXHIBIT INDEX

Exhibit No.**Description**

99.1

Assembly Biosciences, Inc. Corporate Presentation January 2017.



assembly
biosciences

Assembly Biosciences, Inc.

**Corporate Presentation
January 2017**

Nasdaq: ASMB

Cautionary note regarding forward-looking statements



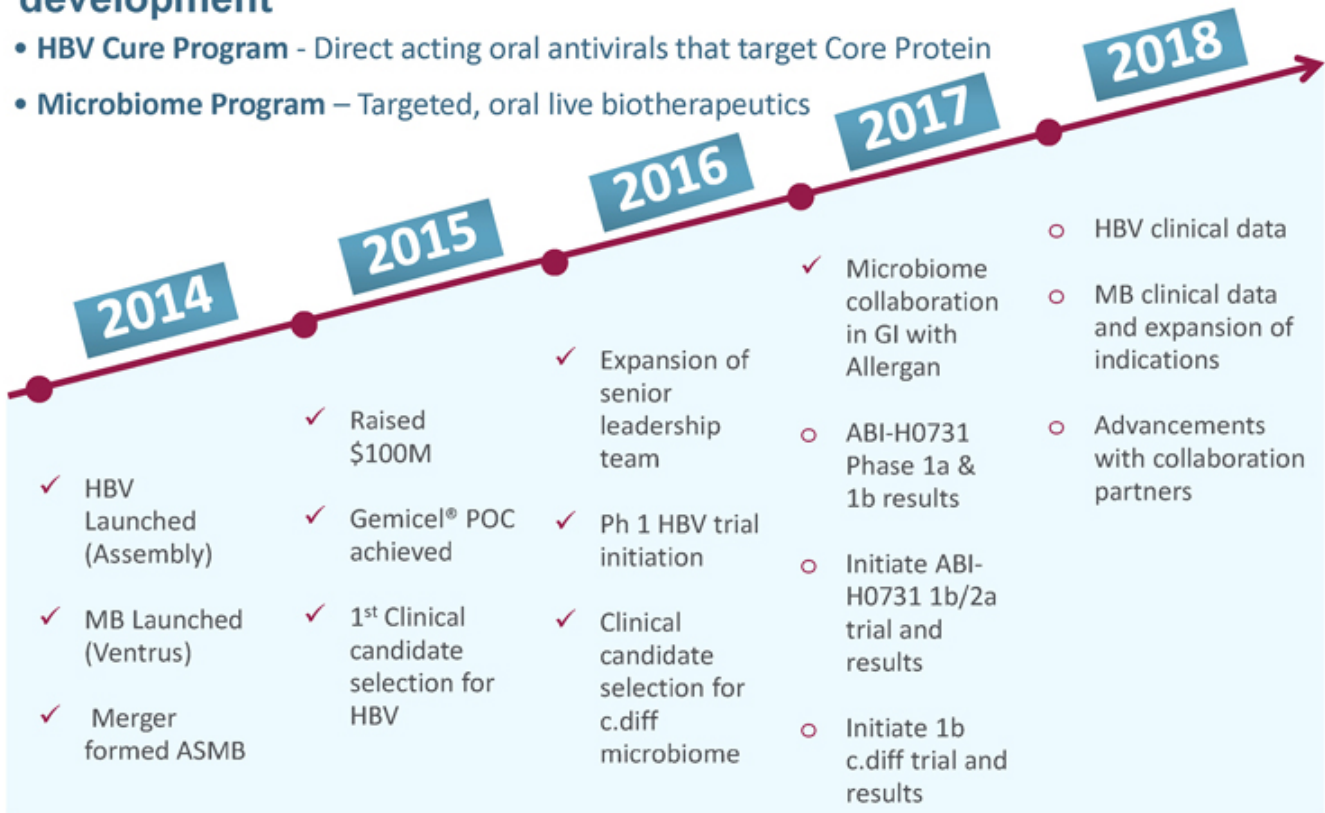
The information in this presentation contains estimates and other forward-looking statements regarding future events, including statements about the clinical and therapeutic potential of our HBV-Cure and Microbiome programs, our ability to receive payments from Allergan plc under the collaboration agreement, 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. Certain forward looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as “objective”, “planned”, “initiate”, “potential,” “anticipated”, 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: the components, timing, cost and results of clinical trials and other development activities involving our product candidates (including those licensed by Allergan plc); 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 the Quarterly Report on Form 10-Q for the quarter ending September 30, 2016 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.

