

**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 8, 2018**

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)

(317) 210-9311
(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))

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 8, 2018, Assembly Biosciences, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2018. 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 August 8, 2018.

EXHIBIT INDEX

Exhibit No.

Description

[99.1](#)

[Press release dated August 8, 2018.](#)

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 8, 2018

Assembly Biosciences, Inc.

By: /s/ Derek A. Small
Derek A. Small
President and Chief Executive Officer



Assembly Biosciences Announces Second Quarter 2018 Financial Results

- *ABI-H0731 Phase 2a Clinical Trials Actively Enrolling Patients; Initial Data Continues to be Anticipated in H1 2019*
- *Strong Balance Sheet Provides Significant Runway*

SAN FRANCISCO and INDIANAPOLIS, August 8, 2018 – 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 second quarter ended June 30, 2018.

“Based on the positive Phase 1b data for ABI-H0731 that we reported at EASL 2018 in April, we have initiated enrollment in our Phase 2a viral antigen and viral load trials in HBV patients and have raised approximately \$155 million in an oversubscribed public stock offering. This gives us substantial resources to advance our pipeline, including completion of these Phase 2a trials and the introduction of ABI-2158 into the clinic, which is planned for later this year,” said Derek Small, President and Chief Executive Officer. “We also were pleased that ABI-H0731 received Fast Track Designation from the FDA, which allows us to work closely with the agency to bring this new therapeutic candidate to HBV patients as quickly as possible.”

Recent Highlights

- Assembly began enrolling patients in two Phase 2a proof of concept studies evaluating ABI-H0731, the Company’s lead core inhibitor targeting HBV. Initial data from both studies are expected in the first half of 2019. ABI-H0731 was also granted Fast Track Designation by the U.S. Food and Drug Administration (FDA).
- On July 16, 2018, Assembly announced the closing of an underwritten public offering of 4,600,000 shares of common stock at a public offering price of \$36.00 per share, which includes the full exercise of the underwriters’ option to purchase additional shares. Net proceeds to Assembly from this offering were approximately \$155 million.
- Assembly hosted its first Research and Development Day in New York on June 20, 2018. Two key opinion leaders highlighted the need for new and curative treatments for the millions of patients living with HBV. Company management also presented the development plans for ABI-H0731 and the second generation core inhibitor candidate, ABI-H2158. The presentation and recorded replay of the event can be accessed in the Investors section of the Company’s website.

Anticipated Milestones and Events

- ABI-H0731
 - o Initial Phase 2a data expected in the first half of 2019
 - ABI-2158
 - o Phase 1a clinical trial initiation in healthy volunteers expected in the fourth quarter of 2018
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Upcoming events

- o Baird Global Healthcare Conference in New York, September 5-6, 2018
- o Morgan Stanley Global Healthcare Conference in New York, September 12-14, 2018

Second Quarter Financial Results

Cash, cash equivalents and marketable securities were approximately \$94.9 million as of June 30, 2018 compared to approximately \$109.2 million as of March 31, 2018. As of July 16, 2018, Assembly's pro forma cash balance is approximately \$250 million which includes net proceeds from the offering of approximately \$155.4 million.

Revenues consisting of revenue from collaborative research were approximately \$3.2 million for the three months ended June 30, 2018, compared to approximately \$2.4 million for the same period in 2017. The increase in revenue was due to an increase in Allergan-related activities and expense reimbursement.

Research and development expenses, excluding stock-based compensation expense, were approximately \$14.2 million for the three months ended June 30, 2018, compared to approximately \$10.9 million for the same period in 2017. This increase was primarily due to an increase of approximately \$3.1 million in research and development expenses related to the HBV program. Stock-based compensation expense was approximately \$3.7 million for the three months ended June 30, 2018, compared to approximately \$1.2 million for the same period in 2017.

General and administrative expenses, excluding stock-based compensation expense, were approximately \$4.6 million for the three months ended June 30, 2018, compared to approximately \$3.0 million for the same period in 2017. This increase was primarily due to increased headcount across the organization. Stock-based compensation expense was approximately \$7.9 million for the three months ended June 30, 2018, as compared to \$0.8 million for the same period in 2017. This increase was primarily due to a \$4.3 million one-time non-cash expense related to the departure and transition to consultant of a former officer of Assembly and \$3.5 million of expenses related to non-cash, stock-based compensation grants and employee incentive programs including the 2018 Employee Stock Purchase Plan.

Net loss attributable to common stockholders was approximately \$26.7 million, or \$1.30 per basic and diluted share, for the three months ended June 30, 2018, compared to approximately \$13.5 million, or \$0.78 per basic and diluted share for the same period in 2017. This increase was primarily due to an increase in research and development expenses related to the HBV program, and expenses related to non-cash, stock-based compensation, employee incentive programs and increased headcount across the organization.

