ASSEMBLY BIOSCIENCES, INC.

FORM 8-K
(Current report filing)

Filed 09/26/17 for the Period Ending 09/26/17

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          SUITE 310
          CARMEL, IN, 46032

Telephone (212) 554-4388
CIK 0001426800
Symbol ASMB
SIC Code 2834 - Pharmaceutical Preparations
Industry Pharmaceuticals
Sector Healthcare
Fiscal Year 12/31
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 26, 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. ☐
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 26, 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.

Exhibit No. Description
99.1 Assembly Biosciences, Inc. Corporate Presentation dated September 26, 2017.
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 26, 2017

By: /s/ Derek A. Small

Derek A. Small
President and Chief Executive Officer
<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.1</td>
<td>Assembly Biosciences, Inc. Corporate Presentation dated September 26, 2017</td>
</tr>
</tbody>
</table>
Assembly Biosciences, Inc.
Corporate Presentation

September 26, 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 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," "should," "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 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.
<table>
<thead>
<tr>
<th>Challenge</th>
<th>HBV</th>
<th>Microbiome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SOC does NOT CURE</td>
<td>FMT is inadequate as therapy</td>
</tr>
<tr>
<td></td>
<td>Eliminating cccDNA (responsible for viral persistence)</td>
<td>Develop oral, synthetic, live biotherapeutics</td>
</tr>
<tr>
<td>Opportunity</td>
<td>Establish CpAMs as critical component of HBV curative backbone</td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>Prevent replenishment of new cccDNA long enough for established cccDNA to be eliminated</td>
<td>FMT provides clinical POC avenue for strain selection</td>
</tr>
</tbody>
</table>
### Hepatitis B

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Lead Optimization</th>
<th>IND Enabling</th>
<th>Phase 1a</th>
<th>Phase 1b/2a</th>
<th>Phase 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI-H0731 (CpAM)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABI-H215B (CpAM)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd CpAM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novel Target</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Microbiome

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Lead Op / Selection</th>
<th>IND Enabling</th>
<th>Phase 1b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcerative Colitis; ABI-M201</td>
<td></td>
<td>Allergan</td>
<td></td>
</tr>
<tr>
<td>Crohn’s Disease; ABI-M301</td>
<td></td>
<td>Allergan</td>
<td></td>
</tr>
<tr>
<td>Irritable Bowel Syndrome</td>
<td></td>
<td>Allergan</td>
<td></td>
</tr>
<tr>
<td>NASH, I/O &amp; Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clostridium difficile (C. difficile)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gemicel® (targeted oral delivery system)</td>
<td></td>
<td></td>
<td>Clinical POC achieved</td>
</tr>
</tbody>
</table>

Clinical POC achieved
Key Priorities Through 2018

- **HBV**
  - ABI-H0731
    - Complete Phase 1b/2a
    - Present data at scientific meetings
    - Initiate Phase 2
    - Interim POC data

- **HBV**
  - Next Generation CpAMs
    - ABI-H2158 selected as 2nd CpAM candidate
    - Initiate clinical studies
    - Potential to advance 3rd CpAM to clinic

- **MB**
  - Microbiome Assets
    - Advance AGN partnered programs in UC and Crohn’s, IBS
    - Development of additional portfolio assets (i.e., NASH, I/O)

- **MB**
  - Collaborations
    - Potential to achieve significant milestone
    - Continue to monetize platform capabilities

---
## Potential Value Drivers: 3+ Months

### Multiple near term milestones

**Table:**

<table>
<thead>
<tr>
<th>H2 2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI-H0731: Phase 1b</td>
<td></td>
</tr>
</tbody>
</table>
Antiviral potency and decrease in viral DNA |
| ABI-H0731: Phase 2a combo w/ nuc | 
| Selection of 2nd CpAM | 
ABI-H2158 |
| AASLD | 
- ABI-H0731: Phase 1a data
- Next generation CpAM profiles
- Half-life of cccDNA? |
| Third CpAM candidate selection | 

### Key

- **Clinical Data**
- **Pipeline Progress**
## Potential Value Drivers Over the Next 18 months

Opportunity for multiple inflection points from short to long term

<table>
<thead>
<tr>
<th>H2 2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI-H0731: Phase 1b Antiviral potency and decrease in viral DNA</td>
<td>ABI-H0731: Phase 2a combo w/ nuc</td>
<td>ABI-H0731: Phase 2 Longer term effects for cure</td>
</tr>
</tbody>
</table>

- AASLD Phase 1a data
- Next generation profiles
- Half-life of cccDNA?

