# 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): November 5, 2020

# 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.)

331 Oyster Point Blvd., Fourth Floor South San Francisco, California 94080 (Address of principal executive offices, including zip code)

(833) 509-4583

(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))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered			
Common Stock, par value \$0.001	ASMB	The Nasdaq Global Select Market			

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 2.02 Results of Operations and Financial Condition.

On November 5, 2020, Assembly Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2020. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished with this Item 2.02, including Exhibit 99.1, 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 into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

#### Item 8.01 Other Events.

On November 5, 2020, the Company issued a press release announcing an update on the Company's ongoing open label extension study, ABI-H0731-211 ("Study 211"). A copy of the press release is attached as Exhibit 99.2 and is incorporated herein by reference.

#### **Cautionary Note Regarding Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties include: the Company's ability to initiate and complete clinical trials involving its hepatitis B virus therapeutic product candidates in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of the Company's product candidates; clinical and nonclinical data presented at conferences may not differentiate the Company's product candidates from other companies' candidates; the Company may not observe sustained virologic response in patients who stop therapy in Study 211; the Company's ability to maintain financial resources necessary to continue its clinical trials and fund business operations; any impact that the spread of the coronavirus and resulting COVID-19 pandemic may have on the Company's business and operations, including initiation and continuation of its clinical trials or timing of discussions with regulatory authorities; and other risks identified from time to time in the Company's reports filed with the U.S. Securities and Exchange Commission (the "SEC"). Statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words should be considered uncertain and forward-looking. The Company intends such forward-looking statements 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. More information about the Company's risks and uncertainties are more fully detailed under the heading "Risk Factors" in the Company's filings with the SEC, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Re

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press release dated November 5, 2020.
99.2	Press release dated November 5, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

#### 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: November 5, 2020

#### Assembly Biosciences, Inc.

By: /s/ Jason A. Okazaki

Jason A. Okazaki Chief Legal and Business Officer



#### Assembly Biosciences Reports Third Quarter 2020 Financial Results and Business Update

**SOUTH SAN FRANCISCO, CA, November 5, 2020** -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome, today reported financial results and a business update for the third quarter ended September 30, 2020.

"We continue to make progress to develop our pipeline of core inhibitor candidates for the treatment of patients with HBV," said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Biosciences. "We have made great strides toward initiating the vebicorvir Phase 3 registrational program, as well as advancing ABI-H2158 and ABI-H3733, our more potent, next-generation core inhibitor compounds, in the clinic."

# **Recent Updates**

#### HBV Portfolio

- Vebicorvir (VBR or ABI-H0731): Assembly Bio's lead core inhibitor candidate
  - 0 HBV field's first core inhibitor combination study (Study 211) to assess off-treatment response did not achieve a meaningful rate of sustained virologic response (SVR) as 39 of 41 patients have relapsed.
    - Assembly Bio to host webcast and conference call today at 5:00 p.m. ET. The live audio webcast may be accessed through the "Events & Presentations" page in the "Investors" section of Assembly Bio's website at <u>https://investor.assemblybio.com/events-presentations</u>.
    - For more information, see the data press release "Assembly Bio Provides Update on the Ongoing Phase 2 Extension Study of Vebicorvir in Patients with Chronic Hepatitis B Virus Infection" issued today, available on <u>Assembly Bio's website</u>.
  - Reached agreement with the Chinese regulatory body, National Medical Products Administration, Center for Drug Evaluation, and advanced discussions with the U.S. Food and Drug Administration (FDA) on a Phase 3 registrational program for VBR as a chronic suppressive therapy (CST) for HBV infection.
  - Entered into a license and collaboration agreement with BeiGene, Ltd. for Assembly Bio's portfolio of three clinical-stage core inhibitors (VBR, ABI-H2158, ABI-H3733) in the China territory, including Hong Kong, Macau and Taiwan.
  - O Entered into a clinical trial collaboration agreement with Arbutus Biopharma Corporation to evaluate the triple combination of VBR, RNAi therapeutic AB-729 and standard-of-care Nrtl therapy in patients with chronic HBV infection.

