
**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): **April 12, 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 8.01 Other Events.

On April 12, 2018, the Company announced positive interim data for ABI-H0731, the Company's lead product candidate from its hepatitis B virus (HBV)-cure program, from the Phase 1a and 1b portion of its clinical study, which assessed the safety, tolerability and pharmacokinetics, as well as antiviral efficacy of ABI-H0731, a novel, oral Core protein Allosteric Modifier (CpAM) with selective and potent activity against all major HBV genotypes, in patients with chronic HBV infection.

The interim data, which is also being presented on a poster at The International Liver Congress™, the Annual Meeting of the European Association for the Study of the Liver (EASL), includes the interim data from the ongoing Phase 1b antiviral efficacy study and a recently completed Phase 1a safety and pharmacokinetic (PK) study of ABI-H0731. To date, two cohorts (100 mg and 200 mg) of HBV patients have completed dosing in the Phase 1b trial, in addition to three (100 mg, 200 mg and 300 mg) additional cohorts in a Phase 1a study in healthy volunteers. A third HBV patient cohort receiving 300 mg is ongoing, though only initial results are reported in the EASL poster. Two HBeAg negative patients have also been treated at 400 mg.

The Phase 1b patient study enrolled both HBeAg positive and negative patients. Potent antiviral activity was observed across patient cohorts in a dose dependent manner. Specifically, in the ongoing 300 mg dose cohort, the mean overall decline from baseline is currently $\geq 2.8 \log_{10}$ IU/mL, with ≥ 2.9 and $2.5 \log_{10}$ IU/mL mean declines in HBeAg positive and negative patients, respectively. Maximal viral load declines of 3.6 to $4.0 \log_{10}$ IU/mL were observed in certain HBeAg negative patients treated at all dose levels (100 mg to 400 mg). The Company intends to report complete results from this study at a scientific conference later in 2018.

Across all cohorts in the Phase 1a and Phase 1b studies, ABI-H0731 was generally safe and well tolerated. No serious adverse effects or dose-limiting toxicities were identified, and there was no pattern of treatment emergent clinical or laboratory abnormalities observed. Among the 62 patients and volunteers treated, all treatment emergent adverse events (TEAEs) were observed to be minor (Grade 1), with the exception of an isolated Grade 3 rash at the 400 mg dose that resolved rapidly without intervention other than treatment discontinuation. To date, no other treatment discontinuations have occurred in these studies.

The interim study results support the advancement of ABI-H0731 into Phase 2a combination studies using a 300 mg dose expected to begin this summer. The first study will enroll HBeAg positive patients on standard of care nucleos(t)ide therapy with fully suppressed viral loads. Patients will continue their nucleos(t)ide therapy and be randomized to either placebo or ABI-H0731 for six months. This study is designed to demonstrate that ABI-H0731 can inhibit the generation of cccDNA molecules by showing a decline in the surrogate markers of cccDNA. A second Phase 2a study will enroll treatment naïve HBeAg positive patients and is designed to compare the antiviral effectiveness of standard of care nucleoside therapy alone compared to standard of care in combination with ABI-H0731 for six months. The Company anticipates results from these studies during the first half of 2019.

Forward-Looking Statements

The information in this Current Report on Form 8-K contains forward-looking statements regarding future events, including statements about the clinical and therapeutic potential of ABI-H0731 and the Company's development programs, interim data's reliability to predict completed clinical study results, the initiation, progress and results of the Company's ongoing and planned clinical trials, and the timing of these events. Certain forward-looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as "plan," "intends," "designed" or "developing." The Company 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 the Company are more fully detailed under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission. Except as required by law, the Company assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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: April 12, 2018

Assembly Biosciences, Inc.

By: /s/ Derek A. Small

Derek A. Small

President and Chief Executive Officer