Assembly Biosciences




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


- **HBV Cure Program** - Direct acting oral antivirals that target Core Protein
- **Microbiome Program** – Targeted, oral live biotherapeutics



Announcement Today: Assembly and Allergan enter Microbiome Collaboration



 **NEWS RELEASE**



CONTACTS:

ALLERGAN INVESTORS: Lisa DeFrancesco (862) 261-7152	ASSEMBLY INVESTORS: Lauren Glasser (415) 521-3828
MEDIA: Mark Marmor (862) 261-7558	MEDIA: Barbara Lindheim (212) 564-2276

Allergan Enters Into Licensing Agreement with Assembly Biosciences to Obtain Worldwide Rights to Microbiome Gastrointestinal Development Programs

— Expands Allergan's Innovative GI Pipeline with ABI-M201 and ABI-M301, Preclinical Compounds Targeting Ulcerative Colitis and Crohn's Disease, as well as Future Compounds for Irritable Bowel Syndrome —

DUBLIN, IRELAND and INDIANAPOLIS, INDIANA (USA) – January 9, 2017 – Allergan plc (NYSE: AGN) and Assembly Biosciences, Inc. (NASDAQ: ASMB) today announced that Allergan has entered into a research, development, collaboration and license agreement for the worldwide rights to Assembly's microbiome gastrointestinal (GI) development programs. The agreement provides Allergan with worldwide rights to preclinical compounds ABI-M201 and ABI-M301, targeting ulcerative colitis (UC) and Crohn's disease (CD), as well as two additional compounds to be identified by Assembly for Irritable Bowel Syndromes (IBS), with Diarrhea (IBS-D), with Constipation (IBS-C) or Mixed (IBS-M).

Under the terms of the agreement, Allergan will make an upfront payment to Assembly of \$50 million for the exclusive, worldwide rights to develop and commercialize the UC, CD and IBS compounds. Additionally, Assembly will be entitled to receive success-based development and commercial milestone payments. Assembly is also eligible to receive tiered royalties based on net sales. Allergan and Assembly will generally share development costs through proof-of-concept (POC) studies, and Allergan will assume all post-POC development costs.

- January 9, 2017 Announcement
- Allergan and Assembly collaboration to jointly develop Assembly's microbiome compounds for IBD and IBS
- Partnership includes license to:
 - ABI-M201 for Ulcerative Colitis
 - ABI-M301 for Crohn's Disease
 - Research programs Irritable Bowel Syndrome (IBS)