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 synthetic 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, including ABI-H0731 and ABI-H2158, Assembly's development programs, the results of earlier nonclinical and clinical trials being predictive of future clinical trials, the initiation, progress and results of Assembly's ongoing and planned clinical studies and the timing of these events, our estimates and projections regarding expenses, use of cash, cash equivalents and marketable securities, future revenue, capital requirements, adequacy of capital and financing requirements. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "anticipated", "upcoming," "look forward," "will," "expected," and "potential." 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. 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, 2018 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.

Assembly Biosciences, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2018	December 31, 2017
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 54,192,131	\$ 82,033,209
Marketable securities, at fair value	38,480,105	37,914,482
Accounts receivable from collaboration	2,125,597	2,273,421
Prepaid expenses and other current assets	2,731,385	897,400
Total current assets	97,529,218	123,118,512
Long-term assets		
Marketable securities, at fair value	2,204,103	3,347,213
Property, plant and equipment, net	639,897	860,026
Security deposits	406,735	339,558
Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,638,136
Total long-term assets	44,888,871	46,184,933
Total assets	\$ 142,418,089	\$ 169,303,445
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,538,976	\$ 2,123,939
Accrued expenses	5,079,780	6,139,000
Deferred revenue - short-term	5,512,109	5,229,227
Total current liabilities	13,130,865	13,492,166
Long-term liabilities		
Deferred tax liabilities	2,108,367	2,135,802
Deferred revenue - long-term	38,078,292	40,555,708
Total long-term liabilities	40,186,659	42,691,510
Total liabilities	53,317,524	56,183,676
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, \$0.001 par value; 100,000,000 and 50,000,000 shares authorized as of June 30, 2018 and December 31, 2017, respectively; 20,614,498 and 20,137,974 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	20,614	20,138
Additional paid-in capital	383,543,035	364,528,037
Accumulated other comprehensive loss	(372,078)	(392,391)
Accumulated deficit	(294,091,006)	(251,036,015)
Total stockholders' equity	89,100,565	113,119,769
Total liabilities and stockholders' equity	\$ 142,418,089	\$ 169,303,445

Assembly Biosciences, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaboration revenue	\$ 3,217,865	\$ 2,359,311	\$ 6,782,925	\$ 3,043,680
Operating expenses:				
Research and development	17,840,128	12,125,021	32,381,302	22,698,760
General and administrative	12,543,658	3,801,541	18,239,693	7,842,000
Total operating expenses	<u>30,383,786</u>	<u>15,926,562</u>	<u>50,620,995</u>	<u>30,540,760</u>
Loss from operations	<u>(27,165,921)</u>	<u>(13,567,251)</u>	<u>(43,838,070)</u>	<u>(27,497,080)</u>
Other income (expenses)				
Interest and other income	453,016	239,858	899,422	376,342
Realized loss from marketable securities	(127,234)	(340,984)	(150,250)	(478,232)
Total other income	<u>325,782</u>	<u>(101,126)</u>	<u>749,172</u>	<u>(101,890)</u>
Loss before income taxes	<u>(26,840,139)</u>	<u>(13,668,377)</u>	<u>(43,088,898)</u>	<u>(27,598,970)</u>
Income tax benefit	33,907	69,513	33,907	69,513
Net loss	<u>\$ (26,806,232)</u>	<u>\$ (13,598,864)</u>	<u>\$ (43,054,991)</u>	<u>\$ (27,529,457)</u>
Other comprehensive (loss) income				
Unrealized loss recognized in accumulated other comprehensive loss before reclassification, net of tax benefit of \$29,835, \$57,437, \$29,835 and \$57,437, respectively	(39,962)	(31,203)	(129,937)	(92,359)
Reclassification adjustment of unrealized loss included in net loss, net of tax expense of \$36,307, \$183,371, \$36,307 and \$183,371, respectively	127,234	157,613	150,250	294,861
Comprehensive loss	<u>\$ (26,718,960)</u>	<u>\$ (13,472,454)</u>	<u>\$ (43,034,678)</u>	<u>\$ (27,326,955)</u>
Net loss per share, basic and diluted	<u>(1.30)</u>	<u>(0.78)</u>	<u>(2.11)</u>	<u>(1.59)</u>
Weighted average common shares outstanding, basic and diluted	<u>20,541,549</u>	<u>17,342,623</u>	<u>20,387,532</u>	<u>17,305,657</u>

Contacts

Assembly Biosciences, Inc.

Investors:

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