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): March 4, 2020

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 March 4, 2020, Assembly Biosciences, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2019. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated March 4, 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 thereunto duly authorized.

Assembly Biosciences, Inc.

Date: March 4, 2020

By: /s/ John G. McHutchison, A.O., M.D.
John G. McHutchison, A.O., M.D.
Chief Executive Officer and President

Exhibit 99.1

Assembly Biosciences Reports Fourth Quarter and Year End 2019 Financial Results

SOUTH SAN FRANCISCO, Calif., March 4, 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, today reported financial results and recent highlights for the fourth quarter and year ended December 31, 2019.

“We closed out 2019 with exciting Phase 2 data from our HBV core inhibitor program at AASLD, where ABI-H0731 showed superior antiviral activity to nucleos(t)ide therapy alone as well as significant declines in pgRNA that we believe are reflective of decreases in cccDNA levels. With these encouraging findings and input from our investigators, we are finalizing plans to this year begin transitioning patients meeting certain criteria off 731+Nrtl therapy in the ongoing extension study, to observe if viral suppression can be sustained,” said John McHutchison, AO, MD, Chief Executive Officer and President. “Importantly, we begin 2020 well-resourced to advance our strategy and pipeline. During the fourth quarter we further strengthened our senior leadership team with the appointments of our Chief Financial Officer, our Chief Medical Officer and our Senior Vice President of Regulatory Affairs. With our experienced and dedicated team and a strong balance sheet following our successful December equity offering, we are well positioned to move our lead HBV candidate toward registration studies, to advance our second generation HBV candidate into Phase 2, and to further progress our microbiome program. We are also pleased to note that abstracts from both our HBV and microbiome therapeutic programs will be featured in presentations at medical meetings during the second quarter of 2020.”

Fourth Quarter 2019 and Recent Highlights

- At the American Association for the Study of Liver Diseases (AASLD) Annual Meeting in November 2019, Assembly presented final 24-week data from two Phase 2 studies (201 and 202) and interim data from the ongoing Phase 2 long-term extension study (211) of ABI-H0731 (731), as well as interim data from the Phase 1b study of ABI-H2158 (2158).
    - 731 + nucleos(t)ide analogs (NrtI) in HBeAg positive patients with chronic Hepatitis B infection demonstrated favorable longer-term safety and tolerability, greater reductions in HBV DNA and HBV pgRNA than in NrtI alone. Data also showed that significant declines in HBV pgRNA, a primary surrogate marker of cccDNA, were associated with reductions in hepatitis B viral antigens (HBeAg, HBcrAg and HBsAg).
    - Interim data from the ongoing Phase 1b study of 2158 demonstrated potent antiviral activity and tolerability in the initial low dose cohort of 100 mg in HBeAg-positive patients treated for 14 days. The study is ongoing, and the company expects to report data on higher dose cohorts in Q2 2020.

- Abstracts featuring data from Assembly's HBV portfolio have been accepted for presentation at the International Liver Congress (EASL) in London, April 15-19, 2020.
- An abstract featuring preclinical data from Assembly's microbiome therapeutics program focused on ulcerative colitis has been accepted for poster presentation during Digestive Disease Week in Chicago, May 2-5, 2020, and an abstract featuring preclinical data from Assembly's proprietary oncology microbiome therapeutics program has also been accepted for a poster presentation during the American Association for Cancer Research Annual Meeting in San Diego, April 24-29, 2020.
- Assembly strengthened its balance sheet with an underwritten public offering that closed in December 2019 and resulted in net proceeds of $134.7 million.

Upcoming Milestones

HBV Program

- ABI-H0731
  - Additional interim analyses from study 211 planned in Q2 2020
- ABI-H2158
  - Final Phase 1b data on higher dose cohorts to be reported in Q2 2020.
  - Phase 2 trial expected to initiate in Q2 2020.
- ABI-H3733
  - Phase 1a trial expected to initiate in Q1 2020.

Microbiome Program

- ABI-M201
  - Enrollment is ongoing in a multi-center randomized, placebo-controlled Phase 1b trial in patients with mildly to moderately active ulcerative colitis (UC).
- Microbiome Platform
  - Leveraging Assembly's rational function-based microbial discovery platform and in-house high-quality manufacturing expertise to advance new proprietary live biotherapeutic consortium candidates for oncology and other disease indications.

Fourth Quarter 2019 and Year End Financial Results

- **Cash, cash equivalents and marketable securities** were $274.0 million as of December 31, 2019, compared to $156.9 million as of September 30, 2019 and $218.1 million as of the year ended December 31, 2018. This year end cash position is projected to fund operations into 2022.

- **Revenues** from collaborative research were $4.8 million for the three months ended December 31, 2019 compared to $3.7 million for the same period in 2018, and $16.0 million for the year ended December 31, 2019 compared to $14.8 million in 2018. The increase was related to an increase in research and development efforts for our microbiome program, including the initiation of a Phase 1b study.