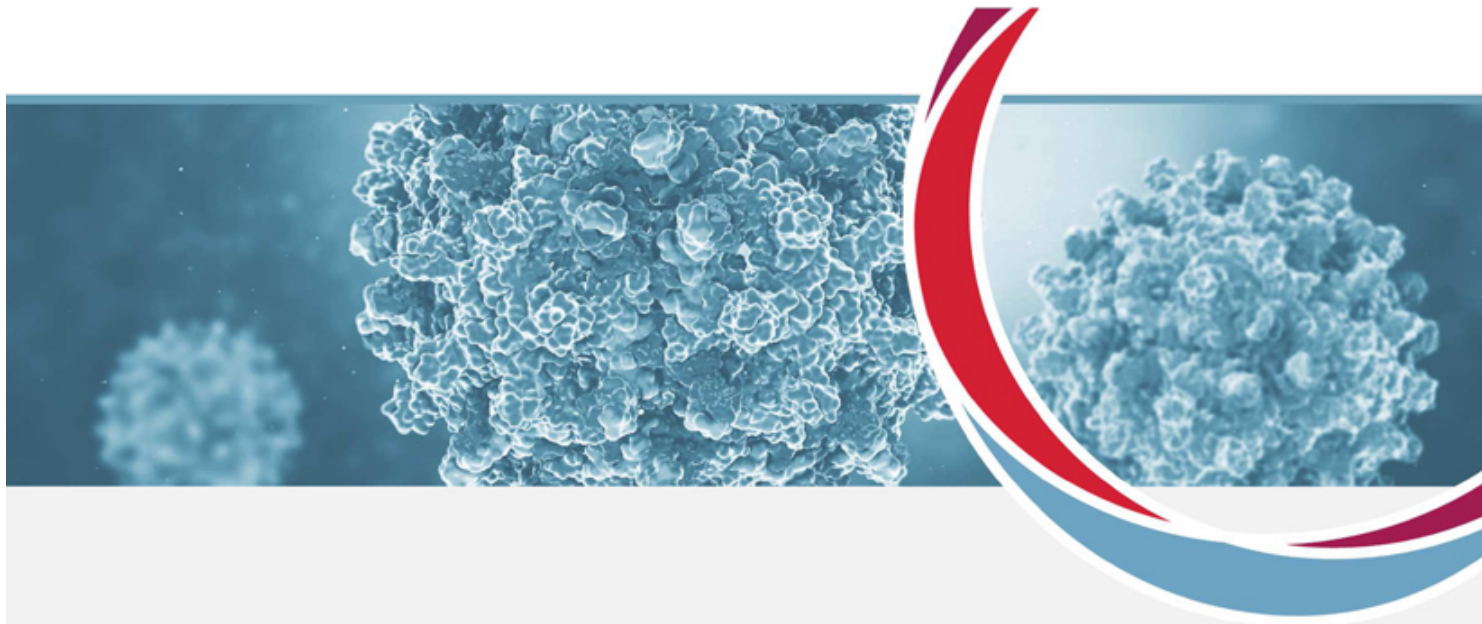
"Inflammatory diseases of the GI tract, including Crohn's disease and ulcerative colitis, are debilitating conditions that remain poorly treated for many patients. Therapies leveraging the microbiome may be able to address these disorders in fundamentally new ways. I am encouraged that microbiome innovators such as Assembly and Allergan are working to convert their promising new approaches into clinically useful products to help these patients."

• - Martin J. Blaser, MD, Director of the New York University Human Microbiome Program.

Development Pipeline



Program	Drug Candidate (Mech. / Indication)	Discovery	Lead Op / Selection	IND Enabling	Phase 1	Rights
Hepatitis B	ABI-H0731 (CpAM)					
	CpAM 2 nd Generation					
	CpAM 3 rd Generation					
	Novel Target					
Microbiome	ABI-M101 (Recurrent <i>C.diff.</i>)					
	ABI-M201 (Ulcerative Colitis)					
	ABI-M301 (Crohn's Disease)					
	IBS compounds					
	Other Indications					
	Gemicel [®] (targeted oral delivery system)	Clinical POC achieved				
Leveraging our Microbiome Platform to Rapidly Expand to Other High-rationale Indications						
Gastrointestinal		Liver • NASH • PSC	CNS • Neurodegenerative • Psychiatric	Oncology • Immuno-oncology • Colorectal cancer	Metabolic Disease • Obesity • Type 2 Diabetes	



assembly
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Hepatitis B – Cure Program