### 2018
- Initiate clinical studies of ABI-H2158
- Advancement of partnered microbiome programs to significant milestone
- Establish clinical candidate selection in NASH and I/O
- Establish additional collaborations across both platforms

### KEY
- Clinical Data
- Pipeline Progress
- Collaborations
Hepatitis B: Cure Program

Market overview and deficiencies of current treatment
Assembly’s HBV Cure Program
Low cure rates with current SOC / Vaccines are preventative but do not cure those who are chronically infected.

Global Prevalence: >300 million

- EU Prevalence: ~20 million
- Japan Prevalence: ~1.3 million
- U.S. Prevalence: ~1.5 million
- China Prevalence: ~90 million

~ 1 Million deaths/year
Chronic HBV infection results in chronic inflammation and progressive liver damage, potentially leading to liver cirrhosis, HCC and death.

Putting the HBV Opportunity into Perspective

Number of HBV patients outnumber HCV + HIV combined with high unmet need for diagnosis and cure

<table>
<thead>
<tr>
<th></th>
<th>HCV</th>
<th>HBV</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Prevalence</td>
<td>3 M</td>
<td>1.2-3 M</td>
</tr>
<tr>
<td>Worldwide Prevalence</td>
<td>160 M</td>
<td>350 M</td>
</tr>
<tr>
<td>% Diagnosed in US</td>
<td>50%</td>
<td>30%</td>
</tr>
<tr>
<td>% Diagnosed that are</td>
<td>33%</td>
<td>6-10%</td>
</tr>
<tr>
<td>Treated in US</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nature</td>
<td>RNA virus</td>
<td>DNA virus</td>
</tr>
<tr>
<td>Challenge</td>
<td>Eliminating RNA virus existing in host cytoplasm</td>
<td>Eliminating/silencing new and existing cccDNA</td>
</tr>
<tr>
<td>2015 US Sales*</td>
<td>$12.5 B</td>
<td>$700 M</td>
</tr>
</tbody>
</table>

* GILD master model – Jefferies Research Report 8.30.17
### Current Treatment Paradigm is Inadequate to CURE HBV

**Deficiencies of current approved therapies**

<table>
<thead>
<tr>
<th>Mechanism of Action</th>
<th>Benefits</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nucleo(t)side Analogs</strong></td>
<td>• Inhibit DNA polymerase</td>
<td>• Does NOT completely stop replenishment of cccDNA</td>
</tr>
<tr>
<td></td>
<td>• Knock out replication virus from RNA to DNA</td>
<td>• Most patients must stay on drug for life</td>
</tr>
<tr>
<td></td>
<td>(reverse transcription)</td>
<td>• No immuno-stimulatory benefits</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Peg-IFN</strong></td>
<td>• Immuno-stimulatory protein which indirectly</td>
<td>• Does NOT completely stop replenishment of cccDNA</td>
</tr>
<tr>
<td></td>
<td>combats viral replication</td>
<td>• Poorly tolerated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Requires weekly injections</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Poor response rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Current treatments inadequately reduce cccDNA → Low cure rates**
Thought we had curative therapy in 2005

Clear evidence that ETV can cure woodchucks based on multiple parameters

- ETV exhibited potent activity against Woodchuck HBV
- Sustained suppression of viral DNA levels (≥ 8 logs) for 1-3 years with weekly treatment
  - No rebounds or evidence of resistance
- cccDNA levels reduced >4 logs
- Average HBsAg levels reduced 91.3% at 24 month time point

Unfortunately, this is not what happens in HBV patients with prolonged therapy

  R. Colonno, et al. JID 2001;184:1236-45
We want what we achieved in woodchucks!

- Defined length of treatment to remission
- Convenient dosing (QD?) and low pill burden
- Excellent safety profile, with minimal side effects
- Sustained remission off therapy
  - Viral DNA replication remains undetectable
  - Reversal of liver damage, lack of hepatic inflammation
- Significant reduction in the risk of future HCC development
- Elimination and/or silencing of cccDNA

To achieve clinical cure, therapy must target and prevent new cccDNA generation, and if possible, facilitate the elimination or silencing of existing cccDNA
CpAMs are only modality that stop cccDNA generation.

