

**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 7, 2019**

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)

(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 November 7, 2019, Assembly Biosciences, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 7, 2019
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 7, 2019

Assembly Biosciences, Inc.

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

Assembly Biosciences Reports Third Quarter 2019 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, Calif., November 7, 2019 (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 third quarter ended September 30, 2019.

“I’m thrilled to have joined Assembly during the third quarter; this is an exciting time as our HBV and microbiome programs are building important momentum. We have also had the opportunity to attract industry-leading talent to our team with the recent additions of Tom Russo as CFO and Luisa Stamm as CMO,” said John McHutchison, AO, MD, Chief Executive Officer and President. “We look forward to presenting data from our Phase 2a trials of ABI-H0731 in more detail on Monday, November 11 during the AASLD Annual Meeting in Boston. As our abstract indicated, the combination of ‘731 with nucleos(t)ide therapy not only showed superior antiviral activity to nucleos(t)ide therapy alone, but is also associated with declines in surrogate markers predictive of cccDNA pool depletion, suggesting our core inhibitor regimens may be on the path to HBV cure. We also continue to advance our second and third core inhibitor candidates, with interim data from the Phase 1b trial of 2158 scheduled for presentation at AASLD.”

Third Quarter 2019 and Recent Highlights

- Abstracts with data highlighting safety and antiviral activity of Assembly’s first and second generation core inhibitor candidates in the treatment of chronic HBV were accepted for late-breaking posters at the upcoming American Association for the Study of Liver Diseases (AASLD) Annual Meeting (The Liver Meeting®) in Boston.
 - Phase 2a studies of ABI-H0731 + nucleos(t)ide analogs (Nrtl) in HBeAg+ patients show faster and deeper declines in HBV DNA and pgRNA with combination than Nrtl alone, as well as subsequent declines in the surrogate markers of cccDNA with long-term treatment
 - Potent antiviral activity was observed in first cohort of HBeAg+ patients treated in 14-day monotherapy study of ABI-H2158
 - The posters will be displayed during the 8:00am-5:30pm ET session on Monday, November 11, 2019, with presentation scheduled from 12:30-1:30pm ET.
 - John McHutchison, AO, MD, joined Assembly in August as Chief Executive Officer and President. Dr. McHutchison is a world-renowned hepatologist, gastroenterologist, and anti-viral drug developer who previously led the research and development of five marketed therapies for chronic hepatitis B and chronic hepatitis C.
 - Further strengthened the leadership team with appointments of Thomas Russo as Chief Financial Officer in October and Luisa Stamm, MD, PhD as Chief Medical Officer, as announced separately today.
 - Mr. Russo brings 25 years of experience in the biotechnology and pharmaceutical industry, spanning finance and operations (including commercial planning and manufacturing), as well as equity research.
 - Dr. Stamm is an infectious disease specialist whose industry career has focused on the development of therapeutics for hepatitis C (HCV) and liver disease, as well as HIV and other viral diseases.
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Anticipated Milestones and Events

HBV Program

- ABI-H0731
 - Data from the ongoing long-term open label extension Phase 2 trial, Study 211, combining 731 with Nrtl therapy, including 48-week interim results, as well as final 24 week data from Studies 201 and 202 to be presented at AASLD on November 11, 2019.
- ABI-H2158
 - Data from the initial dose cohort in the Phase 1b trial in HBV-infected subjects to be presented at AASLD on November 11, 2019. Full study data anticipated in Q1 2020.
- ABI-H3733
 - Phase 1a trial expected to initiate in Q1 2020.

Microbiome Program

- ABI-M201
 - Enrollment and dosing ongoing in Phase 1b trial in patients with mildly to moderately active ulcerative colitis (UC).
- Microbiome Platform
 - Leveraging discovery and development capabilities and manufacturing expertise to advance new proprietary candidates for multiple other disease indications.

Upcoming Events and Conferences

- Conference call on Monday, November 11, 2019 at 8:30am ET to review AASLD data
- William Blair Biotech Focus Day Series: Boston Area Innovation on November 12, 2019
- Jefferies London Healthcare Conference, November 20-21, 2019
- Hep-DART, December 8-12, 2019 in Kauai, HI

Upcoming Conference Call and Webcast Information

Assembly will host a live conference call and audio webcast on Monday, November 11, 2019, at 8:30 am ET following the start of the late breaking poster session at the AASLD meeting. The live audio webcast can be accessed through the Events & Presentations page in the Investors section of the company's website at assemblybio.com. Alternatively, participants can dial (866) 438-0453 (domestic) or (409) 220-9366 (international) and refer to conference ID 4283686.