Significant need for curative HBV therapies

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

Current therapies are inadequate

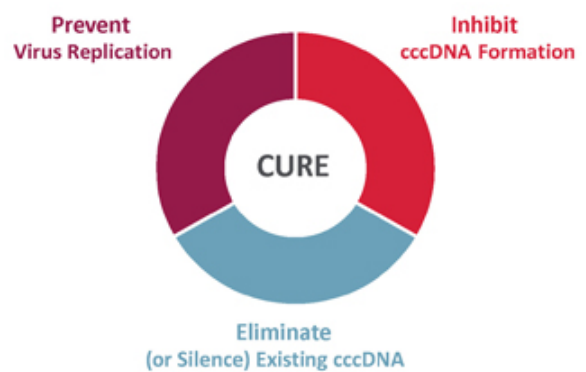
Limited to nucleos(t)ide analogues (Nucs) [entecavir, tenofovir] or pegylated-interferon-alpha (PegIFN- α)
Nucs suppress and maintain viral load at undetectable levels for years, allow for 1x/day dosing, well tolerated, and have a high barrier to resistance, BUT:

- 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
- Some patients have been cured
- Woodchucks cure correlated with elimination of detectable cccDNA*

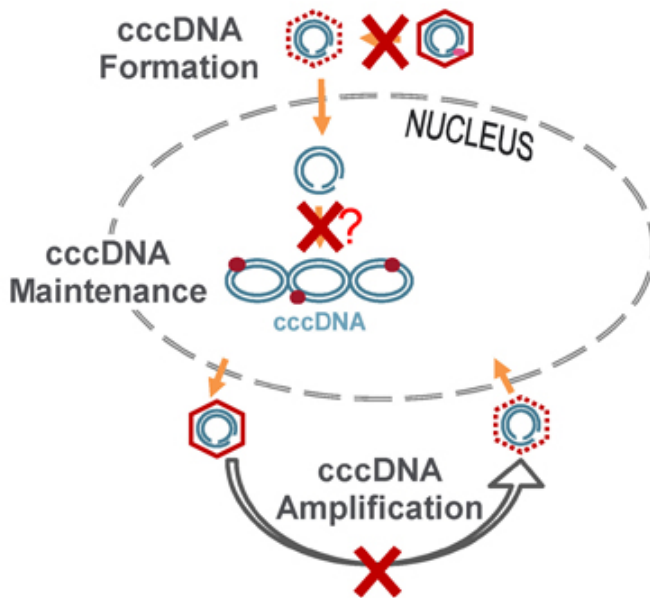
Tennant, et al. Viral Hepatitis and Liver Disease 1988: 462-464
R. Colonna, et al. JID 2001;184:1236-45





HBV lifecycle

- 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



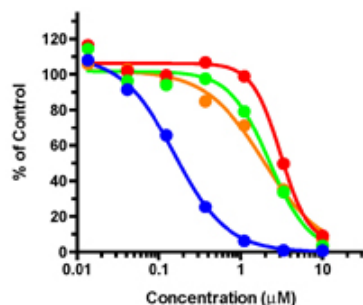
ASMB has identified and developed a series of potent CpAMs that inhibit at least two of the three critical steps involved in cccDNA



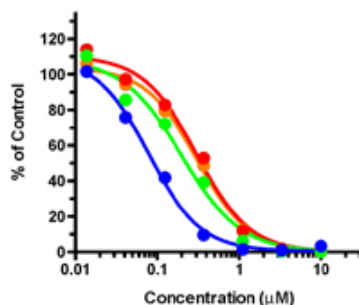
CpAMs inhibit cccDNA formation in PHH cells

