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): February 25, 2021

Assembly Biosciences, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-35005**	**20-8729264**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

331 Oyster Point Blvd., Fourth Floor, South San Francisco, California	**94080**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (833) 509-4583

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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))

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 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 2.02 Results of Operations and Financial Condition.

On February 25, 2021, Assembly Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 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 February 25, 2021, the Company issued a press release announcing an update to its pipeline strategy. 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 studies involving its hepatitis B virus ("HBV") therapeutic product candidates, including studies contemplated by the Company's clinical collaboration agreements, 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; continued development and commercialization of the Company's HBV product candidates, if successful, in the China territory will be dependent on, and subject to, the Company's collaboration agreement governing its activity in the China territory; the Company's ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on the Company's business and operations, including initiation and continuation of its clinical studies 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"). 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. 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 Reports on Form 8-K. Except as required by law, the Company assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated February 25, 2021.
99.2	Press release dated February 25, 2021.
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 thereunto duly authorized.

Assembly Biosciences, Inc.

Date: February 25, 2021

By: /s/ Jason A. Okazaki
Jason A. Okazaki
Chief Legal and Business Officer

Exhibit 99.1

Assembly Biosciences Reports Fourth Quarter and Year End 2020 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, CA, February 25, 2021 -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV), today reported financial results and recent highlights for the fourth quarter and year ended December 31, 2020.

"Our strategy for 2021 and beyond is to focus entirely on developing finite and curative therapies that have the potential to free patients with chronic HBV infection from a lifetime of therapy. We are well positioned to do this by advancing our more potent next generation core inhibitors, which include three novel compounds in the clinic and a fourth candidate in pre-IND development, exploring multiple triple combination studies of vebicorvir with complementary mechanisms of action, and expanding our internal research efforts to discover and develop candidates against novel targets," said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Bio.

Fourth Quarter 2020 and Recent Highlights

- Strategy and resources fully focused on pursuing finite and curative therapies for chronic HBV:
  - As announced separately today, Assembly Bio will forgo initiation of Phase 3 registrational studies of vebicorvir (VBR) as a chronic suppressive therapy to concentrate research and development efforts on identifying a finite and curative therapy.
  - By directing all resources to support its finite and curative strategy, the company expects to advance these initiatives more quickly, while simultaneously extending its cash runway into 2023.
  - Assembly Bio is hosting a 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 https://investor.assemblybio.com/events-presentations.

- Initiated a Phase 2 triple combination study evaluating the addition of peg-IFNα to the VBR+ nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) antiviral backbone in patients with chronic HBV infection.
- Entered into collaboration with Door Pharmaceuticals to discover and develop a novel class of HBV cccDNA disruptors that target different phases of the HBV replication cycle distinct from and complementary to those targeted by Assembly Bio's existing pipeline compounds.

- Presented four posters at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting in November 2020, including data from the company's HBV core inhibitor research and development programs, as well as a collaborative translational study using Assembly Bio's sensitive HBV nucleic acid assays.
- Reported data in early November 2020 from Study 211 on the dual combination of VBR+Nrtl to assess off-treatment response in patients with chronic HBV infection, which did not achieve a meaningful rate of sustained virologic response (SVR).
- Substantially completed wind-down of Assembly Bio's Microbiome program.
- Appointed Nicole S. White, PhD, as Senior Vice President of Pharmaceutical Development and Manufacturing.
- Appointed Gina Consylman, Senior Vice President, Chief Financial Officer of Ironwood Pharmaceuticals, Inc. to Board of Directors.

2021 Key Objectives and Anticipated Progress

- Initiate Phase 2 triple combination study with Arbutus Biopharma Corporation evaluating VBR, RNAi therapeutic AB-729, and NrtI therapy in virologically-suppressed patients in H1 2021.
- Nominate a best-in-class fourth core inhibitor candidate in H1 2021.
- Anticipate interim data from Phase 2 study with ABI-H2158 in H2 2021.
- Expect to progress two additional internal programs evaluating differentiated and undisclosed targets.

Fourth Quarter 2020 and Year End Financial Results

- **Cash, cash equivalents and marketable securities** were $216.4 million as of December 31, 2020, compared to $237.9 million as of September 30, 2020, and $274.0 million as of the year ended December 31, 2019. This result includes the $5.5 million of net proceeds from the issuance of common shares under Assembly Bio's at-the-market (ATM) program. Subsequently, net proceeds from Assembly Bio's ATM program during January and February 2021 to-date were $25.5 million. The company's cash position is projected to fund operations into 2023.
- **Revenues** from collaborative research were $1.0 million for the three months ended December 31, 2020, compared to $4.8 million for the same period in 2019, and $79.1 million for the year ended December 31, 2020, compared to $16.0 million in 2019. The year-over-year increase was primarily due to the $31.0 million recognized under the collaboration agreement with BeiGene, Ltd. (BeiGene) and the remaining deferred revenue balance of $37.0 million incurred under the collaboration agreement with Abbvie Inc. (Allergan Pharmaceuticals International Limited prior to Abbvie's acquisition of Allergan).