- Presented clinical data for Assembly Bio's HBV core inhibitors in an oral presentation and three posters at EASL 2020 The Digital International Liver Congress<sup>TM</sup>.
- ABI-H2158 (2158): Assembly Bio's second core inhibitor candidate
  - O Continued to enroll patients in the ongoing multi-center, randomized, placebo-controlled Phase 2 trial to evaluate 2158 with entecavir versus placebo with entecavir in treatment naïve patients with HBeAg positive chronic HBV infection.
- ABI-H3733 (3733): Assembly Bio's third core inhibitor candidate
  - Continued the ongoing Phase 1 trial to evaluate the safety, tolerability, and pharmacokinetics following single ascending dose and multiple ascending dose administrations in healthy subjects.

# Corporate Highlights

• Appointed Gina Consylman to the Board of Directors and Audit Committee in October 2020.

# **Anticipated Milestones and Events**

# HBV Portfolio

- Four abstracts, including two late-breaking submissions, will be presented at the annual meeting of the American Association for Liver Diseases (AASLD), The Liver Meeting<sup>®</sup> Digital Experience (TLMdX) being hosted virtually November 13-16, 2020.
- Vebicorvir
  - Phase 3 registrational studies for CST expected to initiate in H1 2021 in collaboration with BeiGene.
  - <sup>o</sup> Phase 2 triple combination study with Arbutus Biopharma expected to initiate in H1 2021.
  - Phase 2 triple combination study evaluating the addition of interferon to VBR and Nrtl expected to initiate in H1 2021.
  - Interim data from Phase 2 intensification study in partially virologically suppressed patients anticipated in 2021.
- 2158
  - Interim data from Phase 2 study anticipated in 2021.

# Upcoming Conference

• Jefferies Virtual London Healthcare Conference: November 17-19, 2020.

# Third Quarter 2020 Financial Results

- **Cash, cash equivalents and marketable securities** were \$237.9 million as of September 30, 2020, compared to \$226.7 million as of June 30, 2020. This increase is due to the \$40.0 million upfront payment received in July 2020 as part of the collaboration agreement with BeiGene offset by cash used in operations. Assembly Bio's cash position is projected to fund operations into the second half of 2022.
- **Revenues** from collaborative research were \$34.6 million for the three months ended September 30, 2020 compared to \$4.2 million for the same period in 2019. This includes the recognition of \$31.0 million under the collaboration agreement with BeiGene as well as reimbursements incurred under the collaboration agreement with AbbVie Inc. (Allergan Pharmaceuticals International Limited prior to AbbVie's acquisition of Allergan).
- Research and development expenses were \$26.9 million for the three months ended September 30, 2020, compared to \$21.7 million for the same period in 2019. The increase was primarily due to an increase of \$4.0 million in research and development expenses related to the HBV program. Research and development expenses include non-cash stock-based compensation expenses of \$2.8 million for the three months ended September 30, 2020 and \$2.5 million for the same period in 2019.
- **General and administrative expenses** were \$11.7 million for the three months ended September 30, 2020 compared to \$8.5 million for the same period in 2019. The increase was primarily due to an increase of \$2.7 million in professional fees associated with entering into the BeiGene agreement. General and administrative expenses include non-cash stock-based compensation expenses of \$3.3 million for the three months ended September 30, 2020 and \$2.9 million for the same period in 2019.
- Net loss attributable to common stockholders was \$3.3 million, or \$0.09 per basic and diluted share, for the three months ended September 30, 2020 compared to \$25.0 million, or \$0.96 per basic and diluted share, for the same period in 2019.

# **About Assembly Biosciences**

Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The HBV program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. The microbiome program is developing novel oral live microbial biotherapeutic candidates with Assembly Bio's fully integrated platform, including a robust process for strain identification and selection, GMP manufacturing expertise and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology. For more information, visit assemblybio.com.