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

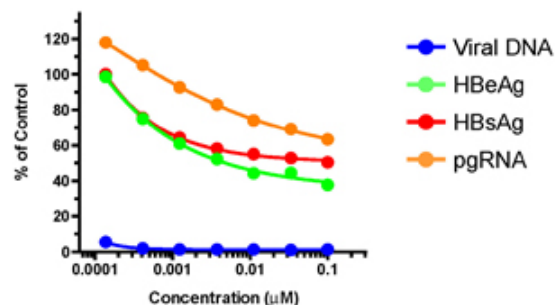
CpAM - ABI-H0731



CpAM - ABI-H0808



Nuc - Entecavir



Compound	EC ₅₀ (nM)			
	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



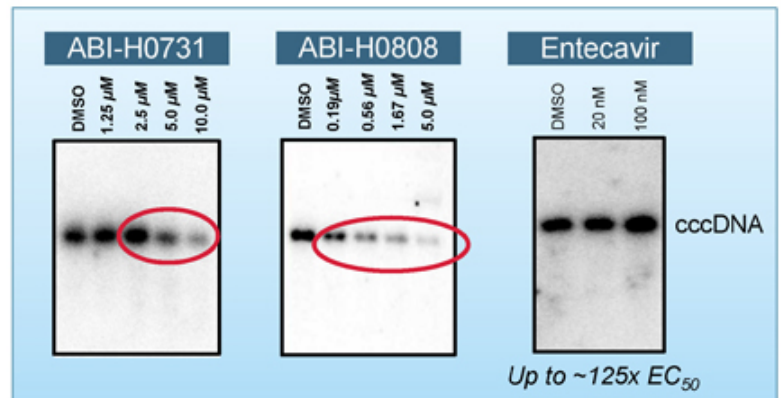
Sequential digestion with T5 exonuclease and EcoRI endonuclease



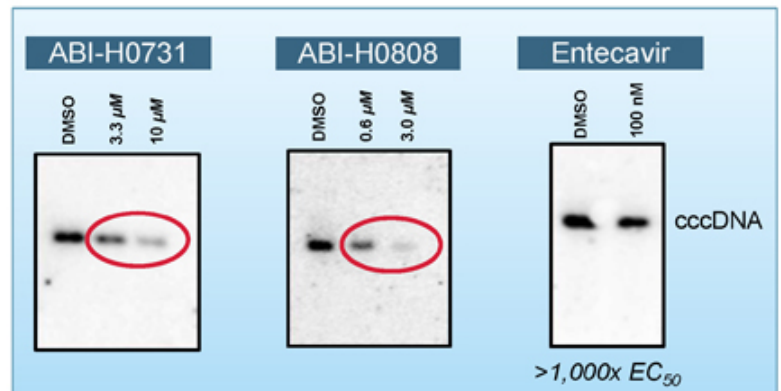
Southern Blot

- 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**

Program	Drug Candidate (Mech. / Indication)	Discovery	Lead Op / Selection	IND Enabling	Phase 1	Phase 2
Hepatitis B	ABI-H0731 (CpAM)					
	CpAM 2 nd Generation					
	CpAM 3 rd Generation					
	Novel Target					



assembly
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Microbiome Program



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**

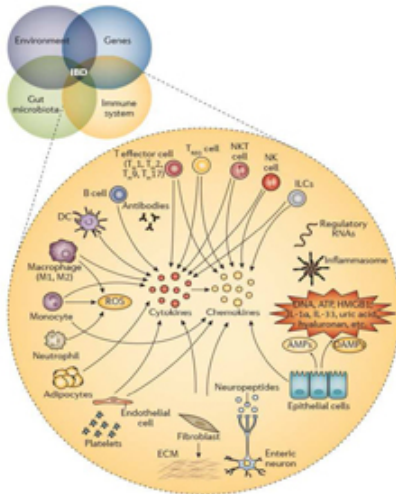
PoC data has demonstrated that fecal microbiota transplants (FMT) will restore dysbiotic microbiome to health

But, FMT is inadequate as a therapy: lack of consistency, not scalable, not controlled, unreliable, poor route of administration safety risk