- **Research and development expenses** were $33.5 million for the three months ended December 31, 2020, compared to $22.6 million for the same period in 2019, and $106.8 million for the year ended December 31, 2020, compared to $85.8 million in 2019. The increase was primarily due to an increase of $14.4 million in research and development expenses related to the HBV program and one-time expenses of $5.7 million related to the microbiome program wind down. Research and development expenses include non-cash stock-based compensation expenses of $11.4 million for both of the years ended December 31, 2020 and 2019.
- **General and administrative expenses** were $7.2 million for the three months ended December 31, 2020 compared to $10.8 million for the same period in 2019, and $37.1 million for the year ended December 31, 2020 compared to $32.9 million in 2019. The increase was primarily due to an increase of $2.7 million of expenses related to entering into the collaboration agreement with BeiGene. General and administrative expenses include non-cash stock-based compensation expenses of $10.5 million for year ended December 31, 2020 and $9.2 million for the same period in 2019.
- **Net loss attributable to common stockholders** was $39.4 million, or $1.10 per basic and diluted share, for the three months ended December 31, 2020, compared to $27.1 million, or $1.06 per basic and diluted share, for the same period in 2019. For the year ended December 31, 2020, net loss was $62.2 million, or $1.75 per basic and diluted share, compared to $97.6 million, or $3.72 per basic and diluted share, for the year ended December 31, 2019.

About Assembly Biosciences

Assembly Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 270 million people living with hepatitis B virus (HBV) worldwide. A pioneer in the development of a new class of potent, oral core inhibitor drug candidates, Assembly Bio's approach aims to break the complex viral replication cycle of HBV to free patients from a lifetime of therapy. Assembly Bio's strategy toward cure includes a leading portfolio of more potent, next-generation core inhibitors, proof-of-concept combination studies and a research program focused on the discovery of novel HBV targets. 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 studies involving its HBV therapeutic product candidates, including studies contemplated by Assembly Bio's clinical collaboration agreements, 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; continued development

and commercialization of Assembly Bio's HBV product candidates, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing its activity in the China territory; Assembly Bio's ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical studies 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.

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 59,444	$ 46,732
Marketable securities	156,969	227,311
Accounts receivable from collaboration	1,230	3,374
Prepaid expenses and other current assets	6,850	5,363
Total current assets	224,493	282,780
Property and equipment, net	1,600	1,830
Operating lease right-of-use (ROU) assets	9,131	11,975
Other assets	6,392	1,684
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 283,254**	**$ 339,907**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 4,598	$ 1,731
Accrued clinical expenses	4,444	4,826
Other accrued expenses	11,987	8,286
Deferred revenue - short-term	—	6,411
Operating lease liabilities - short-term	3,404	3,186
Total current liabilities	24,433	24,440
Deferred tax liabilities	2,531	2,531
Deferred revenue - long-term	8,987	30,637
Operating lease liabilities - long-term	6,725	9,082
Total liabilities	**42,676**	**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, $0.001 par value; 100,000,000 shares authorized as of December 31, 2020 and 2019; 34,026,680 and 32,558,307 shares issued and outstanding as of December 31, 2020 and 2019, respectively	34	32
Additional paid-in capital	742,387	712,807
Accumulated other comprehensive loss	(270)	(201)
Accumulated deficit	(501,573)	(439,421)
Total stockholders' equity	240,578	273,217
Total liabilities and stockholders' equity	**$ 283,254**	**$ 339,907**

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

	Year Ended December 31,		
	2020	**2019**	**2018**
Collaboration revenue	$ 79,105	$ 15,963	$ 14,804
Operating expenses:			
Research and development	106,823	85,757	72,741
General and administrative	37,058	32,919	34,798
Total operating expenses	143,881	118,676	107,539
Loss from operations	**(64,776)**	**(102,713)**	**(92,735)**
Other income			
Interest and other income, net	2,624	4,305	3,083
Total other income	2,624	4,305	3,083
Loss before income taxes	**(62,152)**	**(98,408)**	**(89,652)**
Income tax benefit	—	774	(1,099)
Net loss	**$ (62,152)**	**$ (97,634)**	**$ (90,751)**
Other comprehensive (loss) income			
Unrealized (loss) gain on marketable securities, net of tax	(69)	146	45
Comprehensive loss	**$ (62,221)**	**$ (97,488)**	**$ (90,706)**
Net loss per share, basic and diluted	$ (1.75)	$ (3.72)	$ (3.98)
Weighted average common shares outstanding, basic and diluted	35,427,120	26,258,790	22,801,644

Exhibit 99.2

Assembly Biosciences Updates Pipeline Strategy, Focusing on Finite and Curative Therapies for Chronic Hepatitis B Virus Infection

