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**UNITED STATES  
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): **September 7, 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**  
(I.R.S. Employer  
Identification No.)

**11711 N. Meridian St., 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:

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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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, that the Company intends to use from time to time in meetings with investors and others beginning on September 7, 2017. The corporate presentation will also be available on the Company’s website at <http://investor.assemblybio.com/events.cfm>.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is 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.

<b>Exhibit No.</b>	<b>Description</b>
<u>99.1</u>	<u><a href="#">Assembly Biosciences, Inc. Corporate Presentation September 2017.</a></u>

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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: September 7, 2017

Assembly Biosciences, Inc.

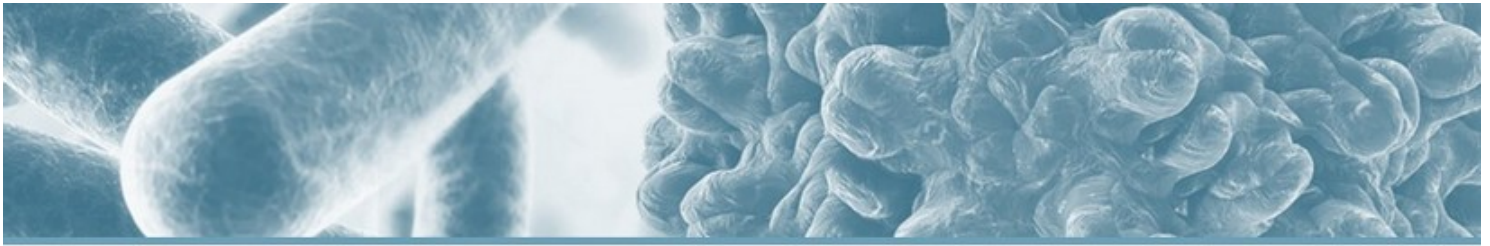
By: /s/ Derek A. Small  
Derek A. Small  
President and Chief Executive Officer

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EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
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Assembly Biosciences, Inc.  
Corporate Presentation  
September 7, 2017

Nasdaq: ASMB



## Cautionary note regarding forward-looking statements

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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 Pharmaceuticals International Limited ("Allergan") 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 "believe", "planned", "initiate", "potential," "anticipated", or "expected." 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); the unpredictability of the nonclinical 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, 2016 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 each 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. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size. These estimates involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. 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: Overview



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

## HBV

Deep pipeline of CpAMs with potential to achieve CURE  
Large market opportunity with high unmet need

## Microbiome

Delivering oral, synthetic live biotherapeutics to targeted location  
Allergan partnership for GI assets, rest of pipeline wholly owned

