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): December 26, 2024

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.)**
Two Tower Place, 7th 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 December 26, 2024, Assembly Biosciences, Inc. (the "Company") issued a press release announcing interim results from its ongoing Phase 1b clinical study evaluating its investigational next-generation capsid assembly modulator candidate ABI-4334 in participants with chronic hepatitis B virus 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 December 26, 2024.
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: December 26, 2024

By: /s/ John O. Gunderson
John O. Gunderson
VP, General Counsel and Corporate Secretary

Exhibit 99.1

Assembly Biosciences Reports Interim Phase 1b Results from Clinical Trial Evaluating Next-Generation Capsid Assembly Modulator Candidate ABI-4334 in Chronic Hepatitis B

– ABI-4334 was well-tolerated with a favorable safety profile and half-life supporting once-daily oral dosing observed –

– In the first 150 mg dose cohort, ABI-4334 showed strong antiviral activity with a mean reduction of 2.9 log IU/mL in plasma HBV DNA over 28 days of treatment –

– Enrollment in final cohort of 400 mg ongoing with data anticipated in 1H 2025–

SOUTH SAN FRANCISCO, Calif., December 26, 2024 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced encouraging interim safety, pharmacokinetic (PK) and efficacy results from participants with chronic hepatitis B virus (HBV) infection in its ongoing Phase 1b study evaluating ABI-4334, an investigational next-generation capsid assembly modulator (CAM).

Improvements in trial-defined measures of antiviral activity were observed in the first Phase 1b cohort that received an oral, once-daily dose of 150 mg of ABI-4334 over a 28-day treatment period. A mean decline in HBV DNA of 2.9 $\log_{10}$ IU/mL was observed in a population of predominately hepatitis B e antigen (HBeAg) negative participants. Among the subset of participants with detectable HBV RNA at baseline, a mean decline of 2.5 $\log_{10}$ U/mL for HBV RNA was observed. As anticipated, limited changes in viral antigens were observed for the study population over the 28-day treatment period. These initial antiviral data are consistent with the high potency seen preclinically for ABI-4334.

In this initial 150 mg cohort, ABI-4334 continued to show a half-life supportive of once-daily oral dosing and maintained clinical exposures multiple-folds above those anticipated to be required for potent antiviral activity and inhibition of cccDNA formation. Safety data for study participants in both cohorts to date demonstrated that ABI-4334 was well-tolerated with a favorable safety profile observed.

“We are pleased to see strong antiviral activity in this first Phase 1b cohort for ABI-4334, our most potent CAM,” said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. “While this is an early read, these interim data reinforce the potential of ABI-4334 to achieve our target clinical profile. The goal of this Phase 1b study is to provide an initial efficacy and safety profile for ABI-4334 in the chronic HBV population and, when completed, the trial will support our evaluation of next steps for the program in tandem with our partner Gilead’s evaluation of their option.”

Enrollment is ongoing for the second cohort, evaluating an oral once-daily dose of ABI-4334 of 400 mg. Based on antiviral activity observed in the first cohort, Assembly Bio expects that the 400 mg cohort will be the final cohort for this Phase 1b study and anticipates releasing data from this cohort in the first half of 2025. Under the collaboration agreement between

Assembly Bio and Gilead Sciences, Inc. (Gilead), Gilead has the right to opt in to further development and commercialization for ABI-4334 after Assembly Bio's delivery of a data package following completion of this Phase 1b study.

ABI-4334 is an investigational product candidate that has not been approved anywhere globally, and its safety and efficacy have not been established.

Study ABI-4334-102 – Phase 1b Interim Results

Study Overview

ABI-4334-102 is a randomized, blinded, placebo-controlled dose-ranging Phase 1b clinical study evaluating the safety, PK and antiviral activity of ABI-4334. The study is being conducted in treatment-naive or off-treatment participants, with HBeAg positive or negative chronic HBV infection. The study is anticipated to enroll two sequential cohorts of 10 subjects each, randomized 8:2 to receive ABI-4334 or placebo daily for a 28-day treatment period. Dosing is complete for the first cohort, evaluating a dose of 150 mg, and enrollment is ongoing for the second cohort, evaluating a dose of 400 mg.

Data for the first cohort evaluating a 150 mg dose are reported here. Safety data to date for the second cohort evaluating a 400 mg dose are also included. The study team remains blinded and the reported interim safety data include pooled data from both active and placebo treatment groups reported collectively.

Interim Results

In safety data to date for both cohorts, ABI-4334 was well-tolerated with a favorable safety profile observed. No safety signals have been identified and there were no serious adverse events or adverse events that led to study drug discontinuation. Two grade three lab abnormalities were observed in the 150 mg cohort, one alanine aminotransferase (ALT) elevation and one total bilirubin elevation. These elevations were observed in separate participants and both resolved with continued dosing of ABI-4334 or placebo.

No other grade three or four laboratory abnormalities were observed.

In the predominately HBeAg negative participants receiving 150 mg of ABI-4334, a mean decline in HBV DNA of 2.9 $\log_{10}$ IU/mL and a mean decline in HBV RNA of 2.5 $\log_{10}$ U/mL in the subset with detectable HBV RNA at baseline were observed over 28 days. As expected, given the patient population and 28-day treatment period, limited changes in viral antigens were observed.

In the 150 mg cohort, ABI-4334 continued to show a half-life supportive of once-daily oral dosing. In addition, based on PK data from this cohort and preclinical studies, daily minimum plasma trough concentrations (C_{min}) at the 150 mg dose achieved double-digit multiples over protein-adjusted EC_{50} for both antiviral activity and cccDNA formation.

Additional information about the Phase 1b trial is available at clinicaltrials.gov using the identifier NCT06384131. Assembly Bio expects to submit complete data from the trial for presentation at future scientific meetings.

About Assembly Biosciences

Assembly Biosciences is a biotechnology company dedicated to the development of innovative small-molecule therapeutics designed to change the path of serious viral diseases and improve the lives of patients worldwide. Led by an accomplished team of leaders in virologic drug development, Assembly Bio is committed to improving outcomes for patients struggling with the serious, chronic impacts of herpesvirus, hepatitis B virus (HBV) and hepatitis delta virus (HDV) infections. For more information, visit assemblybio.com.

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 maintain financial resources necessary to continue its research activities, clinical studies and other business operations; Assembly Bio's ability to realize the potential benefits of its collaboration with Gilead Sciences, Inc., including all financial aspects of the collaboration and equity investments; Assembly Bio's ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's collaboration with Gilead, in the currently anticipated timeframes or at all; safety and efficacy data from clinical or nonclinical 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; results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of clinical studies; 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.

Contacts
Investor and Corporate:
Shannon Ryan
SVP, Investor Relations, Corporate Affairs and Alliance Management
(415) 738-2992
investor_relations@assemblybio.com

Media:
Sam Brown Inc.
Hannah Hurdle
(805) 338-4752
ASMBMedia@sambrown.com