# 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 8, 2018**

# 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.) |

**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 November 8, 2018, Assembly Biosciences, Inc. issued a press release announcing its financial results for the quarter ended September 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 November 8, 2018. |

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release dated November 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: November 8, 2018

**Assembly Biosciences, Inc.**

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

**Exhibit 99.1**

**Assembly Biosciences Announces Third Quarter 2018 Financial Results and Provides HBV Program Update**

*- ABI-H0731 Phase 2a Clinical Trials Actively Enrolling Patients; Data Continues to be Anticipated in 1H 2019*

*- ABI-H2158 Phase 1a Study Initiated*

*- ABI-H3733 Nominated as Third Core Inhibitor Candidate*

**SAN FRANCISCO, November 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 third quarter ended September 30, 2018 and provided an update on the progress in its HBV and microbiome pipelines.

"We are excited about the advancements we have made in our HBV portfolio, with two core inhibitors now in clinical trials and the selection of a third potent, novel clinical candidate," said Derek Small, President and Chief Executive Officer. "With the nomination of ABI-H3733 as our third candidate, we have a deep pipeline of HBV core inhibitors in development and continue our discovery efforts focused on identifying additional chemical scaffolds. We are actively enrolling patients in our ongoing ABI-H0731 Phase 2a proof-of-concept studies, and our team is committed to advancing potential curative therapy to HBV patients. Our microbiome platform has also made great strides over the past quarter and pending the successful conclusion of IND-enabling studies, we hope to have our first candidate ABI-M201 for ulcerative colitis in the clinic next year. Importantly, our strong balance sheet supports our development plans through multiple inflection points."

**Third Quarter and Recent Highlights**

- Assembly continued enrolling patients in two Phase 2a studies evaluating ABI-H0731, the Company's lead HBV core inhibitor. The Phase 2a viral antigen proof-of-concept study was recently expanded to include an additional cohort of virus suppressed HBeAg negative patients. The addition of this cohort is not expected to significantly impact enrollment timelines and will further Assembly's understanding of outcomes in different patient populations as well as aid in the design of potential registrational studies.

- Assembly initiated a Phase 1a dose-ranging clinical trial of ABI-H2158, the Company's second, highly potent core inhibitor, in healthy volunteers.

- Assembly has nominated its third core inhibitor candidate, ABI-H3733, derived from a new chemical class distinct from Assembly's other core inhibitors in development. In nonclinical studies, ABI-H3733 has exhibited superior potency while maintaining good drug-like properties. ABI-H3733 is currently undergoing investigational new drug (IND) enabling studies.

- Microbiome candidate ABI-M201 (partnered with Allergan) is currently completing IND-enabling studies and is expected to enter the clinic in 2019 in patients with mild to moderate ulcerative colitis.

**Anticipated Milestones and Events**

- ABI-H0731
    - Final Phase 1b data will be presented at the American Association for the Study of Liver Diseases Annual Meeting (AASLD) on Sunday, November 11, 2018 in San Francisco by MF Yuen, MD, PhD, Chief of Division of Gastroenterology and Hepatology, Queen Mary Hospital, Hong Kong.
    - Interim Phase 2a data is expected in the first half of 2019.
- ABI-H2158
    - Interim Phase 1a data expected in mid 2019.
- ABI-M201
    - Initiate Phase 1b clinical study in 2019 in patients with mild to moderate ulcerative colitis.
- Upcoming events
    - AASLD, San Francisco, November 9-13, 2018
    - Jefferies London Healthcare Conference, November 14-15, 2018
    - Global Mizuho Investor Conference in New York, December 3-4, 2018

**Third Quarter Financial Results**

- **Cash, cash equivalents and marketable securities** were approximately $233.9 million as of September 30, 2018 compared to approximately $94.9 million as of June 30, 2018.
- **Revenues** consisting of revenue from collaborative research were approximately $4.3 million for the three months ended September 30, 2018, compared to approximately $2.7 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 $16.6 million for the three months ended September 30, 2018, compared to approximately $9.4 million for the same period in 2017. This increase was primarily due to an increase of approximately $5.5 million in research and development expenses related to the HBV program and an increase of approximately $1.6M in research and development expenses related to the microbiome program. Stock-based compensation expense was approximately $2.5 million for the three months ended September 30, 2018, compared to approximately $1.6 million for the same period in 2017.
- **General and administrative expenses,** excluding stock-based compensation expense, were approximately $4.2 million for the three months ended September 30, 2018, compared to approximately $3.1 million for the same period in 2017. This increase was primarily due to increased headcount across the organization. Stock-based compensation expense was approximately $3.5 million for the three months ended September 30, 2018, as compared to $1.0 million for the same period in 2017.
- **Net loss attributable to common stockholders** was approximately $21.5 million, or $0.87 per basic and diluted share, for the three months ended September 30, 2018, compared to approximately $12.3 million, or $0.71 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, ABI-H2158 and ABI-H3733, Assembly's development programs, the initiation, progress and results of Assembly's ongoing and planned clinical studies and the timing of these events, and the sufficiency of capital through inflection points. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "plan," "upcoming," "anticipated," "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 September 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.