## Team

Industry leaders w/ expertise in drug discovery → drug development



Strong balance sheet with cash through anticipated inflection points



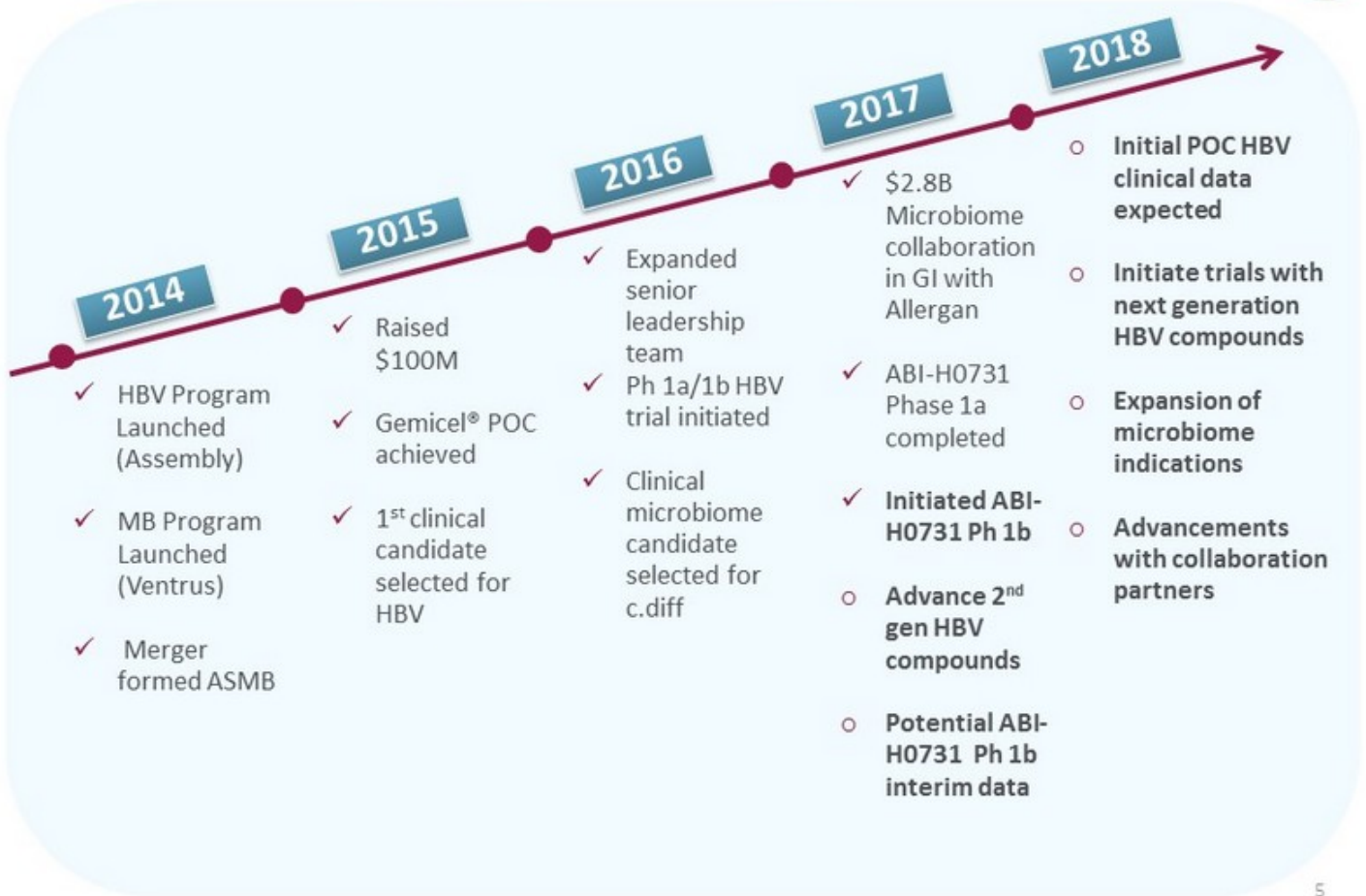
# Development Pipeline

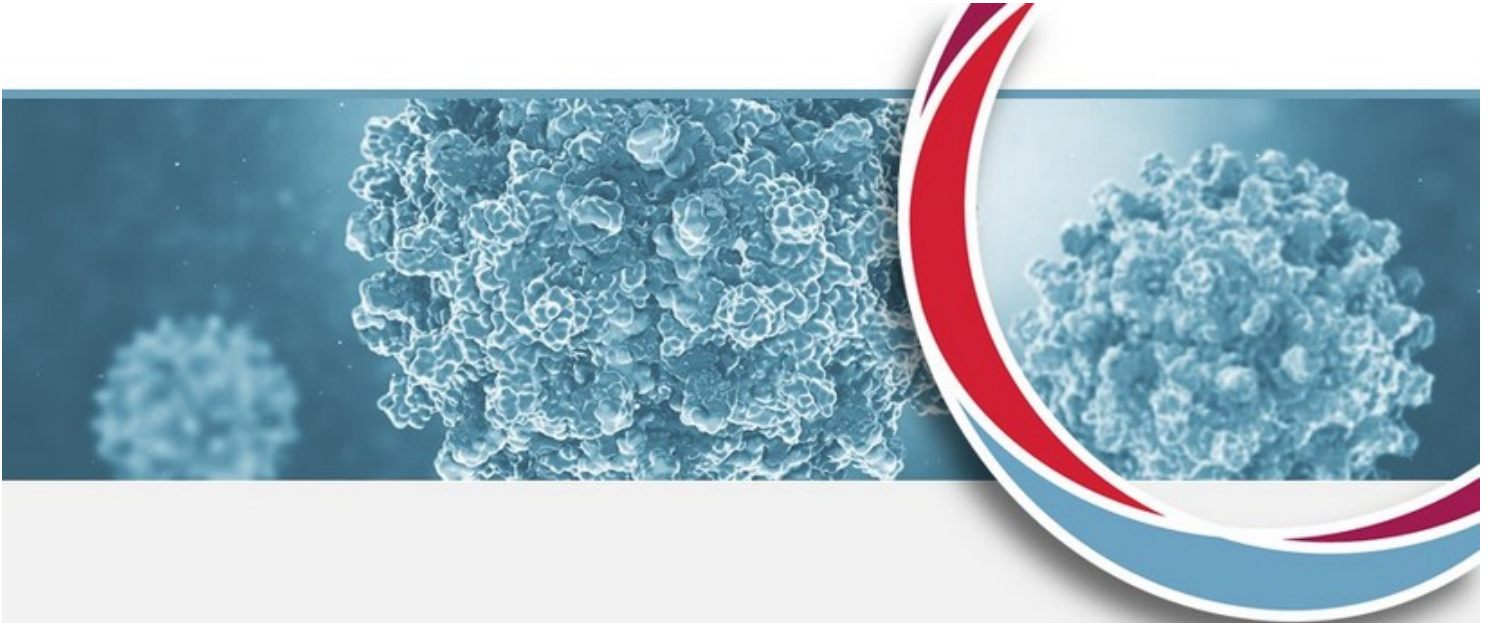


Program	Drug Candidate (Mech. / Indication)	Discovery	Lead Op / Selection	IND Enabling	Phase 1	Rights
Hepatitis B	ABI-H0731 (CpAM)					
	CpAM 2 <sup>nd</sup> Generation					
	CpAM 3 <sup>rd</sup> Generation					
	Novel Target					
Microbiome	ABI-M201 (Ulcerative Colitis)					
	ABI-M301 (Crohn's Disease)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



# Our Timeline Highlights Significant Progress to Date





## *Hepatitis B – Cure Program*

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## Significant need for curative HBV therapies

Market Opportunity ~240 million patients worldwide, ~90 million in China, ~2 million in US and >600,000 deaths/year globally

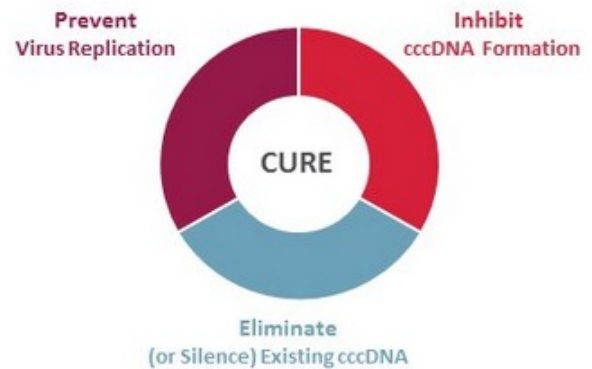
### Current therapies are inadequate

Limited to nucleos(t)ide analogs (Nucs) [entecavir, tenofovir] or pegylated-interferon-alpha (PegIFN- $\alpha$ ) Nucs suppress and maintain viral load at undetectable levels for years, BUT:

- *Less than 10% of patients achieve a sustained response off therapy*<sup>1</sup>
- *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
- Woodchuck model shows cure correlated with elimination of detectable cccDNA<sup>2</sup>



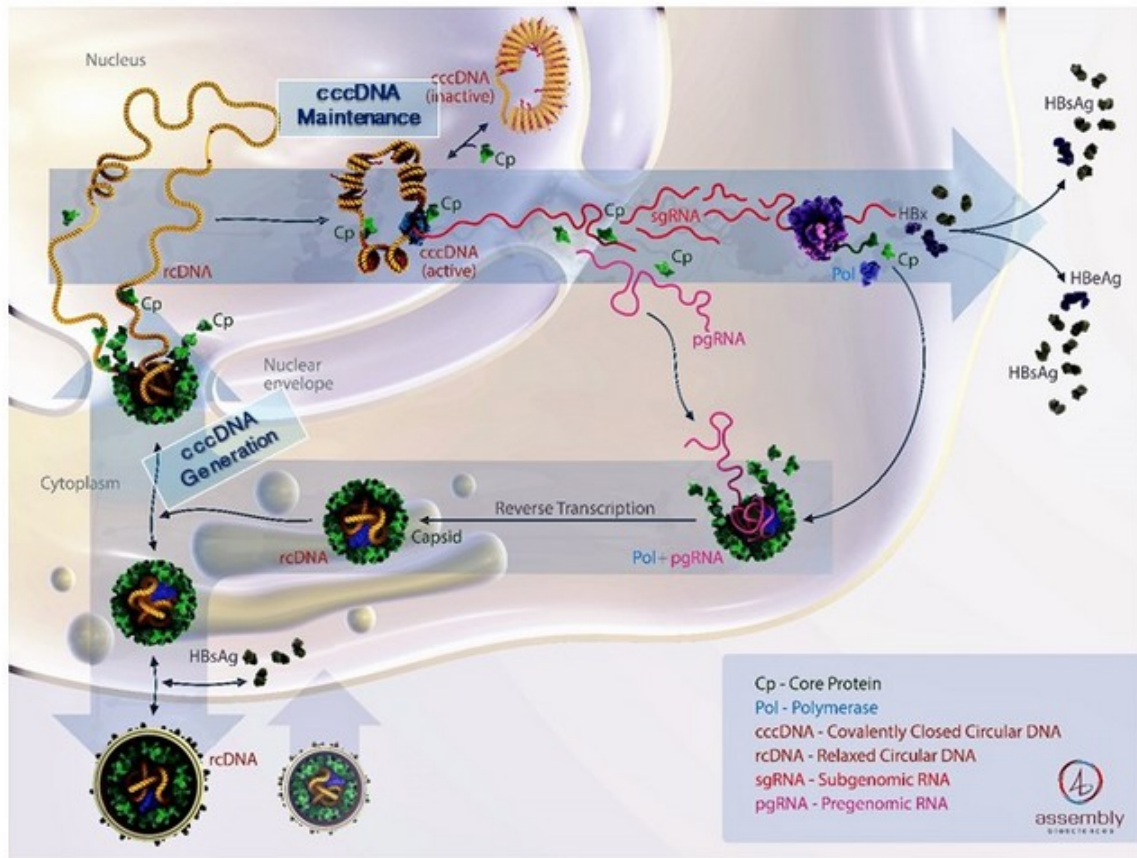
<sup>1</sup>Marcellin, P. et al. (2016). Combination of Tenofovir Disoproxil Fumarate and Peginterferon-2a Increases Loss of Hepatitis B Surface Antigen in Patients with Chronic Hepatitis B. *Gastroenterology*, 150(1), 134–144.e10. <https://doi.org/10.1053/j.gastro.2015.09.043>