- Prioritizing next generation, more potent core inhibitors, triple combinations with complementary mechanisms of action, and expanding research programs to advance multiple candidates against novel targets

- Extends cash runway into 2023

- Company to host conference call today at 5:00 p.m. ET/2:00 p.m. PT

SOUTH SAN FRANCISCO, Calif., February 25, 2021 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV), today announced that it is foregoing its plans to initiate Phase 3 registrational studies of vebicorvir (VBR, or ABI-H0731) as a chronic suppressive therapy (CST) to concentrate its research and development efforts on finite and curative HBV therapies. As part of this focused strategy on finite and curative HBV therapies, Assembly Bio will prioritize its portfolio of potent next generation core inhibitors and combinations of VBR with complementary mechanisms of action, and plans to rapidly advance multiple research programs focused on novel targets and new mechanisms to the clinic.

The decision to not initiate the global registrational studies of VBR as CST followed extensive discussions with leading experts in the field and regulatory agencies, and with respect to the China territory, discussions and agreement with the company's partner, BeiGene, Ltd. By redirecting the company's resources previously reserved for the CST registrational studies and other activities to concentrate fully on pursuing finite and curative therapies, Assembly Bio expects to be able to advance these initiatives faster, while simultaneously extending its cash runway into 2023.

"Many of us at Assembly Bio have spent our careers developing drugs aimed at addressing tremendous unmet needs in viral diseases and making a marked difference in patients' lives. We remain committed to the vision of freeing HBV patients from a lifetime of treatment by advancing finite duration and curative therapies, and we continue to believe that core inhibitors will be a central component of these future regimens," said John McHutchison, AO, MD, Chief Executive Officer and President at Assembly Bio. "We have the right team and resources in place to advance these efforts, and we are excited about the opportunity before us."

"Both of our companies are committed to addressing the highest unmet medical need of patients," said John Oyler, Chairman, Co-Founder and Chief Executive Officer at BeiGene. "We support Assembly Bio's focus on pursuing a cure for HBV, and are hopeful that the Assembly Bio team and their portfolio of core inhibitors will bring finite and curative therapies closer to reality for the nearly 90 million HBV patients in China."

Assembly Bio's HBV pipeline includes three clinical-stage core inhibitor candidates and multiple research and discovery programs. The company has two clinical studies underway with one more study expected to begin during the first half of 2021.

Potent Next Generation Core Inhibitors

- ABI-H2158 (2158):
  - Phase 2 study is ongoing with interim data anticipated in the second half of 2021.
  - Potent antiviral activity and a favorable safety profile has been demonstrated in a Phase 1b study.
  - Candidate is ~10-fold more potent than VBR *in vitro* against the formation of new cccDNA.
- ABI-H3733 (3733):
  - Phase 1a study completed in healthy subjects.
- Fourth Core Inhibitor Candidate:
  - New candidate on track to be nominated during the first half of 2021 with a potential best-in-class profile, including greater potency against cccDNA formation.

VBR + Nucleos(t)ide Analogue Reverse Transcriptase Inhibitor (NrtI) in Combination with Other Complementary Mechanisms

- VBR + NrtI + interferon (peg-IFNα):
  - Phase 2a triple combination study has been initiated.
- VBR + NrtI + RNAi:
  - Phase 2a triple combination study including Arbutus' RNAi therapeutic AB-729 is expected to initiate in the first half of 2021.
- Additional Combinations:
  - Further potential combination studies are under review to build upon the VBR + NrtI antiviral "backbone" by evaluating the addition of one or more complementary mechanisms of action.

Research Programs on New Targets

- Core Protein cccDNA Disruptors:
  - A collaboration with Door Pharmaceuticals is underway to discover and develop a novel class of HBV cccDNA disruptors that target different phases of the HBV replication cycle distinct from and complementary to those targeted by Assembly Bio's existing pipeline compounds.
- Novel HBV Targets:
  - Assembly Bio has two additional internal programs underway evaluating differentiated and undisclosed targets.

Assembly Bio's Webcast and Conference Call

Assembly Bio will host a webcast and conference call today at 5:00 p.m. ET/2:00 p.m. PT. 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 (888) 771-4371 (domestic) or +1 (847) 585-4405 (international) and refer to conference ID 50110189. To ensure timely access to the event, participants are encouraged to connect to the call 15 minutes before the start time 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 HBV

Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts approximately 270 million people worldwide, 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, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

About Assembly Biosciences

Assembly Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 270 million people living with hepatitis B virus (HBV) worldwide. A pioneer in the development of a new class of potent, oral core inhibitor drug candidates, Assembly Bio's approach aims to break the complex viral replication cycle of HBV to free patients from a lifetime of therapy. Assembly Bio's strategy toward cure includes a leading portfolio of more potent, next-generation core inhibitors, proof-of-concept combination studies and a research program focused on the discovery of novel HBV targets. For more information, visit assemblybio.com.

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initiation and continuation of its clinical studies 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.

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