#### **Forward-Looking Statements**

The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially

differ. These risks and uncertainties include: Assembly Bio's ability to initiate and complete clinical trials involving its HBV Cure and Microbiome therapeutic product candidates in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of Assembly Bio's product candidates; clinical and nonclinical data presented at conferences may not differentiate Assembly Bio's product candidates from other companies' candidates; Assembly Bio may not observe sustained virologic response in patients who stop therapy in Study 211; the timing and ability to implement strategic alternatives with respect to Assembly Bio's Microbiome program; Assembly Bio's ability to maintain financial resources necessary to continue its clinical trials and fund business operations; any impact that the spread of the coronavirus and resulting COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical trials or timing of discussions with regulatory authorities; and other risks identified from time to time in Assembly Bio's reports filed with the U.S. Securities and Exchange Commission (the SEC). You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. Assembly Bio intends such forward-looking statements 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. More information about Assembly Bio's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly Bio's filings with the SEC, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly Bio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

#### Contacts

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Media: Sam Brown Inc. Audra Friis (917) 519-9577 <u>ASMBMedia@sambrown.com</u>

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# ASSEMBLY BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands except for share amounts and par value)

	September 30, 2020			December 31, 2019		
ACCETC	(U	naudited)				
ASSETS						
Current assets	\$	E0 211	\$	46.732		
Cash and cash equivalents	Ф	58,311	Ъ	- / -		
Marketable securities		179,630		227,311 3,374		
Accounts receivable from collaboration		3,590				
Prepaid expenses and other current assets		4,856		5,363		
Total current assets		246,387		282,780		
Property and equipment, net		1,904		1,830		
Operating lease right-of-use (ROU) assets		10,397		11,975		
Other assets		5,980		1,684		
Indefinite-lived intangible asset		29,000		29,000		
Goodwill		12,638		12,638		
Total assets	\$	306,306	\$	339,907		
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities						
Accounts payable	\$	1.611	\$	1.731		
Accrued clinical expenses	Ψ	4,451	Ψ	4,826		
Other accrued expenses		7,404		8,286		
Deferred revenue - short-term				6,411		
Operating lease liabilities - short-term		3,338		3,186		
Total current liabilities		16,804		24,440		
Deferred tax liabilities		2,531		2,531		
Deferred revenue - long-term		8,987		30,637		
Operating lease liabilities - long-term		7,435		9,082		
Total liabilities		35,757		66,690		
Commitments and contingencies						
Stockholders' equity						
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding		_		_		
Common stock, \$0.001 par value; 100,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 32,924,536 and 32,558,307 shares issued and outstanding as of						
September 30, 2020 and December 31, 2019, respectively		33		32		
Additional paid-in capital		732,829		712,807		
Accumulated other comprehensive loss		(158)		(201		
Accumulated deficit		(462,155)		(439,421)		
Total stockholders' equity		270,549		273.217		
Total liabilities and stockholders' equity	\$	306,306	\$	339,907		

# ASSEMBLY BIOSCIENCES, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (In thousands except for share and per share amounts)

(Unaudited)

	 Three Mon Septem		Nine Months Ended September 30,				
	 2020		2019		2020		2019
Collaboration revenue	\$ 34,611	\$	4,231	\$	78,068	\$	11,197
Operating expenses:							
Research and development	26,941		21,736		73,314		63,141
General and administrative	 11,689		8,488		29,888		22,085
Total operating expenses	38,630		30,224		103,202		85,226
Loss from operations	 (4,019)		(25,993)	_	(25,134)		(74,029)
Other income							
Interest and other income, net	670		983		2,400		3,446
Total other income	 670		983		2,400		3,446
Loss before income taxes	 (3,349)		(25,010)	_	(22,734)		(70,583)
Income tax benefit	_		15		_		33
Net loss	\$ (3,349)	\$	(24,995)	\$	(22,734)	\$	(70,550)
Other comprehensive (loss) income							
Unrealized (loss) gain on marketable							
securities, net of tax	(262)		(18)		43		142
Comprehensive loss	\$ (3,611)	\$	(25,013)	\$	(22,691)	\$	(70,408)
Net loss per share, basic and diluted	\$ (0.09)	\$	(0.96)	\$	(0.64)	\$	(2.74)
Weighted average common shares outstanding, basic and diluted	35,506,042	_	25,912,568	_	35,321,393	_	25,765,414