- **Research and development expenses,** excluding stock-based compensation expense, were $19.6 million for the three months ended December 31, 2019, compared to $18.1 million for the same period in 2018, and $74.4 million for the year ended December 31, 2019 compared to $60.9 million for the year ended December 31, 2018. This increase was primarily due to an increase of $9.4 million in research and development expenses related to the HBV program and an increase of $4.1 million in gross research and development expenses related to the microbiome program. Stock-based compensation expense was $3.1 million for the three months ended December 31, 2019 compared to $3.1 million for the same period in 2018 and $11.4 million for the year ended December 31, 2019 as compared to $11.8 million in 2018.

- **General and administrative expenses,** excluding stock-based compensation expense, were $7.4 million for the three months ended December 31, 2019 compared to $6.3 million for the same period in 2018, and $23.7 million for the year ended December 31, 2019 compared to $18.1 million in 2018. The increase was primarily due to increased headcount and a one-time expense for severance packages in conjunction with the relocation of the corporate headquarters to South San Francisco. Stock-based compensation expense was $3.4 million for the three months ended December 31, 2019 compared to $3.7 million for the same period in 2018 and $9.2 million for the year ended December 31, 2019 as compared to $16.7 million in 2018. This decrease was primarily due to a one-time expense incurred in 2018 coupled with the reversal in 2019 of previously recognized 2018 expenses related to the departures of two executive officers in 2018 and 2019, respectively.

- **Net loss attributable to common stockholders** was $27.1 million, or $0.99 per basic and diluted share, for the three months ended December 31, 2019 compared to $26.1 million, or $1.03 per basic and diluted share, for the same period in 2018. For the year ended December 31, 2019, net loss was $97.6 million, or $3.72 per basic and diluted share, compared to $90.8 million, or $3.98 per basic and diluted share, for the year ended December 31, 2018.

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'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 regarding future events, including statements about the timing of data from our clinical studies involving our HBV and Microbiome therapeutic product candidates, the initiation of clinical studies for our HBV product candidates, the presentation of Microbiome non-clinical data at scientific conferences, adequacy of our financial resources and projected cash runway. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as “expected,” “planned,” “projected,” “upcoming” and “will.” Assembly 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. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. These risks and uncertainties include, among others: the components, timing, cost and results of clinical trials and other development activities involving our product candidates; whether our cash resources will be sufficient to fund continuing operations for the periods and/or trials. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading “Risk Factors” in Assembly's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Contacts
Assembly Biosciences, Inc.
Investors:
Lauren Glaser
(415) 521-3828
lglaser@assemblybio.com

Assembly Biosciences, Inc.
Consolidated Balance Sheets
(In thousands except for share and per share amounts)

	As of December 31,	
	2019	**2018**
ASSETS		
Current assets		
Cash and cash equivalents	$ 46,732	$ 41,471
Marketable securities	227,311	176,609
Accounts receivable from collaboration	3,374	2,430
Prepaid expenses and other current assets	5,363	1,992
Total current assets	282,780	222,502
Property and equipment, net	1,830	557
Operating lease right-of-use assets	11,975	—
Other assets	1,684	3,348
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 339,907**	**$ 268,045**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,731	$ 3,693
Accrued clinical expenses	4,826	3,561
Other accrued expenses	8,286	6,118
Deferred revenue - short-term	6,411	5,100
Operating lease liabilities - short-term	3,186	—
Total current liabilities	24,440	18,472
Deferred rent	—	108
Deferred tax liabilities	2,531	3,252
Deferred revenue - long-term	30,637	35,560
Operating lease liabilities - long-term	9,082	—
Total liabilities	**66,690**	**57,392**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of December 31, 2019 and 2018; 32,558,307 and 25,495,425 shares issued and outstanding as of December 31, 2019 and 2018, respectively	32	25
Additional paid-in capital	712,807	552,762
Accumulated other comprehensive loss	(201)	(347)
Accumulated deficit	(439,421)	(341,787)
Total stockholders' equity	273,217	210,653
Total liabilities and stockholders' equity	**$ 339,907**	**$ 268,045**

Assembly Biosciences, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands except for share and per share amounts)

	Year ended December 31,		
	2019	**2018**	**2017**
Collaboration revenue	$ 15,963	$ 14,804	$ 9,019
Operating expenses:			
Research and development	85,757	72,741	44,225
General and administrative	32,919	34,798	17,021
Total operating expenses	118,676	107,539	61,246
Loss from operations	**(102,713)**	**(92,735)**	**(52,227)**
Other income (expenses)			
Interest and other income	4,300	3,083	983
Other income (expense), net	5	—	(615)
Total other income	4,305	3,083	368
Loss before income taxes	**(98,408)**	**(89,652)**	**(51,859)**
Income tax benefit (expense)	774	(1,099)	9,050
Net loss	**$ (97,634)**	**$ (90,751)**	**$ (42,809)**
Other comprehensive (loss) income			
Unrealized gain on marketable securities, net of tax	146	45	209
Comprehensive loss	**$ (97,488)**	**$ (90,706)**	**$ (42,600)**
Net loss per share, basic and diluted	$ (3.72)	$ (3.98)	$ (2.41)
Weighted average common shares outstanding, basic and diluted	26,258,790	22,801,644	17,750,380