Strain selection

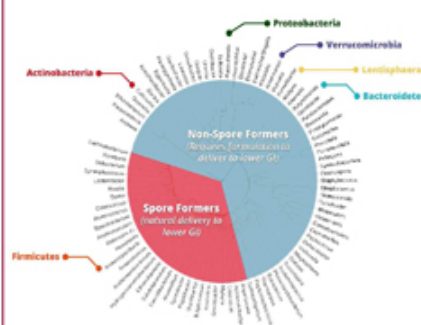
Mechanisms of disease pathology must be considered in context with environment, genome and microbiota



Manufacturing

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

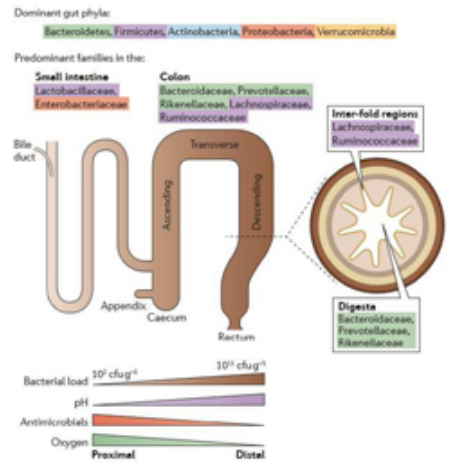
Diversity is needed for optimal microbiotic therapeutics



Targeted delivery

Unique microhabitats require targeted delivery

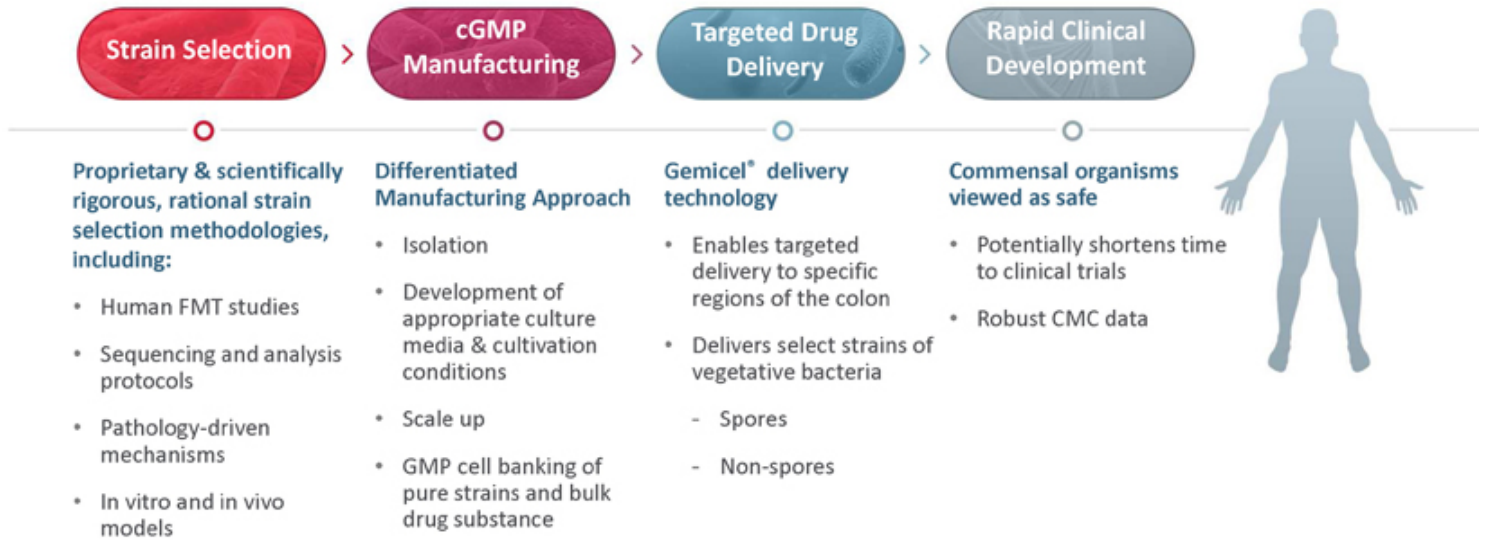
- pH
- Oxygen
- Antimicrobials
- Nutrients





