
**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): **August 5, 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 August 5, 2019, Assembly Biosciences, Inc. issued a press release announcing its financial results for the quarter ended June 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:

Exhibit No.	Description
<u>99.1</u>	<u>Press release dated August 5, 2019.</u>

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated August 5, 2019.

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: August 5, 2019

Assembly Biosciences, Inc.

By: /s/ Derek A. Small

Derek A. Small

President and Chief Executive Officer



Assembly Biosciences Reports Second Quarter 2019 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, August 5, 2019 – 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 second quarter ended June 30, 2019.

“The second quarter of 2019 has been a period of great progress as we continue our transition into later stage clinical development. Following a series of data presentations at EASL in Vienna and IASL in China, we have continued to progress our HBV clinical candidates, now on a global scale,” said Derek Small, President and Chief Executive Officer. “We are also excited that the first oral microbiome biologic drug candidate from our proprietary platform is being evaluated in patients, with our Phase 1b clinical trial of ABI-M201 for mildly to moderately active ulcerative colitis underway.”

Second Quarter 2019 and Recent Highlights

- Oral presentation, “*New Therapies to More Effectively Eliminate Viral Replication and Increase Cure Rates in CHB Patients*,” at the first International Association for the Study of the Liver (IASL) Congress on June 22, 2019 in Beijing, China by Richard Colonno, EVP and CSO of Virology Operations.
 - o Reviewed science and strategies for utilizing HBV core inhibitors as well as interim clinical data previously reported by the company in April 2019 at The International Liver Congress™(ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL).
- Received Clinical Trial Application (CTA) approvals from China’s Center for Drug Evaluation (CDE), part of the National Medical Products Administration (NMPA) in China, enabling Assembly’s plans to initiate Phase 2 and Phase 1 clinical trials of both 731 and 2158, respectively, at leading HBV trial sites in China.
- Dosed first patient with ABI-H2158 in Phase 1b dose escalation study in HBV patients.
- Dosed first patient with ABI-M201 in a Phase 1b clinical trial for mildly to moderately active ulcerative colitis (UC).
 - o First oral microbiome biologic drug candidate from Assembly’s proprietary microbiome platform to enter clinical trials in patients.
- Steve Knox, SVP, Clinical Development and David Houck, PhD, SVP Product Development & Portfolio Management joined Assembly’s leadership team as the company transitions to a later stage development organization.

Anticipated Milestones and Events

HBV Program

- ABI-H0731
 - o Additional data from the ongoing long-term Phase 2a trial combining 731 with Nuc therapy, including 48-week interim results, expected in Q4 2019.
 - ABI-H2158
-

- o Data from Phase 1b trial in HBV-infected subjects expected in Q1 2020.

- ABI-H3733

- o Phase 1a trial expected to initiate in Q1 2020.

Microbiome Program

- ABI-M201

- o Enrollment and dosing ongoing in Phase 1b trial in patients with mildly to moderately active UC.

- Microbiome Platform

- o Leveraging discovery and development capabilities and manufacturing expertise to advance new proprietary candidates for other disease indications.

Upcoming Conferences

- Baird's 2019 Global Healthcare Conference, in New York on September 5, 2019 at 10:15am ET

Second Quarter 2019 Financial Results

- **Cash, cash equivalents and marketable securities** were approximately \$173.8 million as of June 30, 2019, compared to approximately \$193.5 million as of March 31, 2019. This quarter-end cash position is projected to fund operations into 2021.
 - **Revenues** from collaborative research were approximately \$3.1 million for the three months ended June 30, 2019 compared to \$3.2 million for the same period in 2018.
 - **Research and development expenses**, excluding stock-based compensation expense, were approximately \$15.6 million for the three months ended June 30, 2019, compared to approximately \$14.2 million for the same period in 2018. Stock-based compensation expense was approximately \$3.1 million for the three months ended June 30, 2019, compared to approximately \$3.7 million for the same period in 2018.
 - **General and administrative expenses**, excluding stock-based compensation expense, were approximately \$5.1 million for the three months ended June 30, 2019, compared to \$4.6 million for the same period in 2018. Stock-based compensation expense was approximately \$(1.1) million for the three months ended June 30, 2019, compared to approximately \$7.9 million for the same period in 2018. This decrease was primarily due to the reversal of previously recognized expense of \$3.6 million related to forfeited awards to a former officer who departed during the most recent period coupled with a \$4.3 million one-time expense related to the departure and transition to consultant of a former officer in 2018.
 - **Net loss attributable to common stockholders** was approximately \$18.5 million, or \$0.72 per basic and diluted share, for the three months ended June 30, 2019, compared to approximately \$26.8 million, or \$1.30 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; our anticipated capital expenditures and our estimates regarding our capital requirements; 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 June 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

Assembly Biosciences, Inc.

Investors:

Lauren Glaser

(415) 521-3828

lglaser@assemblybio.com

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

	June 30, 2019	December 31, 2018
	<u>(Unaudited)</u>	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 34,258	\$ 41,471
Marketable securities	139,553	176,609
Accounts receivable from collaboration	2,903	2,430
Prepaid expenses and other current assets	6,746	1,992
Total current assets	<u>183,460</u>	<u>222,502</u>
Property and equipment, net	2,048	557
Operating lease right-of-use assets	12,672	-
Other assets	1,693	3,348
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	<u><u>\$ 241,511</u></u>	<u><u>\$ 268,045</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,414	\$ 3,693
Accrued expenses	7,585	9,679
Deferred revenue - short-term	6,082	5,100
Operating lease liabilities - short-term	2,854	-
Total current liabilities	<u>19,935</u>	<u>18,472</u>
Deferred rent	-	108
Deferred tax liabilities	3,252	3,252
Deferred revenue - long-term	33,582	35,560
Operating lease liabilities - long-term	10,035	-
Total liabilities	<u><u>66,804</u></u>	<u><u>57,392</u></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 June 30, 2019 and December 31, 2018; 25,646,783 and 25,495,425 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	26	25
Additional paid-in capital	562,210	552,762
Accumulated other comprehensive loss	(187)	(347)
Accumulated deficit	(387,342)	(341,787)
Total stockholders' equity	<u>174,707</u>	<u>210,653</u>
Total liabilities and stockholders' equity	<u><u>\$ 241,511</u></u>	<u><u>\$ 268,045</u></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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ 3,080	\$ 3,218	\$ 6,966	\$ 6,783
Operating expenses:				
Research and development	18,700	17,840	41,405	32,381
General and administrative	4,080	12,544	13,597	18,240
Total operating expenses	22,780	30,384	55,002	50,621
Loss from operations	(19,700)	(27,166)	(48,036)	(43,838)
Other income (expenses)				
Interest and other income	1,182	453	2,458	899
Other income (expense), net	4	(127)	5	(150)
Total other income	1,186	326	2,463	749
Loss before income taxes	(18,514)	(26,840)	(45,573)	(43,089)
Income tax benefit	11	34	18	34
Net loss	\$ (18,503)	\$ (26,806)	\$ (45,555)	\$ (43,055)
Other comprehensive (loss) income				
Unrealized gain on marketable securities, net of tax	52	87	160	20
Comprehensive loss	\$ (18,451)	\$ (26,719)	\$ (45,395)	\$ (43,035)
Net loss per share, basic and diluted	\$ (0.72)	\$ (1.30)	\$ (1.77)	\$ (2.11)
Weighted average common shares outstanding, basic and diluted	25,740,500	20,541,549	25,690,617	20,387,532