

**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): June 12, 2020

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
(IRS Employer
Identification No.)

**331 Oyster Point Blvd., Fourth Floor,
South San Francisco, California**
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's Telephone Number, Including Area Code: (833) 509-4583

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 1.02 Termination of a Material Definitive Agreement.

On June 12, 2020, Assembly Biosciences, Inc. (the “Company”) received notice from AbbVie Inc. (“AbbVie”) that AbbVie has decided to terminate the Company’s Research, Development, Collaboration and License Agreement (the “Collaboration Agreement”) with Allergan Pharmaceuticals International Limited (“Allergan”) to develop and commercialize select microbiome gastrointestinal programs. AbbVie’s decision to terminate the Collaboration Agreement was a strategic portfolio decision and unrelated to any efficacy, safety, or other data related to the collaboration program. The termination of the Collaboration Agreement will be effective 120 days following the notice of termination on October 10, 2020.

Pursuant to the terms of the Collaboration Agreement, Allergan paid the Company an upfront payment of \$50.0 million in February 2017. Additionally, the Company was eligible to receive up to approximately \$631.0 million in payments related to seven development milestones and up to approximately \$2.14 billion in payments related to 12 commercial development and sales milestones in connection with the successful development and commercialization of licensed compounds for up to six different indications. The Company had agreed with Allergan to share development costs up to an aggregate of \$75.0 million through proof-of-concept (POC) studies on a 1/3, 2/3 basis, respectively, and Allergan had agreed to assume all post-POC development costs. Additionally, the Company had an option to co-promote the licensed programs in the United States and China, subject to certain conditions set forth in the Collaboration Agreement. This summary is qualified in its entirety by reference to the full text of the Collaboration Agreement, which was filed as Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q filed on May 8, 2017, and is incorporated by reference herein.

As a result of the termination of the Collaboration Agreement, the Company will regain worldwide rights to all microbiome gastrointestinal programs licensed under the Collaboration Agreement, including ABI-M201, which is currently being evaluated in a multi-center, randomized, placebo-controlled Phase 1b trial in patients with mild to moderate ulcerative colitis, and ABI-M301, which is a preclinical program for Crohn’s disease.

A copy of the press release announcing the termination of the Collaboration Agreement is filed as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

| Exhibit Number | Description |
|-----------------------|--|
| 99.1 | Press Release dated June 18, 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 thereunto duly authorized.

Assembly Biosciences, Inc.

Date: June 18, 2020

By: /s/ Jason A. Okazaki

Jason A. Okazaki

Chief Legal and Business Officer



Assembly Biosciences Regains Worldwide Rights to Microbiome Gastrointestinal Development Programs

-- Process to explore strategic alternatives underway --

SOUTH SAN FRANCISCO, Calif., June 18, 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 announced that the Company will regain worldwide rights to all microbiome gastrointestinal programs licensed under its collaboration agreement with AbbVie (formerly Allergan pre-acquisition). AbbVie has decided to terminate the research, development, collaboration and license agreement. This decision was not based on any efficacy, safety, or other data related to the collaboration programs.

“We are grateful for the opportunity to work collaboratively on the development of our microbiome gastrointestinal programs. Together, we were able to advance ABI-M201 into the clinic to evaluate this novel biotherapeutic in patients with ulcerative colitis. With the return of all rights to the program, we have now begun to explore a broader set of strategic alternatives to continue development of these programs,” said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly.

The Company will regain worldwide rights to all microbiome candidates subject to the collaboration, including ABI-M201 and ABI-M301. ABI-M201 is currently being evaluated in a multi-center, randomized, placebo-controlled Phase 1b trial in patients with mild to moderate ulcerative colitis. ABI-M301 is a preclinical program for Crohn’s disease.

The Company anticipates the transition to be completed in the fourth quarter of 2020. The agreement provides for a transition period of 120 days during which AbbVie will continue to fulfill its obligations under the contract. As Assembly explores strategic alternatives for the microbiome franchise, the Company will continue to focus on advancing the HBV portfolio, which includes three clinical-stage core inhibitors.

The Company anticipates no change to its projected cash runway and that its cash, cash equivalents and investments will continue to be sufficient to fund operations into 2022. As of March 31, 2020, Assembly had cash, cash equivalents and investments totaling \$249.1 million.

About Assembly Biosciences' Microbiome Platform

From concept to clinic, Assembly has developed an integrated live biotherapeutic product (LBP) program from discovery through manufacturing that features an in-house bacterial strain inventory, creating a broad-based platform that is capable of addressing multiple therapeutic indications. Individual bacteria and consortia are selected for development based on a platform of in silico, in vitro and in vivo capabilities. The biologic drug candidates are manufactured under scalable GMP conditions. Assembly's in-house, end-to-end capabilities also include its in-licensed patented GEMICEL® capsule-in-capsule oral delivery system designed for targeted dual release within the lower gastrointestinal tract (GI).

Assembly's lead live biotherapeutic product candidate, ABI-M201, is being evaluated in a multi-center randomized, double-blind, placebo-controlled Phase 1b trial in patients with mildly to moderately active UC. Assembly's discovery and development capabilities and manufacturing expertise also are being leveraged to advance new proprietary candidates for immuno-oncology and other disease indications.

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 development potential of our microbiome product candidates and potential strategic alternatives with respect to those candidates. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "will," "may," "potential," "explore," and "strategy." 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 timing and ability to implement strategic alternatives with respect to the microbiome program; timing, cost and results of clinical trials and other development activities involving our microbiome product candidates; the impact of the coronavirus pandemic on planned and on-going clinical trials, and results of earlier preclinical and nonclinical studies may not be predictive of future clinical studies results. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's filings with the Securities and Exchange Commission, 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 resulting from new information, future events or otherwise.

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