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): **May 7, 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)	(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)

☐ 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2020, Assembly Biosciences, Inc. issued a press release announcing its financial results for the quarter ended March 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 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press release dated May 7, 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: May 7, 2020

Assembly Biosciences, Inc.

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

Assembly Biosciences Reports Updates on Corporate Progress and First Quarter 2020 Financial Results

-- Advancing the development of three clinical-stage core inhibitor candidates in HBV portfolio --
-- Cash position of $249 million projected to fund operations into 2022 --
-- Company to host HBV portfolio progress update call / webcast today at 1:30 pm PT / 4:30 pm ET --

SOUTH SAN FRANCISCO, CA, May 7, 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 for the first quarter ended March 31, 2020 and provided an update on recent corporate progress.

“I am proud of the exceptional commitment and focus that our team has demonstrated during the first quarter, in light of the unprecedented events unfolding throughout the world and the healthcare sector with the COVID-19 pandemic. We have managed to achieve our key business objectives while keeping the health and safety of patients, study staff, and employees top of mind, and continuing to assess and adapt to this environment,” said John McHutchison, AO, MD, Chief Executive Officer and President. “Importantly, we have finalized the stopping criteria by which patients with chronic HBV infection in Study 211 will be transitioned off combination therapy with our core inhibitor candidate ABI-H0731 and a nucleos(t)ide therapy later this year. This is a critical next step in the development of hepatitis B therapies, as ours would be the first trial of a core inhibitor to stop therapy and monitor patients for potential sustained virologic response.”

First Quarter 2020 and Recent Highlights

HBV Portfolio

- ABI-H0731: Assembly’s lead core inhibitor candidate
  - The Phase 2 open-label extension study (Study 211) is ongoing with subjects reaching 12-18 months of combination treatment with ABI-H0731 and standard-of-care nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy.
  - Assembly has determined the stopping criteria by which it will begin transitioning patients off therapy, and these criteria have been discussed with its lead investigators and reviewed and agreed upon by the U.S. Food and Drug Administration (FDA).
  - Assembly has submitted an End of Phase 2 meeting request and briefing document for review with China regulatory authorities to plan for the initiation of studies aimed at supporting the registration of ABI-H0731 with NrtI for chronic suppressive therapy in China.

- ABI-H2158, Assembly's second-generation, more potent core inhibitor candidate, has completed the dose-ranging Phase 1b clinical trial and the Company has selected the 300 mg daily dose of ABI-H2158 to advance into Phase 2 development. The Company is preparing to initiate a multi-center, randomized, placebo-controlled Phase 2 trial evaluating ABI-H2158 with entecavir versus placebo with entecavir in approximately 80 treatment-naïve, HBeAg positive patients with chronic HBV infection.
- ABI-H3733, Assembly's third core inhibitor candidate, has continued to advance in development. A Phase 1 trial is now open for enrollment and will evaluate safety, tolerability, and pharmacokinetics following single ascending dose and multiple ascending dose administrations of ABI-H3733 in healthy subjects.
- Additional information on the above, and Assembly's other recent progress with its HBV core inhibitor portfolio, will be shared today at 1:30 pm PT during a conference call and simultaneous webcast (connection information provided below). The slides presented during the webcast will be available shortly after the call on Assembly's website.
- In March 2020, research into the turnover and presumed half-life of covalently closed circular DNA (cccDNA) pools, which play a pivotal role in the establishment and persistence of HBV infection, was first published online in *Hepatology*, the journal of the American Association for the Study of Liver Diseases.

Microbiome Portfolio

- Preclinical data on Assembly Biosciences' Microbiome program in ulcerative colitis (UC) were presented in a poster during Digestive Disease Week's 2020 Virtual Meeting. A copy of the poster is available on Assembly Biosciences' website. In addition, the abstract is scheduled for publication in the May online supplements to the journals *Gastroenterology* and *GIE: Gastrointestinal Endoscopy*.

Corporate Highlights

- In March 2020, Jason Okazaki joined as Chief Legal and Business Officer.
- In April 2020, Carl Henrik Enell joined as Senior Vice President, Corporate Development.

Upcoming Milestones

HBV Portfolio

- ABI-H0731
  - Presentation of additional interim analyses from Study 211 at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress, rescheduled to August 27-29, 2020; abstracts were accepted as an oral presentation (HBeAg negative patients) and as a late-breaking poster (HBeAg positive patients).
  - Plan to begin taking patients off of combination therapy later this year, to then monitor for sustained virologic response.

- ABI-H2158
  - Plan to initiate a Phase 2 clinical trial in the second quarter of 2020.
  - Presentation of Phase 1b clinical data on multiple dose cohorts accepted for inclusion at EASL as a late-breaking poster.
- ABI-H3733
  - Continuation of ongoing Phase 1 clinical trial.
- Proprietary In-House HBV DNA and pgRNA Assays
  - Poster presentation of Assembly's highly sensitive assays at EASL.