HBV Life Cycle: A DNA Virus with Limited Targets

Cp - Core Protein
Pgl - Polymerase
cccDNA - Covalently Closed Circular DNA
rcDNA - Relaxed Circular DNA
sgRNA - Subgenomic RNA
pgRNA - Pre-genomic RNA
Rationale for CpAM Treatment Resulting in Higher Cure Rates?

- **Inhibit HBV life cycle** at several steps

- **Inhibit cccDNA generation** in Primary Human Hepatocytes

- cccDNA exhibit a *reasonable half-life* (weeks to months)

- ASMB CpAMs: **Potent with Excellent Drug-Like Characteristics**
  - In Vitro data indicates potency is enough to effect establishment of cccDNA

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**Potential Curative Regimen = SOC (nuc) + CpAM**
CpAMs Inhibit Several Steps of HBV Life Cycle

- Generate empty aberrant capsid formation
  - Bind to dimer-dimer interface disrupting formation of functional nucleocapsids
- Prevent encapsidation of pgRNA and Pol
  - A pre-requisite for RT activity and generation of rcDNA
- Prevent maturation of infectious viral particles
- Prevent trafficking of encapsidated rcDNA to nucleus
  - Inhibiting subsequent conversion to cccDNA
- Alter phosphorylation levels of Core protein
  - May also lead to Core protein elimination in infected cells

CpAMs work differently than nuc's: They target Core protein & stop cccDNA generation
New study shows that the half-life of cccDNA may be shorter than previously believed

All biological molecules have a half-life, including cccDNA

- Longitudinal study conducted on samples (serum and biopsies) from patients with emerging resistance to LVD and TBV
- Appearance and enrichment of resistant mutations used as a genetic marker in monitoring populations of viral DNA, pgRNA and cccDNA
- Results demonstrated rapid establishment of newly formed cccDNA harboring Nuc-resistant mutations
- Significant turnover of wt pgRNA molecules within months suggests that existing cccDNA may decay faster than previously predicted
- Little evidence for the maintenance of substantial pools of inactive wt cccDNA in patient samples

Data from study to be presented at AASLD, October 2017 in Washington, DC
Hepatitis B: Cure Program

Market overview and deficiencies of current treatment
Assembly’s HBV Cure Program
ASMB CpAMs: Potent with Excellent Drug-Like Characteristics

**Potent and Predictable**

- Intrinsic potency to significantly inhibit new cccDNA as measured by surrogate markers such as pgRNA and HBsAg
  - EC$_{50}$ = 154 nanomolar potency in Primary Human Hepatocytes (PHH)
- 10-30x exposure in liver above plasma concentrations in pre-clinical studies
- Exposures exceeding targeted potency ranges
- Controlled and predictable liver: plasma concentrations

**Optimal Treatment Regimen**

- Convenient oral dosing
  - One pill, Once a day
- Highly potent and selective
- Good oral bioavailability
  - Half-life, $C_{\text{max}}$ and $C_{\text{min}}$
- Metabolically stable in liver hepatocytes to enable maximal sustained inhibition
- Limited drug-drug interactions
- Well tolerated – good safety profile to enable prolonged dosing
 ABI-H0731: Candidate Summary

Lead molecule from a deep pipeline of CpAMs

Phase 1b/2a currently enrolling
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

Data to be presented at AASLD, October 2017 in Washington, DC
CpAMs Inhibit cccDNA Generation in Primary Human Hepatocytes

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

**Primary Human Hepatocytes (PHH)**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Viral DNA</th>
<th>HBeAg</th>
<th>HBsAg</th>
<th>pgRNA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI-H0731</td>
<td>154</td>
<td>2,210</td>
<td>3,000</td>
<td>1,840</td>
</tr>
<tr>
<td>ETV</td>
<td>&lt;0.1</td>
<td>Incomplete</td>
<td>Incomplete</td>
<td>Incomplete</td>
</tr>
</tbody>
</table>

- 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 surrogates of cccDNA establishment.

