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): February 26, 2021

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)**	**(IRS Employer Identification No.)**

331 Oyster Point Blvd., Fourth Floor, South San Francisco, California	**94080**
(Address of Principal Executive Offices)	**(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 8.01 Other Events.

On February 26, 2021, Assembly Biosciences, Inc. (“Assembly”) and Arbutus Biopharma Corporation (“Arbutus”) issued a joint press release announcing the initiation of a Phase 2 clinical study to evaluate Assembly’s investigational lead hepatitis B virus (“HBV”) core inhibitor candidate vebicorvir (“VBR” or “ABI-H0731”) in combination with Arbutus’ proprietary GalNAc delivered RNAi compound AB-729 and standard-of-care nucleos(t)ide reverse transcriptase inhibitor (NrtI) therapy for the treatment of patients with chronic HBV infection.

A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated February 26, 2021
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: February 26, 2021

By: /s/ Jason A. Okazaki
Jason A. Okazaki
Chief Legal and Business Officer

Exhibit 99.1

Assembly Biosciences and Arbutus Biopharma Initiate Phase 2 Clinical Trial of Triple Combination Therapy for the Treatment of Chronic Hepatitis B Virus

- *Trial will evaluate Assembly's core inhibitor candidate, vebicorvir, with Arbutus' RNAi therapeutic candidate, AB-729, and standard-of-care Nrtl therapy*

SOUTH SAN FRANCISCO, Calif., and WARMINSTER, Pa. -- Feb. 26, 2021 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB) and Arbutus Biopharma Corporation (Nasdaq: ABUS) today announced the initiation of a Phase 2 clinical trial of Assembly Bio's investigational hepatitis B virus (HBV) core inhibitor candidate, also known as a capsid inhibitor, vebicorvir (VBR), in combination with Arbutus' proprietary GalNAc delivered RNAi therapeutic candidate, AB-729, and standard-of-care nucleos(t)ide reverse transcriptase inhibitor (NrtI) therapy for the treatment of patients with chronic HBV infection. The companies announced a clinical collaboration agreement in August 2020.

The randomized, multi-center, open-label Phase 2 clinical trial will evaluate the safety, pharmacokinetics, and antiviral activity of the triple combination of VBR, AB-729 and an NrtI compared to the double combinations of VBR with an NrtI and AB-729 with an NrtI. Approximately 60 virologically-suppressed patients with HBeAg negative chronic HBV are expected to be enrolled across these three treatment arms. Patients will be dosed for 48 weeks with VBR 300 mg orally once daily and AB-729 60 mg subcutaneously every 8 weeks, with a 48-week follow-up period. The primary objective of the trial is to evaluate the safety and tolerability of the triple combination, while secondary objectives of the trial include evaluating the effect of the triple combination in reducing HBV viral biomarkers such as HBV DNA, HBV pgRNA and HBsAg. Additional cohorts may be added in the future to evaluate other patient populations and/or combinations.

“We are excited to move forward with our collaborators in this proof-of-concept Phase 2 clinical trial designed to evaluate multiple complementary mechanisms of action. Importantly, this trial supports our long-standing belief that multi-drug combinations will be needed to provide patients with chronic hepatitis B a much needed and durable functional cure,” stated Gaston Picchio, PhD, Chief Development Officer at Arbutus. “We believe reducing HBsAg will be a key component of future HBV curative therapies. AB-729, Arbutus' lead HBV asset, has demonstrated competitive HBsAg reductions and a favorable safety and tolerability profile in an ongoing Phase 1b clinical trial, and we are gratified to have it progress in this combination trial.”

"Our lead core inhibitor candidate, vebicorvir, in combination with standard-of-care NrtI therapy, demonstrates enhanced antiviral activity with a favorable safety profile fueling our belief that core inhibitors will become a central component of finite and curative therapies for patients with HBV,” said Luisa Stamm, MD, PhD, Chief Medical Officer at Assembly Bio. “We also believe that exploring multi-drug combinations with complementary mechanisms of action could increase response rates. We look forward to exploring the promise of combination therapies in our work with Arbutus.”