Third Quarter 2019 Financial Results

- **Cash, cash equivalents and marketable securities** were approximately \$156.9 million as of September 30, 2019, compared to approximately \$173.8 million as of June 30, 2019. This quarter-end cash position is projected to fund operations into 2021.
 - **Revenues** from collaborative research were approximately \$4.2 million for the three months ended September 30, 2019 compared to \$4.3 million for the same period in 2018.
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- **Research and development expenses**, excluding stock-based compensation expense, were approximately \$19.3 million for the three months ended September 30, 2019, compared to approximately \$16.6 million for the same period in 2018. Stock-based compensation expense was approximately \$2.5 million for the three months ended September 30, 2019 and 2018.
- **General and administrative expenses**, excluding stock-based compensation expense, were approximately \$5.5 million for the three months ended September 30, 2019, compared to \$4.2 million for the same period in 2018. Stock-based compensation expense was approximately \$2.9 million for the three months ended September 30, 2019, compared to approximately \$3.5 million for the same period in 2018.
- **Net loss attributable to common stockholders** was approximately \$25.0 million, or \$0.96 per basic and diluted share, for the three months ended September 30, 2019, compared to approximately \$21.5 million, or \$0.87 per basic and diluted share, for the same period in 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 banking and production, 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 clinical and therapeutic potential of core inhibitors, the timing of the initiation of and the availability of data from our ongoing and planned clinical trials and cash projections. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "expected," "plans," "potential" and "projected." 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 (including those licensed by Allergan Pharmaceuticals International Limited); the unpredictability of the preclinical 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; whether our cash resources will be sufficient to fund continuing operations for the periods and/or trials; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's Quarterly Report on Form 10-Q for the quarter ended September 30, 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

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ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(\$ in thousands except for share and per share amounts)

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 24,867	\$ 41,471
Marketable securities	132,070	176,609
Accounts receivable from collaboration	2,944	2,430
Prepaid expenses and other current assets	5,441	1,992
Total current assets	<u>165,322</u>	<u>222,502</u>
Property and equipment, net	1,931	557
Operating lease right-of-use assets	12,783	-
Other assets	1,671	3,348
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	<u>\$ 223,345</u>	<u>\$ 268,045</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,709	\$ 3,693
Accrued expenses	9,430	9,679
Deferred revenue - short-term	6,151	5,100
Operating lease liabilities - short-term	3,208	-
Total current liabilities	<u>21,498</u>	<u>18,472</u>
Deferred rent	-	108
Deferred tax liabilities	3,251	3,252
Deferred revenue - long-term	32,268	35,560
Operating lease liabilities - long-term	9,839	-
Total liabilities	<u>66,856</u>	<u>57,392</u>
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, 2019 and December 31, 2018; 25,872,723 and 25,495,425 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	26	25
Additional paid-in capital	569,005	552,762
Accumulated other comprehensive loss	(205)	(347)
Accumulated deficit	(412,337)	(341,787)
Total stockholders' equity	<u>156,489</u>	<u>210,653</u>
Total liabilities and stockholders' equity	<u>\$ 223,345</u>	<u>\$ 268,045</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ 4,231	\$ 4,286	\$ 11,197	\$ 11,069
Operating expenses:				
Research and development	21,736	19,109	63,141	51,490
General and administrative	8,488	7,752	22,085	25,992
Total operating expenses	30,224	26,861	85,226	77,482
Loss from operations	(25,993)	(22,575)	(74,029)	(66,413)
Other income (expenses)				
Interest and other income	983	1,116	3,441	2,015
Other income (expense), net	-	(82)	5	(232)
Total other income	983	1,034	3,446	1,783
Loss before income taxes	(25,010)	(21,541)	(70,583)	(64,630)
Income tax benefit	15	6	33	40
Net loss	\$ (24,995)	\$ (21,535)	\$ (70,550)	\$ (64,590)
Other comprehensive (loss) income				
Unrealized gain (loss) on marketable securities, net of tax	(18)	17	142	37
Comprehensive loss	\$ (25,013)	\$ (21,518)	\$ (70,408)	\$ (64,553)
Net loss per share, basic and diluted	\$ (0.96)	\$ (0.87)	\$ (2.74)	\$ (2.95)
Weighted average common shares outstanding, basic and diluted	25,912,568	24,878,413	25,765,414	21,900,943