Solution: Proprietary microbiome Platform

Differentiated and fully-integrated platform to deliver live biotherapeutics (LBT)





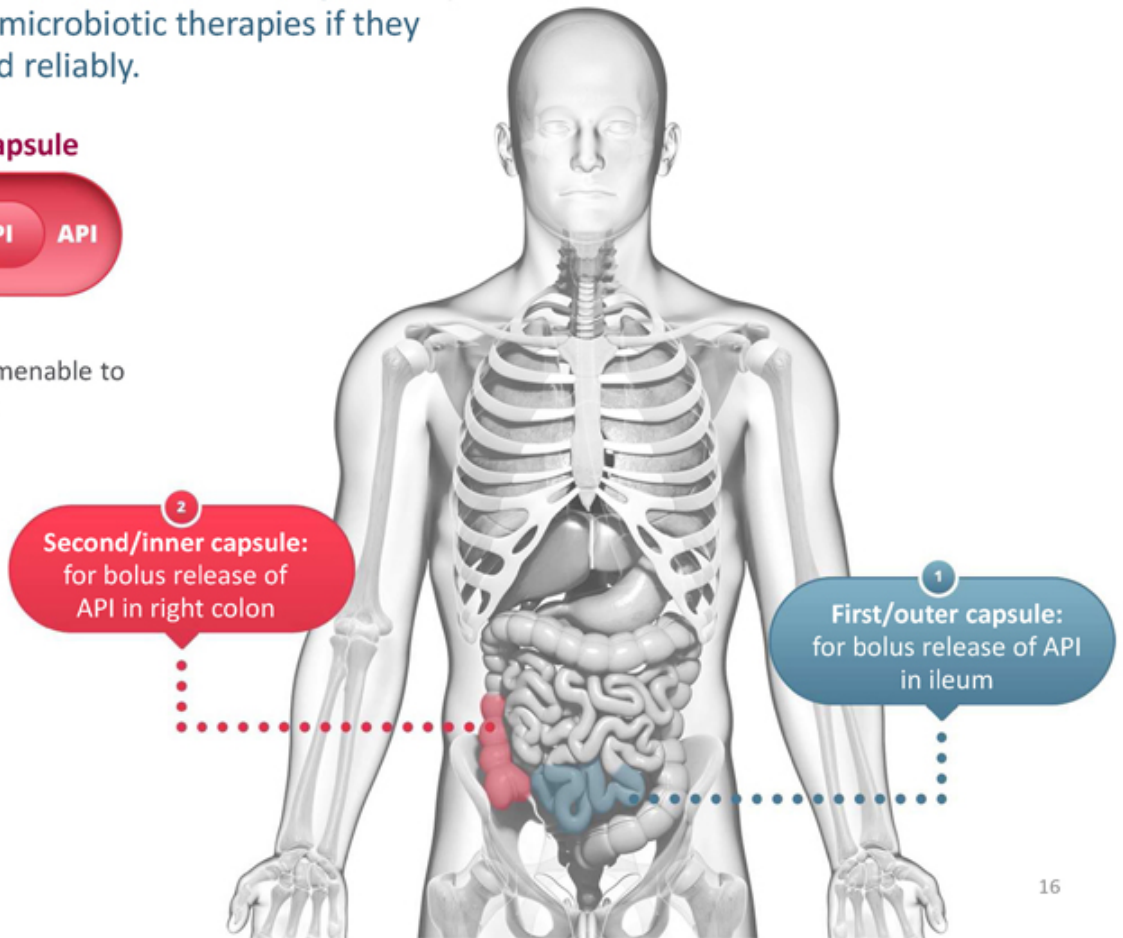
GEMICEL[®]: Targeted delivery to the colon

The colon is an attractive site for drug delivery, particularly for microbiotic therapies if they can be delivered reliably.