<sup>2</sup>R. Colonna, et al. *JID* 2001;184:1236–45

# HBV Life Cycle: Complicated with Limited Targets

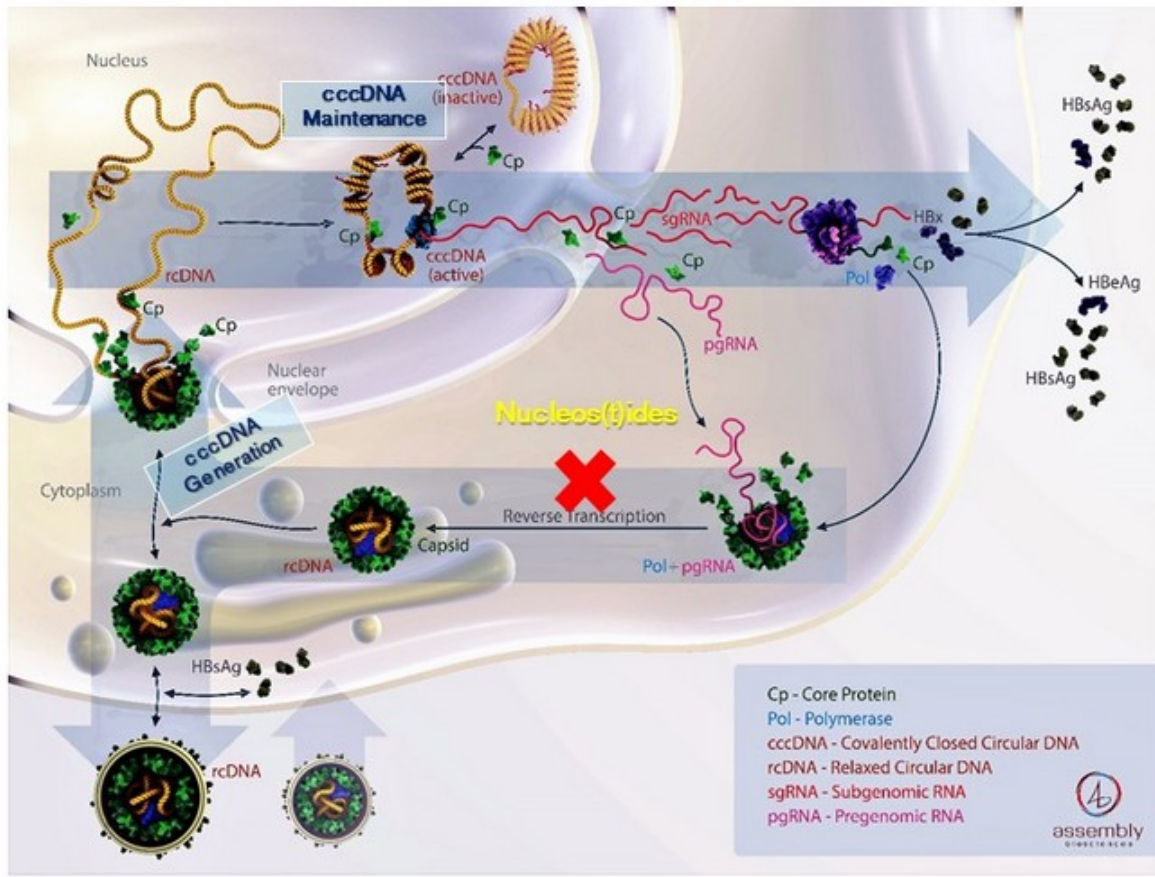


HBV genome only encodes FOUR known genes: Core, X, Polymerase and S (HBsAg)