#### Assembly Bio Provides Update on the Ongoing Phase 2 Extension Study of Vebicorvir in Patients with Chronic Hepatitis B Virus Infection

- HBV field's first core inhibitor combination study to assess off-treatment response has not achieved a meaningful rate of sustained virologic response -

- Vebicorvir Phase 3 registrational program remains on track to initiate in H1 2021 for chronic suppressive therapy - Assembly Bio to host conference call today at 5:00 p.m. ET -

SOUTH SAN FRANCISCO, Calif., November 5, 2020 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome, provided an update on the ongoing open-label Phase 2 extension study (Study 211) of vebicorvir (VBR, or ABI-H0731) in patients with chronic HBV infection. A first of its kind, Study 211 is exploring whether sustained virologic response (SVR) could be achieved after discontinuing therapy in virologically-suppressed patients who had received at least 12-18 months of combination treatment with core inhibitor VBR and a nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI). Study patients who met the treatment stopping criteria discontinued therapy and have been assessed monthly for safety and relapse. The study has not achieved meaningful SVR rates as 39 of 41 patients have now relapsed.

Among the patients who have discontinued treatment, 22 of the 23 with HBeAg negative HBV have relapsed (SVR = 4% at last visit), defined as off-treatment quantifiable HBV DNA by the COBAS TaqMan (2.0) assay (lower limit of quantification = 20 IU/mL). Sixteen of these patients relapsed at post-treatment Week 4, three at post-treatment Week 12, and three patients at post-treatment Week 16. Among the HBeAg positive patients, 17 of 18 relapsed at post-treatment Week 4 (SVR = 6% at last visit). Assembly Bio continues to collect and analyze study data and intends to submit more detailed findings to a future medical meeting.

#### Study 211 Interim Off-Treatment Virologic Results

	Discontinued treatment with	Relapsed at post- treatment Week 4	Relapsed at post- treatment Week 8	Relapsed at post- treatment Week 12	Relapsed at post- treatment Week 16	Have not relapsed*
Number of patients	VBR+NrtI					-
HBeAg negative	23	16	0	3	3	1
HBeAg positive	18	17	0	0	0	1

\*These 2 patients have completed the post-treatment Week 8 visit

John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Biosciences, stated, "With the addition of our first-generation core inhibitor, vebicorvir, to NrtI, we were able to drive viral suppression deeper in patients with chronic HBV infection to levels below the limits of our highly sensitive assays for six months or more. Patients like these normally face a lifetime of therapy, so we took the pioneering step to test whether their virologic response

could be sustained off treatment. As we had previously indicated, we believe an SVR24 rate of at least 15% would have marked a meaningful first advance in HBV finite therapy, but preliminary results have shown that we will fall short of that mark. While we are just beginning to analyze the data and this is not the outcome we were hoping for, we firmly believe it was the right experiment to conduct, and the learnings will inform the field and our ongoing development programs."

Dr. McHutchison continued, "We remain committed to driving the field of HBV therapeutics forward, and have made additional progress toward initiating a Phase 3 registrational program of vebicorvir with BeiGene focused on chronic suppressive therapy in China, home to one-third of the world's individuals living with chronic HBV infection. This Phase 3 program will include a population representing the 10-30% of HBV patients who only achieve partial viral suppression after a year or more on NrtI therapy, a group that has limited treatment options today. In parallel, we continue to advance our second and third core inhibitor candidates, which are substantially more potent than vebicorvir against the generation of cccDNA and have shown a more favorable resistance profile. Enrollment and dosing are underway in the Phase 2 trial of ABI-H2158 in patients with chronic HBV infection and the Phase 1 study of ABI-H3733 in healthy volunteers. Additionally, in the first half of 2021 we plan to begin triple combination Phase 2 trials combining VBR's core inhibitor mechanism with NrtI and an RNAi therapeutic from Arbutus and, separately, with interferon."