GEMICEL[®] Capsule



- GRAS ingredients
- Manufacturing amenable to biologic products





ABI-M101: Clinical Candidate Summary

Potential 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: Gemigel 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

Disclosed key terms for Allergan collaboration



Focus on GI Disorders



Collaboration Highlights:

- Rights for GI development programs:
 - MBI-201 for Ulcerative Colitis (UC)
 - MBI-301 for Crohn's Disease (CD)
 - 2 compounds targeting Irritable Bowel Syndrome (IBS)

Financial Highlights

- \$50M upfront payment
- Milestones & Royalties
 - Development and commercial milestones
 - Tiered royalties based on net sales
- Development Funding
 - Shared R&D funding through POC
 - AGN assumes all post-POC dev't costs

Summary: AGN/ASMB Microbiome Collaboration



Today's announcement supports important aspects of Assembly's microbiome technology platform moving forward:

1. Expedites our efforts into multiple GI indications
2. Leverages our end-to-end microbiome technology platform
3. Advances our ability to move microbiome candidates rapidly into clinical development with strategic partners
4. **Aligns with our strategic goals for the company**
 - **Leverages both our Microbiome and HBV/Antiviral programs long term financially, commercially, and globally**

We will continue to identify the best development and commercial partners to rapidly advance our Microbiome program into other indications

- Such as Liver disease/NASH, Immuno-oncology, Metabolic diseases, CNS, etc.

Microbiome Platform



Multiple Clinical POC Programs planned in 2017

Microbiome Program	Discovery	Lead Selection	IND Enabling	Phase 1b
ABI-M101 (Recurrent <i>C.diff.</i>)				
ABI-M201 (Ulcerative Colitis)				
ABI-M301 (Crohn's Disease)				
IBS Compounds				
Other Indications				
Gemice ^l ® (targeted oral delivery system)				
Other Indications for Our Microbiome Platform				
Gastrointestinal 	Liver <ul style="list-style-type: none"> • NASH • PSC 	CNS <ul style="list-style-type: none"> • Neurodegenerative • Psychiatric 	Oncology <ul style="list-style-type: none"> • Immuno-oncology • Colorectal cancer 	Metabolic Disease <ul style="list-style-type: none"> • Obesity • Type 2 Diabetes



Nasdaq	Cash, cash equivalents & marketable securities	Shares outstanding	Fully diluted
ASMB	~\$66.5M as of Sept. 30, 2016 Q1 2017: ~\$50 M upfront from Allergan collaboration	~17.2M	~21.6M



2016

- ✓ Expansion of leadership team
- ✓ ABI-H0731 candidate selection
- ✓ Ph 1 HBV trial initiation
- ✓ Increased inventory of microbiome drug substance
- ✓ ABI-M101 candidate selection

2017

- ✓ Microbiome collaboration for GI indications
- H1: ABI-H0731 Ph 1a/b safety & PK profile
- Q2: Initiate ABI-H0731 Ph 1b/2a trial
- H1: Initiate ABI-M101 Ph 1 trial in c.diff
- H2: ABI-H0731 Phase 1b/2a results
- H2: 2nd Gen CpAM HBV selection
- MB Indication expansion



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-like oral live biotherapeutics

- First major collaboration with Allergan in GI, 4 development programs
 - Non-GI indications available to partner
 - Three differentiating elements to our MB program
 - **Strain selection** (vegetative and spore formers)
 - **Process development** and **GMP manufacturing**
 - **Targeted drug delivery** with Gemicel®
- Lead product for recurrent CDI anticipated to begin Phase 1b in H1 2017

Experienced team with proven track record

Strong balance sheet with cash to inflection points



Thank You



(Appendix Slide) HBV Lifecycle



- HBV Core Protein plays a critical role in *multiple aspects* of the viral life cycle
- Nucs only inhibit *reverse transcription*