**Contacts**
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**Assembly Biosciences, Inc.**
**Condensed Consolidated Balance Sheets**

| | September 30, 2018 (Unaudited) | December 31, 2017 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 119,752,339 | $ 82,033,209 |
| Marketable securities, at fair value | 114,187,793 | 37,914,482 |
| Accounts receivable from collaboration | 2,589,862 | 2,273,421 |
| Prepaid expenses and other current assets | 3,342,759 | 897,400 |
| Total current assets | 239,872,753 | 123,118,512 |
| Long-term assets | | |
| Marketable securities, at fair value | - | 3,347,213 |
| Property, plant and equipment, net | 515,798 | 860,026 |
| Security deposits | 950,515 | 339,558 |
| Intangible assets | 29,000,000 | 29,000,000 |
| Goodwill | 12,638,136 | 12,638,136 |
| Total long-term assets | 43,104,449 | 46,184,933 |
| **Total assets** | **$ 282,977,202** | **$ 169,303,445** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 2,987,565 | $ 2,123,939 |
| Accrued expenses | 6,517,053 | 6,139,000 |
| Deferred revenue - short-term | 5,105,104 | 5,229,227 |
| Total current liabilities | 14,609,722 | 13,492,166 |
| Long-term liabilities | | |
| Deferred rent | 7,903 | - |
| Deferred tax liabilities | 2,107,300 | 2,135,802 |
| Deferred revenue - long-term | 36,819,053 | 40,555,708 |
| Total long-term liabilities | 38,934,256 | 42,691,510 |
| **Total liabilities** | **53,543,978** | **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, $0.001 par value; 100,000,000 and 50,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 25,460,122 and 20,137,974 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively | 25,460 | 20,138 |
| Additional paid-in capital | 545,388,704 | 364,528,037 |
| Accumulated other comprehensive loss | (354,896) | (392,391) |
| Accumulated deficit | (315,626,044) | (251,036,015) |
| Total stockholders' equity | 229,433,224 | 113,119,769 |
| **Total liabilities and stockholders' equity** | **$ 282,977,202** | **$ 169,303,445** |

**Assembly Biosciences, Inc.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| **Collaboration revenue** | $ 4,285,848 | $ 2,659,613 | $ 11,068,773 | $ 5,703,293 |
| **Operating expenses:** | | | | |
| Research and development | 19,108,918 | 10,929,436 | 51,490,220 | 33,628,196 |
| General and administrative | 7,752,493 | 4,180,357 | 25,992,186 | 12,022,357 |
| Total operating expenses | 26,861,411 | 15,109,793 | 77,482,406 | 45,650,553 |
| **Loss from operations** | **(22,575,563)** | **(12,450,180)** | **(66,413,633)** | **(39,947,260)** |
| Other income (expenses) | | | | |
| Interest and other income | 1,116,053 | 241,326 | 2,015,475 | 617,668 |
| Realized loss from marketable securities | (82,070) | (99,068) | (232,320) | (577,300) |
| Total other income | 1,033,983 | 142,258 | 1,783,155 | 40,368 |
| **Loss before income taxes** | (21,541,580) | (12,307,922) | (64,630,478) | (39,906,892) |
| Income tax benefit | 6,542 | 35,903 | 40,449 | 105,416 |
| **Net loss** | **$ (21,535,038)** | **$ (12,272,019)** | **$ (64,590,029)** | **$ (39,801,476)** |
| **Other comprehensive (loss) income** | | | | |
| Unrealized loss recognized in accumulated other comprehensive loss before reclassification, net of tax benefit of $50,664, $31,844, $44,192 and $89,281, respectively | (8,749) | (51,203) | (138,686) | (143,562) |
| Reclassification adjustment of unrealized loss included in net loss, net of tax expense of $56,139, $37,987, $56,139 and $221,358, respectively | 25,931 | 61,081 | 176,181 | 355,942 |
| **Comprehensive loss** | **$ (21,517,856)** | **$ (12,262,141)** | **$ (64,552,534)** | **$ (39,589,096)** |
| Net loss per share, basic and diluted | $ (0.87) | $ (0.71) | $ (2.95) | $ (2.30) |
| Weighted average common shares outstanding, basic and diluted | 24,878,413 | 17,367,523 | 21,900,943 | 17,326,506 |