Microbiome Portfolio

- ABI-M201
  - Continuation of the ongoing multi-center randomized, placebo-controlled Phase 1b trial in patients with mildly to moderately active UC.
- Microbiome Platform
  - Poster presentation of preclinical data from Assembly's microbiome immuno-oncology program at the American Association for Cancer Research Virtual Annual Meeting II, June 22-24, 2020.
  - Expanded utilization of 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.

First Quarter 2020 Financial Results

- **Cash, cash equivalents and marketable securities** were $249.1 million as of March 31, 2020, compared to $274.0 million as of December 31, 2019. This cash position is projected to fund operations into 2022.
- **Revenues** from collaborative research were $4.1 million for the three months ended March 31, 2020 compared to $3.9 million for the same period in 2019.
- **Research and development expenses** were $23.0 million for the three months ended March 31, 2020, compared to $22.7 million for the same period in 2019. The increase was primarily due to an increase of $0.4 million in gross research and development expenses related to the Microbiome programs and a decrease of $0.1 million in research and development expenses related to the HBV programs. Research and development expenses include non-cash stock-based compensation expenses of $1.9 million for the three months ended March 31, 2020 and $2.7 million for the same period in 2019.
- **General and administrative expenses** were $8.7 million for the three months ended March 31, 2020 compared to $9.5 million for the same period in 2019. General and administrative expenses include non-cash stock-based compensation expenses of $3.0 million for the three months ended March 31, 2020 and $3.8 million for the same period in 2019.

- **Net loss attributable to common stockholders** was $26.7 million, or $0.76 per basic and diluted share, for the three months ended March 31, 2020 compared to $27.1 million, or $1.05 per basic and diluted share, for the same period in 2019.

Conference Call / Webcast Today
Assembly Biosciences is hosting a conference call and webcast today at 1:30 pm PT / 4:30 pm ET. The live audio webcast with accompanying slide presentation may be accessed through the “Events & Presentations” page in the “Investors” section of the Company’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 5156737. *Due to current high volume accessing virtual events, participants are encouraged to connect at 1:15 pm PT / 4:15 pm 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’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
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 that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties include: Assembly’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’s product candidates; clinical and nonclinical data presented at conferences may not differentiate Assembly’s product candidates from other companies’ candidates; Assembly may not observe sustained virologic response in patients who stop therapy in Study 211; Assembly’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’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’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 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's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly'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 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.
Amy Figueroa, CFA
Investor Relations Consultant
(415) 366-5158
afigueroa@assemblybio.com

Solebury Trout
Luke Brown
(646) 378-2944
lbrown@troutgroup.com

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

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 42,326	$ 46,732
Marketable securities	206,803	227,311
Accounts receivable from collaboration	3,055	3,374
Prepaid expenses and other current assets	4,568	5,363
Total current assets	256,752	282,780
Property and equipment, net	1,780	1,830
Operating lease right-of-use assets	11,479	11,975
Other assets	1,661	1,684
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 313,310**	**$ 339,907**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,104	$ 1,731
Accrued clinical expenses	4,633	4,826
Other accrued expenses	4,430	8,286
Deferred revenue - short-term	6,715	6,411
Operating lease liabilities - short-term	3,264	3,186
Total current liabilities	21,146	24,440
Deferred tax liabilities	2,531	2,531
Deferred revenue - long-term	29,326	30,637
Operating lease liabilities - long-term	8,539	9,082
Total liabilities	**61,542**	**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, $0.001 par value; 100,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 32,624,725 and 32,558,307 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	32	32
Additional paid-in capital	717,898	712,807
Accumulated other comprehensive loss	(86)	(201)
Accumulated deficit	(466,076)	(439,421)
Total stockholders' equity	251,768	273,217
Total liabilities and stockholders' equity	**$ 313,310**	**$ 339,907**

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

	Three Months Ended March 31,	
	2020	2019
Collaboration revenue	$ 4,081	$ 3,885
Operating expenses:		
Research and development	23,046	22,704
General and administrative	8,729	9,517
Total operating expenses	31,775	32,221
Loss from operations	**(27,694)**	**(28,336)**
Other income (expenses)		
Interest and other income, net	1,039	1,277
Total other income	1,039	1,277
Loss before income taxes	**(26,655)**	**(27,059)**
Income tax benefit	-	7
Net loss	**$ (26,655)**	**$ (27,052)**
Other comprehensive (loss) income		
Unrealized gain on marketable securities, net of tax	115	108
Comprehensive loss	**$ (26,540)**	**$ (26,944)**
Net loss per share, basic and diluted	$ (0.76)	$ (1.05)
Weighted average common shares outstanding, basic and diluted	35,079,756	25,668,798

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