Assembly Bio's Phase 2 trials, Study 201 and 202, demonstrated that the addition of VBR to NrtI therapy achieved a more rapid and deeper level of viral suppression than seen with NrtI alone and with a similar safety and tolerability profile. Based on these data, Assembly Bio has reached agreement with the Chinese regulatory body, National Medical Products Administration, Center for Drug Evaluation, and continues discussions with the U.S. Food and Drug Administration, on a Phase 3 registrational program for VBR plus NrtI as a chronic suppressive therapy (CST) for certain patient populations with chronic HBV infection. The Company expects to initiate Phase 3 CST trials in the first half of 2021 in collaboration with BeiGene for the partnered China territory as part of the global registration program.

Assembly Bio also continues to advance ABI-H2158 (2158) and ABI-H3733 (3733), which have demonstrated in preclinical studies 10-fold and 40- to 50-fold higher potency, respectively, than VBR in inhibiting the formation of new cccDNA. A multi-center, randomized, placebo-controlled Phase 2 trial is evaluating 2158 with entecavir versus placebo with entecavir in treatment naïve HBeAg positive patients with chronic HBV infection. Additionally, a Phase 1 trial of 3733 is evaluating safety, tolerability, and pharmacokinetics following single ascending dose and multiple ascending dose administrations in healthy subjects.

During the first half of 2021, Assembly Bio also intends to initiate a Phase 2 trial to evaluate the triple combination of VBR, Arbutus Biopharma's RNAi therapeutic AB-729 and NrtI in patients with chronic HBV infection. Combining multi-drug regimens with non-overlapping mechanisms has the potential to generate higher response rates in certain HBV patient populations and potentially shorten their duration of treatment. The Company also anticipates initiating a triple

combination study in the first half of 2021 to evaluate the addition of interferon to VBR and NrtI.

# Assembly Bio's Webcast and Conference Call

Assembly Bio will host a webcast and conference call today at 2:00 p.m. PT / 5:00 p.m. ET. The live audio webcast may be accessed through the "Events & Presentations" page in the "Investors" section of Assembly Bio's website at https://investor.assemblybio.com/events-presentations. Alternatively, participants may dial (866) 438-0453 (domestic) or (409) 220-9366 (international) and refer to conference ID 5739584. Call participants are encouraged to connect at 1:45 p.m. PT / 4:45 p.m. ET to ensure a timely connection to the call or to utilize the webcast link for listen-only access.

The archived webcast will be available on Assembly Bio's website beginning approximately two hours after the event and will be archived and available for replay for at least 30 days after the event.

# About Assembly Biosciences' HBV Core Inhibitor Portfolio

Assembly Bio's HBV portfolio includes three clinical-stage small molecule candidates, all of which are HBV core inhibitors that target multiple steps of the HBV replication cycle. In Phase 2 clinical trials, first-generation core inhibitor vebicorvir (VBR, or ABI-H0731) administered with nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy has been well-tolerated, has shown statistically superior antiviral activity in HBV DNA suppression compared to NrtI therapy alone, and has demonstrated significant declines in HBV pgRNA that may indicate decreased cccDNA levels.

Assembly Bio's HBV portfolio also includes two, more potent core inhibitor candidates, ABI-H2158 (2158) and ABI-H3733 (3733), which have demonstrated in preclinical studies 10-fold and 40- to 50-fold higher potency, respectively, than VBR in inhibiting the formation of new cccDNA. 2158 is in Phase 2 development, and 3733 is in Phase 1 development.

Vebicorvir and 2158 both have been granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of chronic HBV infection.

# **About HBV**

Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts over 250 million people worldwide with up to 90 million people in China, as estimated by the World Health Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate viral replication, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

#### **About Assembly Biosciences**

Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The HBV program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. The microbiome program is developing novel oral live microbial biotherapeutic candidates with Assembly Bio's fully integrated platform, including a robust process for strain identification and selection, GMP manufacturing expertise and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology. For more information, visit <u>assemblybio.com</u>.

#### **Forward-Looking Statements**

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#### Contacts

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