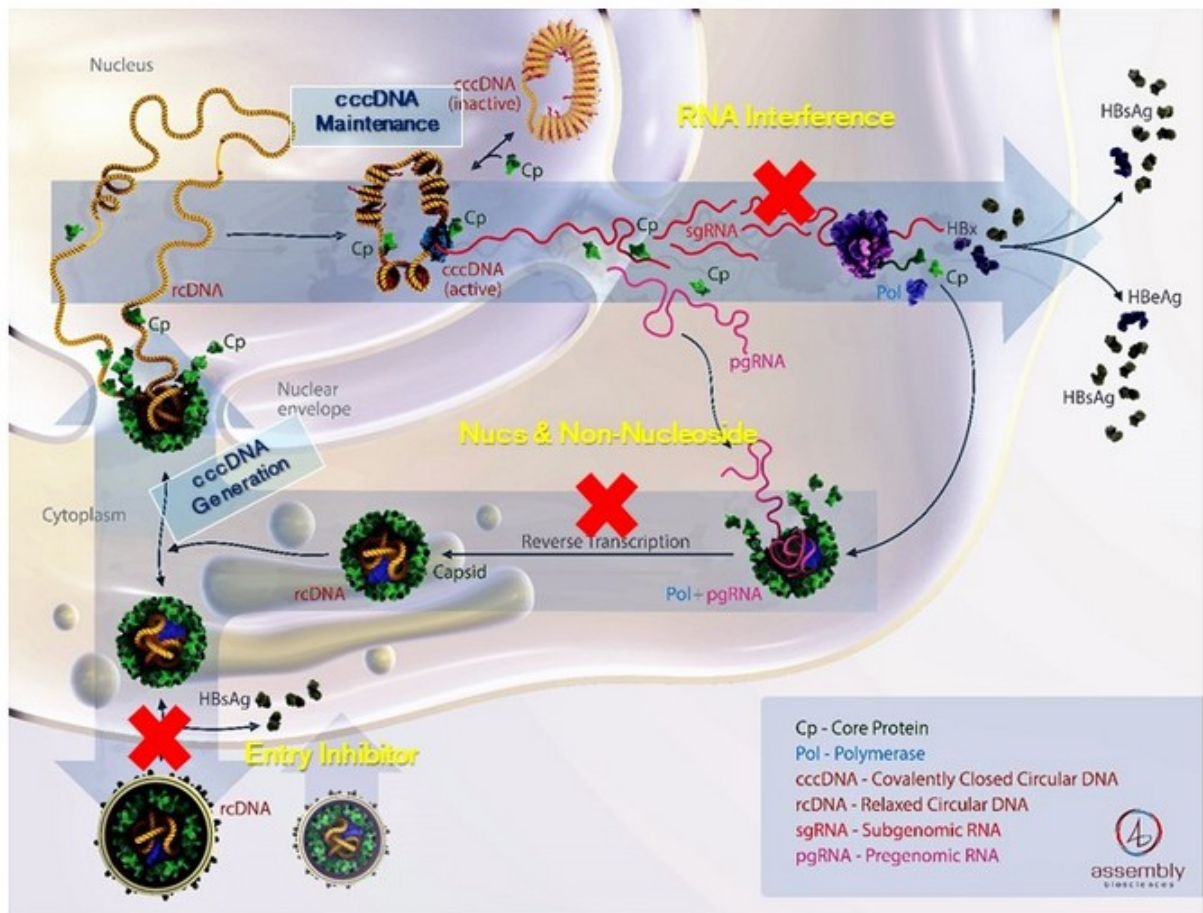




# HBV Life Cycle: Failure of Nuc to Inhibit cccDNA



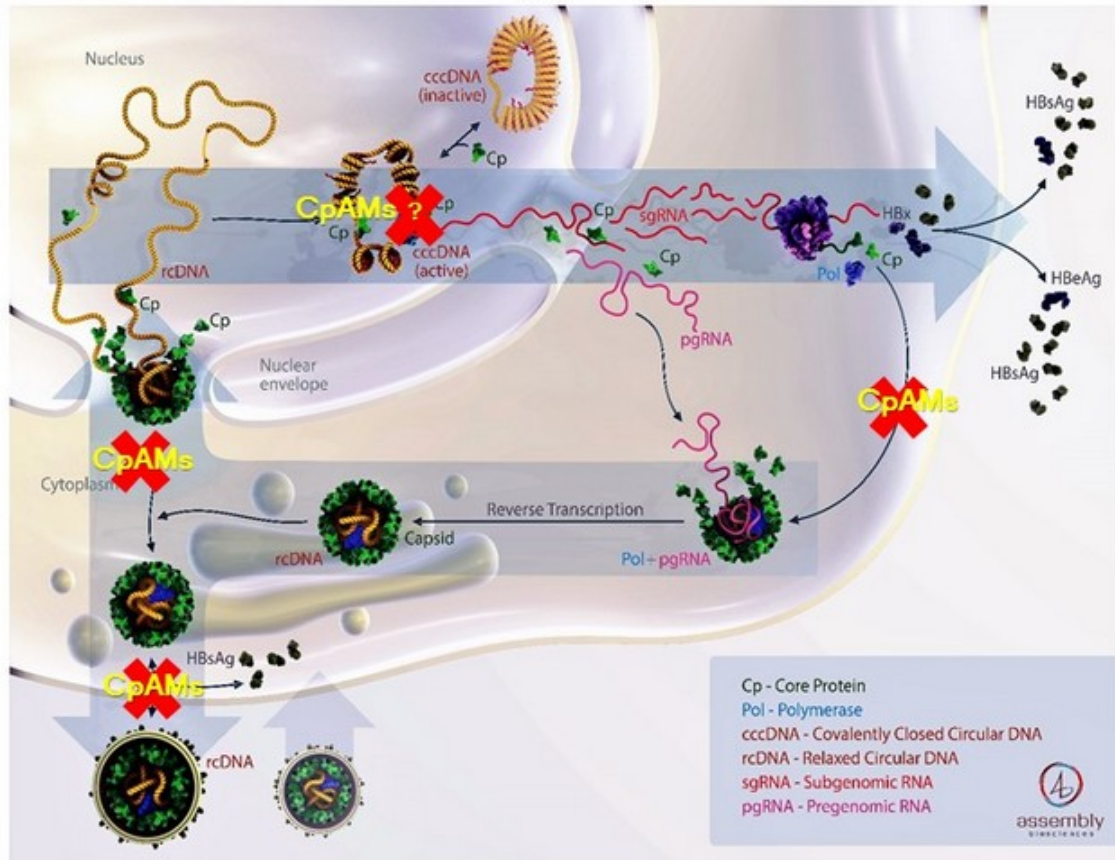
# HBV Life Cycle: New Antiviral Targets Being Pursued



# HBV Core Protein Is Required Throughout Lifecycle

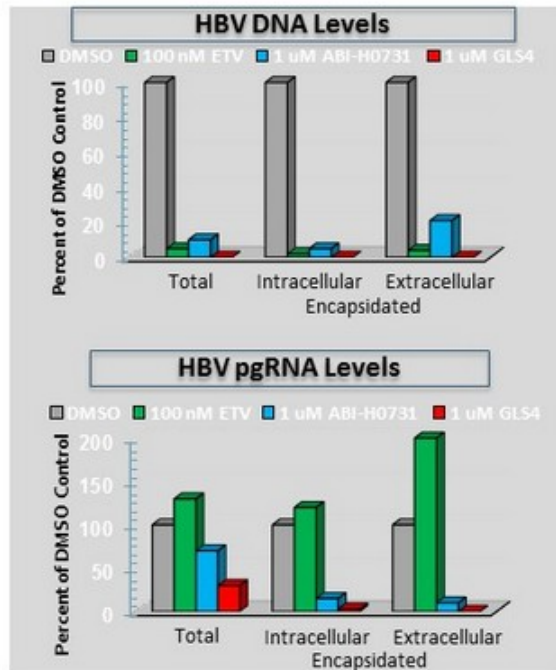
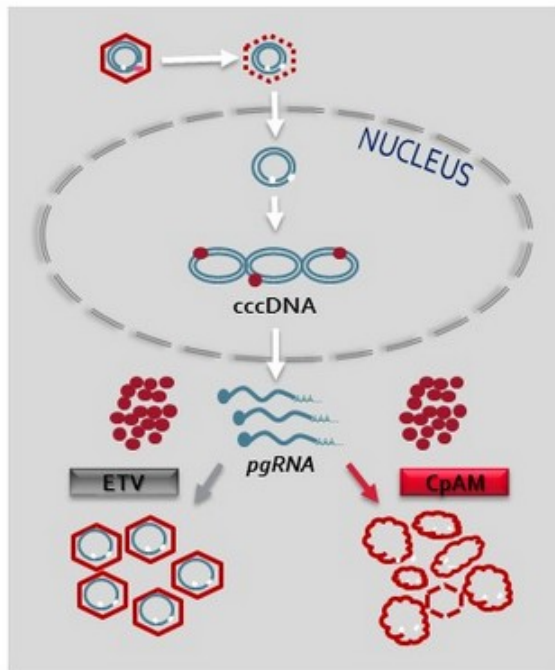


CpAMs (Core Protein Allosteric Modulators) target Core protein and functions related to cccDNA generation