Presented at AASLD2015
### ABI-H0731: General Clinical Investigational Plan

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Duration</th>
<th># treated</th>
<th>Expected Endpoint(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1a</td>
<td>Healthy Volunteers</td>
<td>Single Ascending Multiple Ascending</td>
<td>48 Healthy Volunteers</td>
<td>Safety/ tolerability and PK</td>
</tr>
</tbody>
</table>
| Phase 1b (mono-therapy)    | Viremic patients                | 28 Days                        | Up to ~50          | • Viral Load Decline  
• Decline in circulating pgRNA                                                       |
| Phase 1b/2a (short term combo-therapy) | Nuc suppressed HBeAg (+) only | 28 days                        | Up to ~40          | • Safety in combination with Nuc  
• Decline in circulating pgRNA                                                       |
| Phase 2 (Long term combo (Design under consideration)) | Nuc suppressed | 6-12 months therapy; 100       |                    | • Decline in circulating pgRNA  
• up to 1 log decline in HBsAg (in E+ patients).                                       |

Phase 2/3 development will be determined on outcomes of Phase 2 studies

- Possible scenarios are 6 to 12 month treatment with 6 to 12 month follow up to seek increased cure rate claims
- Early approval scenarios may be feasible if significant viral antigen decline is seen in Phase 2 studies
ABI-H2158: Candidate Summary

Next-generation CpAM selected from proprietary screening

Highly Potent while maintaining favorable drug-like characteristics

ABI-H2158 expected to enter clinic in 2018

<table>
<thead>
<tr>
<th>Key Parameters</th>
<th>ABI-H2158</th>
</tr>
</thead>
<tbody>
<tr>
<td>AD38 VL EC_{50} (μM)</td>
<td>0.014</td>
</tr>
<tr>
<td>HC9AT HBeAg EC_{50} (μM)</td>
<td>0.303</td>
</tr>
<tr>
<td>PHH VL EC_{50} (μM)</td>
<td>0.023</td>
</tr>
<tr>
<td>PHH HBeAg EC_{50} (μM)</td>
<td>0.17</td>
</tr>
<tr>
<td>Human Liver Microsomes (91/85)</td>
<td></td>
</tr>
<tr>
<td>CYP Profile (IC_{50} μM)</td>
<td>All ≥10</td>
</tr>
<tr>
<td>Protein Binding (%)</td>
<td>97</td>
</tr>
<tr>
<td>Rat PK</td>
<td></td>
</tr>
<tr>
<td>%F</td>
<td>50</td>
</tr>
<tr>
<td>T_{1/2} (hr)</td>
<td>2.9</td>
</tr>
<tr>
<td>CL (mL/min/kg)</td>
<td>2.4</td>
</tr>
<tr>
<td>C_{max} (ng/mL)</td>
<td>536</td>
</tr>
<tr>
<td>Oral AUC_{last} hr^{*}ng/mL</td>
<td>3,671</td>
</tr>
</tbody>
</table>

Candidate profile to be presented at AASLD, October 2017 in Washington, DC
Robust HBV Portfolio Focused on Potential Curative Therapies

- Lead product ABI-H0731 completed Phase 1a earlier this year, and initiated Phase 1b/2a in HBV patients
- Second CpAM, ABI-H2158 selected to advance to IND enabling studies
- Third CpAM in research stage nearing candidate selection
CpAMs disrupt viral replication at multiple steps.

CpAMs block the generation of new cccDNA molecules (SOC/nuc’s do not effect cccDNA).

Multiple distinct and proprietary chemical scaffolds.

ASMB CpAMs exhibit a balance of potency AND favorable drug-like properties.

ABI-H0731:
- Favorable safety and PK properties predictive of QD dosing in patients,
- Ongoing Phase 1b study in chronically-infected patients.

ABI-H2158:
- Second generation candidate exhibits enhanced potency while retaining favorable drug-like properties.
- Clinical trials expected to initiate in 2018.

