### 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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-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  $\Box$ 

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

Assembly Biosciences, Inc.

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

### Exhibit No. Description

99.1 Assembly Biosciences, Inc. Corporate Presentation dated September 26, 2017.



# 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 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 guarter 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: Two INNOVATIVE Drug Development Platforms



| Challenge   |  |
|-------------|--|
| Opportunity |  |
| Rationale   |  |

### HBV

- SOC does NOT CURE
- Eliminating cccDNA (responsible for viral persistence)
- Establish CpAMs as critical component of HBV curative backbone
- Prevent replenishment of new cccDNA long enough for established cccDNA to be eliminated

### Microbiome

- FMT is inadequate as therapy
- Develop oral, synthetic, live biotherapeutics
- FMT provides clinical POC avenue for strain selection

# Development Programs in Large Markets with High Unmet Need



### **Hepatitis B**



### Microbiome



## **Key Priorities Through 2018**









### Potential Value Drivers Over the Next 18 months



Opportunity for multiple inflection points from short to long term





# Hepatitis B: Cure Program

Market overview and deficiencies of current treatment Assembly's HBV Cure Program

### HBV: Over 300 Million Chronically Infected Patients Globally

Low cure rates with current SOC /Vaccines are Preventative but do not cure those who are chronically infected



Sources: Jidong Jia. HBV HCV epidem & therapy 2013. 2013 http://www.who.int/hepatitis/en/

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

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

\* GILD master model - Jefferies Research Report 8.30.17

### Deficiencies of current approved therapies

|                       | Mechanism of Action   | Benefits   | Limitations  |
|-----------------------|---|--|--|
| Nucleo(t)side Analogs | <ul> <li>Inhibit DNA<br/>polymerase</li> <li>Knock out replication<br/>virus from RNA to DNA<br/>(reverse transcription)</li> </ul> | <ul> <li>1x daily dosing</li> <li>Well tolerated</li> <li>High resistance barrier</li> </ul>   | <ul> <li>Does NOT completely stop<br/>replenishment of cccDNA</li> <li>Most patients must stay on<br/>drug for life</li> <li>No immuno-stimulatory<br/>benefits</li> </ul> |
| Peg-IFN               | Immuno-stimulatory<br>protein which<br>indirectly combats viral<br>replication  | <ul> <li>Enhances body's ability to<br/>clear or reduce viral load</li> <li>Highest cure rates (&lt;10%) of<br/>currently available therapies</li> </ul> | <ul> <li>Does NOT completely stop<br/>replenishment of cccDNA</li> <li>Poorly tolerated</li> <li>Requires weekly injections</li> <li>Poor response rate</li> </ul>         |

Current treatments inadequately reduce cccDNA  $\rightarrow$  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

\* Historical control. Tennant, et al. Viral Hepatitis and Liver Disease 1988: 462-464 R. Colonno, et al. JID 2001;184:1236-45

### Aspirational Objectives for Clinical Cure in Humans



### 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

### HBV Life Cycle: A DNA Virus with Limited Targets



### CpAMs are only modality that stop cccDNA generation Nucleus CCCDNA Maintenance - PCP C CDNA HBeAc PGRNA Nuclear envelope cccDNA Generation Cytoplasm Cp - Core Protein Pol - Polymerase 6 cccDNA - Covalently Closed Circular DNA rcDNA - Relaxed Circular DNA HBsAg sgRNA - Subgenomic RNA pgRNA - Pregenomic RNA assembly 14

# 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

| Absolute and<br>Complete Cure | Reactivate the host<br>immune response<br>• Decrease in viral<br>antigens                            |
|-------------------------------|--|
| Functional Cure               | • Clearance of cccDNA<br>•By shutting down the<br>replenishment of cccDNA<br>•Natural loss of cccDNA |
| Current SOC                   | Control viral replication<br>•Block reverse<br>transcription   |

### Potential Curative Regimen = SOC (nuc) + CpAM

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# 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

Cp – Core Protein Pol – Polymerase cccDNA – Covalently Closed Circular DNA rcDNA – Relaxed Circular DNA SgRNA – Subgenomic RNA pgRNA – Pregenomic RNA

# Measuring the half-life of cccDNA

### 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



CCCDNA

### 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<sub>50</sub> 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<sub>max</sub> and C<sub>min</sub>
- 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)

| Compound  | Viral DNA | HBeAg      | ▲ HBsAg    | 🔻 pgRNA    |
|-----------|-----------|------------|------------|------------|
| ABI-H0731 | 154       | 2,210      | 3,000      | 1,840      |
| 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 surrogates of cccDNA establishment
 Presented at AASLD 2016
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### ABI-H0731: General Clinical Investigational Plan



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

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
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· 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

|           |  | Key Parameters                                 | ABI-H2158                         |         |
|-----------|--|--|-----------------------------------|---------|
|           | Highly Potent while<br>maintaining favorable<br>drug-like characteristics<br>ABI-H2158 expected to<br>enter clinic in 2018 | AD38 VL EC <sub>50</sub> (μM)                  | 0.014                             |         |
|           |  | HC9AT HBeAg EC <sub>50</sub> (µM)              | 0.303                             |         |
|           |  | PHH VL EC <sub>50</sub> (μM)                   | 0.023                             |         |
|           |  | PHH HBeAg EC <sub>50</sub> (μM)                | 0.17                              |         |
| ABI-H2158 |  | Human Liver Microsomes<br>(% remaining 45 min) | 91/85                             |         |
|           |  | ABI-H2158 expected to                          | CYP Profile (IC <sub>50</sub> µM) | All ≥10 |
|           |  | Protein Binding (%)                            | 97                                |         |
|           |  | Rat PK %F<br>(1 mg/kg) T <sub>1/2</sub> (hr)   | 50<br>2.9                         |         |
|           |  | CL (mL/min/kg)                                 | 2.4                               |         |
|           |  | Oral AUC <sub>last</sub> (hr*ng/mL)            | 3,671                             |         |

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

## Investment Summary for ASMB CpAMs



- ✓ 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



# 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)

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

# 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.



# Assembly and Allergan Enter Microbiome Collaboration



### Significant microbiome platform collaboration with focus on GI disorders



#### **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.

## **Microbiome Platform**



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





# **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 2<sup>nd</sup> 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

- 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 nextgeneration CpAMs
- Select next indications (non-GI) for microbiome
- Advancements with collaboration partners in microbiome

| Nasdaq | Cash, cash equivalents<br>& marketable securities | Shares outstanding | Fully diluted |    |
|--------|---|--------------------|---------------|----|
| ASMB   | ~\$78.6M as of June 30, 2017                      | ~17.3M             | ~22M          | 35 |

## Assembly Biosciences: Summary

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