# CpAMs and ETV inhibit HBV Replication by Distinct Mechanisms



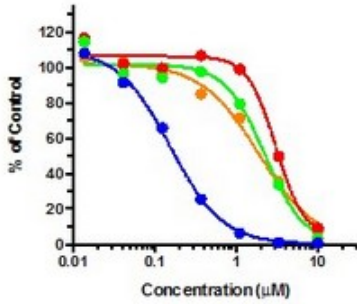
- CpAMs ABI-H0731 & GLS4 inhibit encapsidation of both viral DNA and pgRNA
- ETV inhibited HBV DNA synthesis, but increased levels of pgRNA in intracellular capsids by failing to create the RNA:DNA duplex digested by RNaseH

# CpAMs inhibit cccDNA generation in primary human hepatocytes

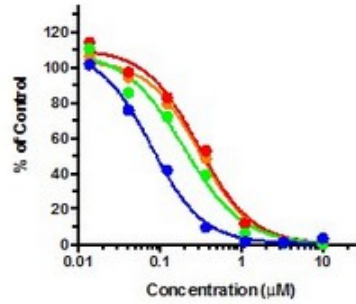


## Viral DNA, pgRNA, HBeAg and HBsAg in Primary Human Hepatocytes

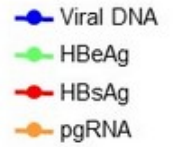
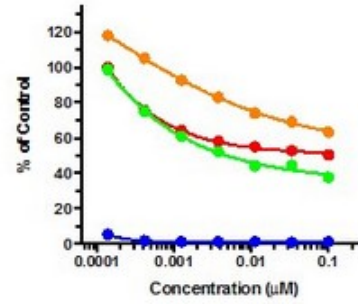
### CpAM - ABI-H0731



### Prototype CpAM - ABI-H0808



### Nuc - Entecavir



Compound	EC <sub>50</sub> (nM)			
	Viral DNA	HBeAg	HBsAg	pgRNA
ABI-H0731	154	2,210	3,000	1,840
Prototype 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

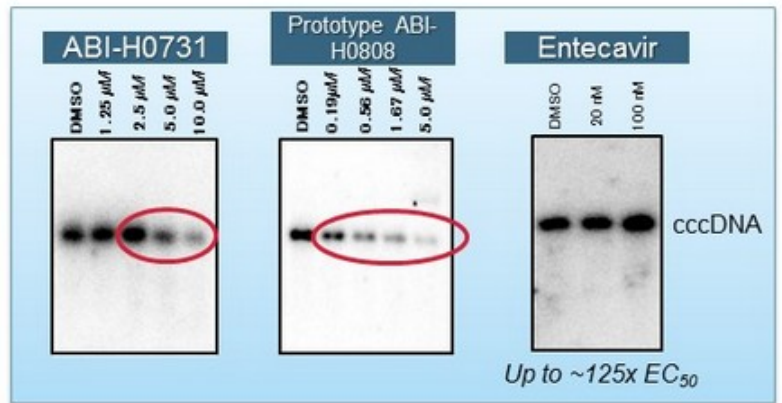


Sequential digestion with T5 exonuclease and EcoRI endonuclease

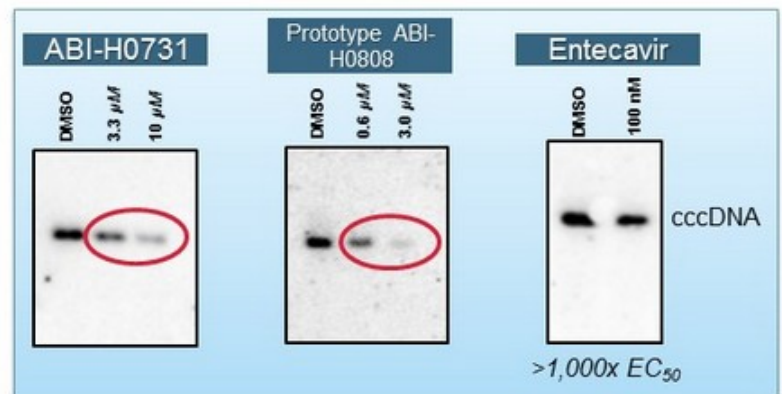


Southern Blot

- Only CpAMs reduced cccDNA formation in HepG2-NTCP and PHH
- ETV (125-1000x EC<sub>50</sub>) had minimal effect on cccDNA levels!



## Primary Human Hepatocytes (PHH)





## ABI-H0731: Candidate Summary

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- Differentiated mechanism(s) that target core protein and impact cccDNA
  - Exhibits activity not seen with current SOC therapies
- Proprietary chemistry designed for optimal treatment regimen
  - Highly potent and selective
  - Good bioavailability and metabolically stable in liver hepatocytes
  - Oral, once daily profile
- **Phase 1a Complete: Dose ranging well tolerated in all cohorts**
  - Single doses 100 - 1,000 mg, multiple doses 800 mg QD and 800 mg BID x 7 days
  - Favorable PK profile with a half-life consistent with potential for QD dosing
  - Well absorbed and associated with plasma concentrations that we believe will be sufficient to suppress viral replication and cccDNA generation
  - No SAEs, no clinically significant AEs and no withdrawals due to AEs
  - Treatment emergent AEs deemed “possibly related,” such as headache and rash, were mild and transient and only observed at the highest doses
  - No clinically significant: treatment emergent laboratory abnormalities, vital sign changes or ECG findings
  - *Data to presented at AASLD, October 2017 in Washington, DC*



- ✓ **ABI-H0731 was safe and well tolerated in Phase 1a study**
- ✓ **Phase 1b initiated** (preliminary antiviral efficacy w/ monotherapy over 28 days)

**H2 2017**

- **Interim Phase 1b data**
- **Select and advance 2<sup>nd</sup> generation CpAM**

**H1 2018**

- **Phase 2a initiation**

**H2 2018**

- **Phase 2a initial POC data**



## Robust HBV Pipeline Focused on Targeting cccDNA



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

- Lead product ABI-H0731 completed Phase 1a earlier this year, and initiated Phase 1b in HBV patients
- We have a pipeline of next generation molecules in research stages nearing candidate selection
- All of our molecules in discovery and development focus on inhibition of cccDNA formation