Combination of a Nuc + CpAM should show strong antiviral activity, have a high resistance barrier, decrease cccDNA levels and most importantly, has the potential to increase cure rates.
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) 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.
The Microbiome: Challenges

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

<table>
<thead>
<tr>
<th>Strain Selection</th>
<th>cGMP Manufacturing</th>
<th>Targeted Drug Delivery</th>
<th>Rapid Clinical Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary &amp; scientifically rigorous, rational strain selection methodologies, including: • Human FMT studies • Sequencing and analysis protocols • Pathology-driven mechanisms • In vitro and in vivo models</td>
<td>Differentiated Manufacturing Approach • Isolation • Development of appropriate culture media &amp; cultivation conditions • Scale up • GMP cell banking of pure strains and bulk drug substance</td>
<td>Gemicel® delivery technology • Enables targeted delivery to specific regions of the colon • Delivers select strains of vegetative bacteria • Spores • Non-spores</td>
<td>Commensal organisms viewed as safe • Potentially shortens time to clinical trials • Robust CMC data</td>
</tr>
</tbody>
</table>
GEMICEL®: 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® Capsule

- GRAS ingredients
- Manufacturing amenable to biologic products

Second/inner capsule

- for bolus release of API in right colon

First/outer capsule

- for bolus release of API in ileum
Assembly and Allergan Enter Microbiome Collaboration

Significant microbiome platform collaboration with focus on GI disorders

Collaboration

Allergan

assembly biosciences

Expertise in gastrointestinal drug development and commercialization

Expertise in microbiome therapeutics, fully-integrated platform

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

- Expedites our efforts into multiple GI indications
- Leverages our end-to-end microbiome technology platform
- Advances our ability to move microbiome candidates rapidly into clinical development with strategic partners
- 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.
Capturing the potential of the human microbiome for development of novel therapeutics

<table>
<thead>
<tr>
<th>Drug Candidate (Mech. / indication)</th>
<th>Discovery</th>
<th>Lead Op / Selection</th>
<th>IND Enabling</th>
<th>Phase 1b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcerative Colitis ABI-M201</td>
<td></td>
<td></td>
<td></td>
<td>Allergan</td>
</tr>
<tr>
<td>Crohn’s Disease ABI-M301</td>
<td></td>
<td></td>
<td></td>
<td>Allergan</td>
</tr>
<tr>
<td>Irritable Bowel Syndrome</td>
<td></td>
<td></td>
<td></td>
<td>Allergan</td>
</tr>
<tr>
<td>NASH, I/O &amp; Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clostridium difficile (C.diff)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gemicol® (targeted oral delivery system)</td>
<td></td>
<td>Clinical POC achieved</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Leveraging our Microbiome Platform to Expand to Other High-rationale Indications

- Gastrointestinal
  - Allergan

- Liver
  - NASH

- Oncology
  - Immuno-oncology
  - Colorectal cancer

- Metabolic Disease
  - Obesity
  - Type 2 Diabetes
Company Summary
ASMB Anticipated Milestones and Financial Summary

### 2017
- ✓ Up to $2.8B microbiome collaboration for GI indications
- ✓ ABI-H0731 dose ranging Ph 1a portion complete
- ✓ Initiated ABI-H0731 Ph 1b/2a trial
- ✓ AASLD: 3 abstracts accepted
- ✓ ABI-H2158 selected as 2nd CpAM clinical candidate
- □ H2: ABI-H0731 Ph 1a safety and PK profile
- □ H2: ABI-H0731 Phase 1b (topline interim) results
- □ H2: 3rd CpAM HBV selection

### 2018
- □ H1: ABI-H0731 Phase 1b data (full)
- □ H1: Initiate Phase 2 trial of ABI-H0731
- □ H2: POC HBV clinical data expected
- □ H2: Initiate clinical studies of next-generation CpAMs
- □ Select next indications (non-GI) for microbiome
- □ Advancements with collaboration partners in microbiome

<table>
<thead>
<tr>
<th>Nasdaq</th>
<th>Cash, cash equivalents &amp; marketable securities</th>
<th>Shares outstanding</th>
<th>Fully diluted</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASMB</td>
<td>~$78.6M as of June 30, 2017</td>
<td>~17.3M</td>
<td>~22M</td>
</tr>
</tbody>
</table>
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

- REYATAZ® (atazanavir sulfate)
- Baraclude® (entecavir)
- Simponi® (golimumab)
- Stelara® (ustekinumab)
Thank You