About Vebicorvir, Assembly's Lead HBV Core Inhibitor
Assembly Bio's HBV portfolio includes three clinical-stage small molecule candidates, all of which are

HBV core inhibitors that target multiple steps of the HBV replication cycle. In Phase 2 clinical trials, first-generation core inhibitor vebicorvir (VBR) administered with nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy demonstrated a favorable safety profile and led to greater viral suppression of both HBV DNA and HBV pgRNA than NrtI therapy alone. VBR is advancing in multiple Phase 2 combination studies.

About Arbutus' AB-729
AB-729 is an RNA interference (RNAi) therapeutic targeted to hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. AB-729 inhibits viral replication and reduces all HBV antigens, including hepatitis B surface antigen in preclinical models. Reducing hepatitis B surface antigen is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. Based upon clinical data generated thus far in an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 has demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

About HBV
Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts approximately 270 million people worldwide with up to 90 million people in China, as estimated by the World Health Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

About Assembly Biosciences
Assembly Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 270 million people living with hepatitis B virus (HBV) worldwide. A pioneer in the development of a new class of potent, oral core inhibitor drug candidates, Assembly Bio's approach aims to break the complex viral replication cycle of HBV to free patients from a lifetime of therapy. Assembly Bio's strategy toward cure includes a leading portfolio of more potent, next-generation core inhibitors, proof-of-concept combination studies and a research program focused on the discovery of novel HBV targets. For more information, visit assemblybio.com.

About Arbutus
Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company primarily dedicated to discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple drug product candidates that may be combined into a potentially curative regimen for chronic HBV infection. Arbutus has also initiated a drug discovery and development effort for treating coronaviruses (including COVID-19). For more information, visit www.arbutusbio.com.

Assembly Bio's Forward-Looking Statements
The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties

include: Assembly Bio's ability to initiate and complete clinical trials involving its HBV therapeutic product candidates, including trials contemplated by Assembly Bio's clinical collaboration agreements, in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of Assembly Bio's product candidates; clinical and nonclinical data presented at conferences may not differentiate Assembly Bio's product candidates from other companies' candidates; continued development and commercialization of Assembly Bio's HBV product candidates, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing its activity in the China territory; Assembly Bio's ability to maintain financial resources necessary to continue its clinical trials and fund business operations; any impact that the COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical studies or timing of discussions with regulatory authorities; and other risks identified from time to time in Assembly Bio's reports filed with the U.S. Securities and Exchange Commission (the SEC). You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. Assembly Bio 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. More information about Assembly Bio's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly Bio's filings with the SEC, 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 Bio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Arbutus' Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and forward-looking information within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Forward-looking statements in this press release include statements about the anticipated trial design of Assembly Bio's and Arbutus' Phase 2 clinical trial; expectations regarding the timing and number of patients enrolled in the Phase 2 clinical trial; the expected dosing of the Phase 2 clinical trial; the possibility of including additional cohorts under the collaboration agreement; the potential for multi-drug combinations to provide patients with chronic hepatitis B a much needed and durable functional cure; and expectations regarding the safety and efficacy of Arbutus' product candidates.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness and timeliness of the Phase 2 clinical trial with Assembly, and the usefulness of the data; the continued demand for Arbutus' and Assembly's assets; and the stability of economic and market conditions. While Arbutus considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies, including uncertainties and contingencies related to the ongoing COVID-19 pandemic.

Additionally, there are known and unknown risk factors which could cause Arbutus' actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: the Phase 2 clinical trial may be more costly or take longer to complete than anticipated, and may never be completed, or may not generate results that warrant future

development; changes in Arbutus' or Assembly's strategy regarding its product candidates and clinical development activities; economic and market conditions may worsen; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt our and/or Assembly's clinical development programs.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Arbutus' Quarterly Reports on Form 10-Q and Arbutus' continuous and periodic disclosure filings, which are available at www.sedar.com and at www.sec.gov. All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Arbutus disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

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