## ***Microbiome Program***

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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

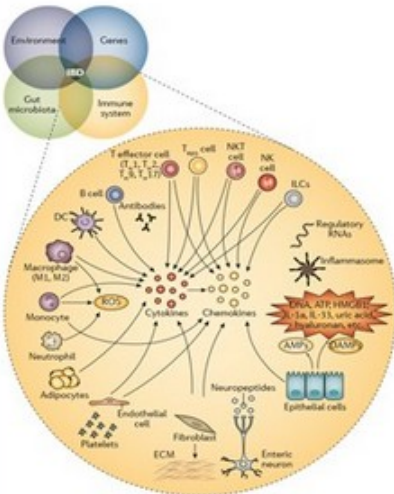
PoC data has demonstrated that fecal microbiota transplants (FMT) can restore dysbiotic microbiome to health

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



## Strain selection

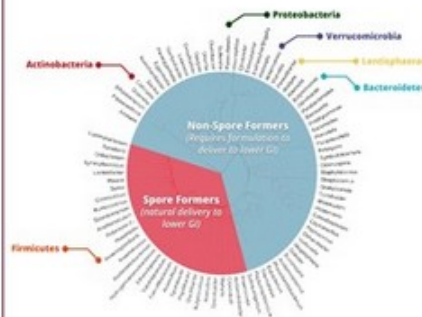
Mechanisms of disease pathology must be considered in context with environment, genome and microbiota



## Manufacturing

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

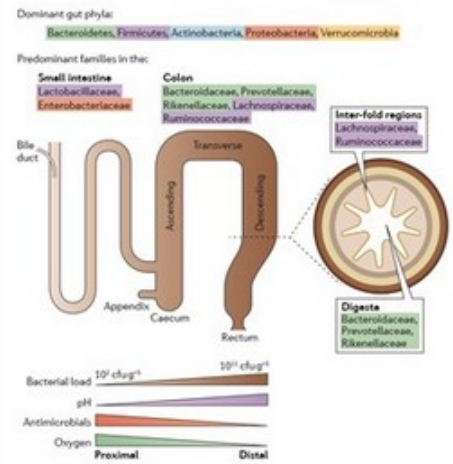
Diversity is needed for optimal probiotic therapeutics



## Targeted delivery

Unique microhabitats require targeted delivery

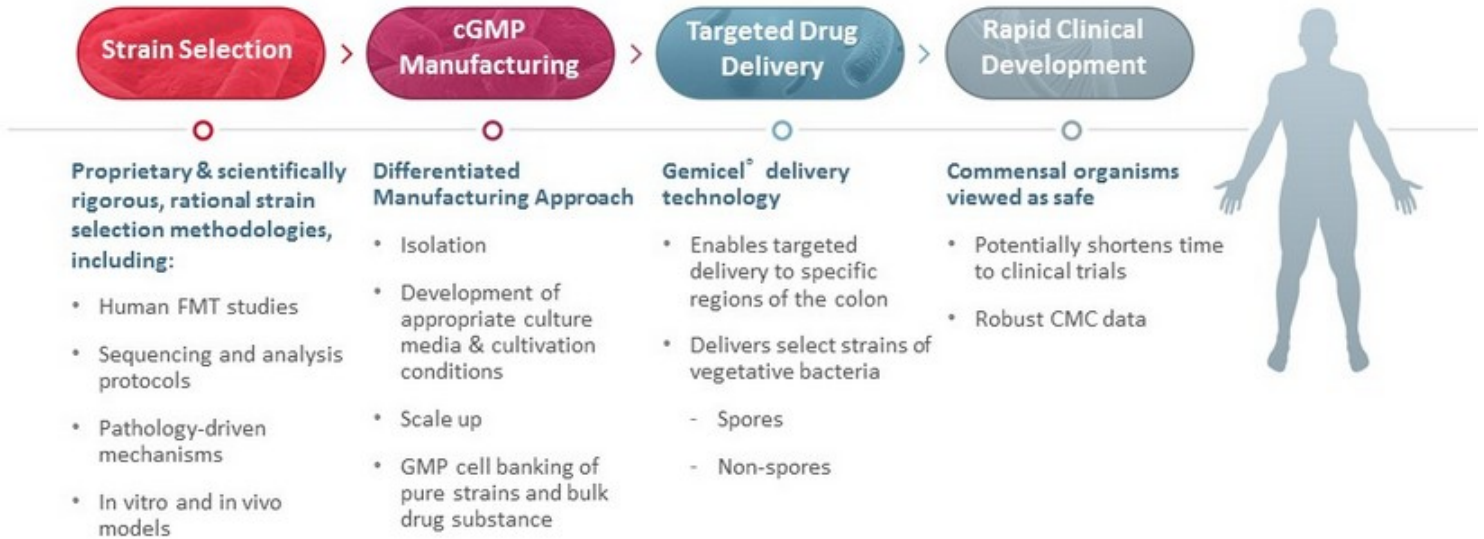
- pH
- Oxygen
- Antimicrobials
- Nutrients



# ASMB Solution: Proprietary Microbiome Platform



Our differentiated and fully-integrated platform to deliver synthetic live biotherapeutics (LBT)



# GEMICEL<sup>®</sup>: ASMB's proprietary targeted delivery technology

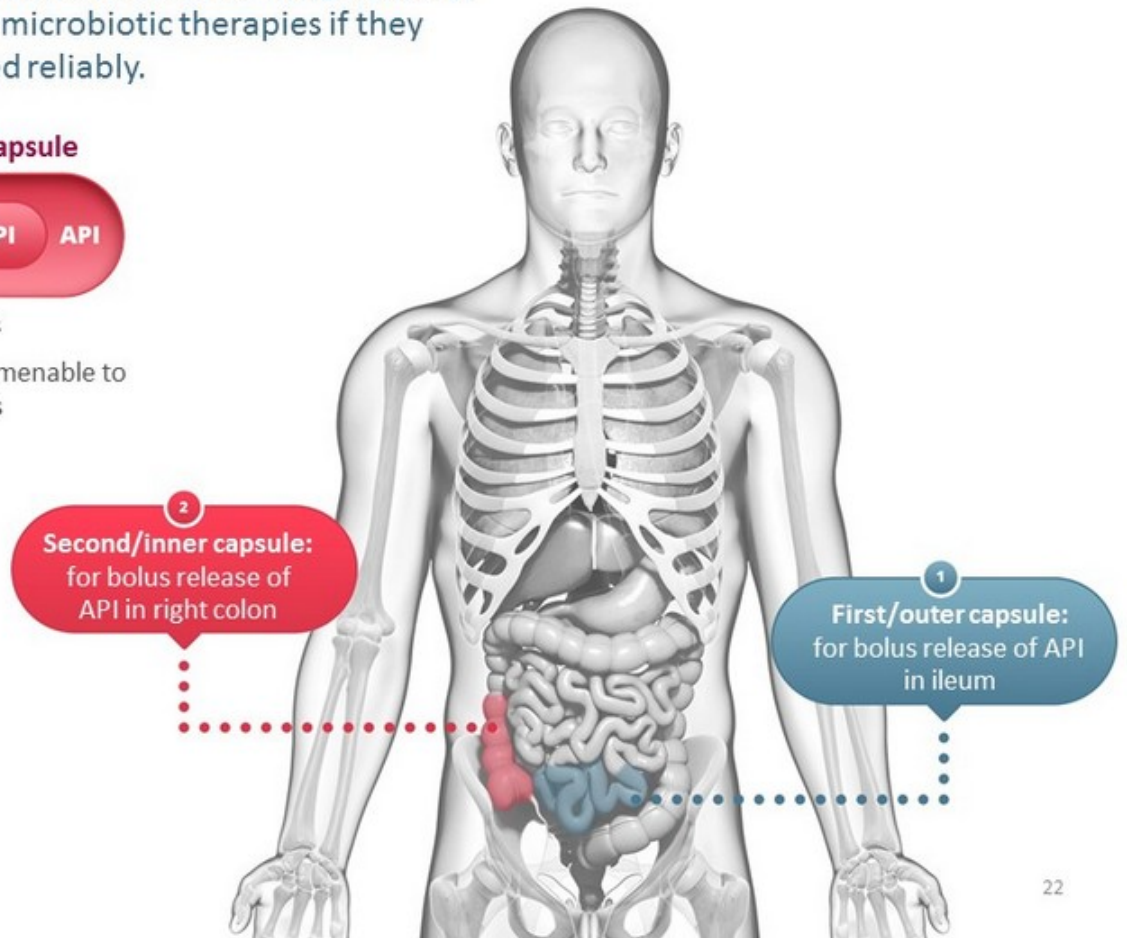


The colon is an attractive site for drug delivery, particularly for microbiotic therapies if they can be delivered reliably.

## GEMICEL<sup>®</sup> Capsule



- GRAS ingredients
- Manufacturing amenable to biologic products



# Assembly and Allergan Enter Microbiome Collaboration



Significant microbiome platform collaboration with focus on GI disorders



Expertise in microbiome therapeutics,  
fully-integrated platform



Expertise in gastrointestinal  
drug development and  
commercialization

## Collaboration Highlights:

- Rights for GI development programs:
  - ABI-M201 for Ulcerative Colitis (UC)
  - ABI-M301 for Crohn's Disease (CD)
  - 2 compounds targeting Irritable Bowel Syndrome (IBS)
  - ASMB has limited option to co-promote in US and China

## Financial Highlights

- \$50M upfront payment
- Milestones & Royalties
  - Up to ~\$630M in development milestones
  - Up to ~\$2.15B in commercial milestones
  - Tiered royalties up to mid-teens on net sales
- Development Funding
  - \$75M R&D funding through POC (shared 2/3 by AGN, 1/3 by ASMB)
  - AGN assumes all post-POC development costs



## Summary: AGN/ASMB Microbiome Collaboration

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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 programs long term financially, commercially, and globally










*We intend to continue identifying appropriate development and commercial partners to rapidly advance our Microbiome program into other indications*

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

# Microbiome Platform



Capturing the potential of the human microbiome for development of novel therapeutics

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





Nasdaq	Cash, cash equivalents & marketable securities	Shares outstanding	Fully diluted
ASMB	~\$78.6M as of June 30, 2017	~17.3M	~22M



2017	2018
<ul style="list-style-type: none"><li>✓ Microbiome collaboration for GI indications</li><li>✓ ABI-H0731 dose ranging Ph 1a portion complete</li><li>✓ Initiate ABI-H0731 Ph 1b trial</li><li>✓ AASLD: 3 abstracts accepted</li><li>❑ H2: ABI-H0731 Ph 1a safety and PK profile</li><li>❑ H2: ABI-H0731 Phase 1b (interim) results</li><li>❑ H2: 2nd Gen CpAM HBV selection</li></ul>	<ul style="list-style-type: none"><li>❑ Initiate Phase 2 trial of ABI-H0731</li><li>❑ Select next indications for microbiome</li><li>❑ POC HBV clinical data expected</li><li>❑ Initiate trials with next gen HBV</li><li>❑ Advancements with collaboration partners</li></ul>

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Thank You

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