

**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): July 19, 2022

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 2.05 Costs Associated with Exit or Disposal Activities.

On July 19, 2022, the Board of Directors (the “Board”) of Assembly Biosciences, Inc. (the “Company”) approved a strategic plan (the “Plan”) to: (1) discontinue development of the Company’s first-generation core inhibitor, vebicorvir (VBR), based on review of interim on-treatment efficacy data from on-going triple combination studies that do not support continuation; (2) advance its next-generation core inhibitors, ABI-H3733 (“3733”) and ABI-4334 (“4334”), in clinical studies; and (3) prioritize research activities, including a small molecule hepatitis B virus (“HBV”)/hepatitis delta virus (“HDV”) entry inhibitor, small molecule interferon- α receptor (“IFNAR”) agonist and two additional undisclosed viral targets. The Plan includes a reduction of the Company’s workforce by 30 employees, resulting in a total of approximately 70 remaining employees. Implementation of the Plan is expected to preserve capital while appropriately resourcing the advancement of 3733, 4334 and the Company’s novel research pipeline and to optimize manufacturing of all candidates.

Impacted employees will be offered customary separation benefits, including severance payments and accelerated vesting of certain restricted stock units. In addition, the Company will continue to pay premiums for continuation of healthcare coverage for a limited period. As a result of the Plan, the Company estimates that it will incur approximately \$1.6 million in costs primarily related to severance costs and related expenses and expects the payments of these costs for all impacted employees other than two executive officers will be complete in the fourth quarter of 2022. The two executive officers impacted by the Plan will receive separation benefits in accordance with their respective employment agreements. Separation payments to the two executive officers will be made in installments for a period of 12 months following their respective separation dates, which are expected to be August 1, 2022 and August 12, 2022.

The Company also expects other immaterial costs related to the discontinuation of the Company’s VBR development. The estimates of costs that the Company expects to incur, and the timing of payment of those costs, are subject to a number of assumptions and actual costs may differ. The Company may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the Plan. The organizational changes under the Plan are expected to be substantially completed during the fourth quarter of 2022.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Management Changes

In connection with the Plan, Michael P. Samar will depart his roles as the Company’s Chief Financial Officer, principal financial officer and principal accounting officer effective August 12, 2022. Jason A. Okazaki, the Company’s Chief Operating Officer, will serve the function of the Company’s principal financial officer effective upon Mr. Samar’s departure. The Company expects to appoint a principal accounting officer following Mr. Samar’s transition and will file a separate Current Report on Form 8-K announcing such appointment.

In addition, effective as of August 1, 2022, Mr. Okazaki will oversee all general and administrative functions of the Company. Due to his increased responsibilities, on July 19, 2022, the Board promoted Mr. Okazaki to President and Chief Operating Officer. The Company’s Chief Executive Officer and President, John G. McHutchison, A.O., M.D., will continue in his role as Chief Executive Officer.

Compensation Arrangements

Consistent with his employment agreement, Mr. Samar will be eligible to receive (1) continued payment, in installments, of his current base salary of \$425,000 for a period of 12 months following his separation from the Company and (2) if he properly and timely elects, continued health insurance benefits under COBRA or applicable state continuation coverage after his separation date, reimbursement for the portion of health continuation coverage premiums that the Company would have paid had Mr. Samar remained employed by the Company, with such reimbursements continuing until the earlier of (a) twelve (12) months following the month in which Mr. Samar’s separation date occurs or (b) the maximum period permitted by applicable law, provided that the Company’s obligation to provide such reimbursements will terminate if Mr. Samar becomes eligible for health insurance benefits from another employer. These severance payments will be contingent on Mr. Samar signing a customary separation and release agreement releasing the Company from any potential claims by Mr. Samar.

In connection with his promotion, the Board’s compensation committee approved an increase of Mr. Okazaki’s annual base salary from \$540,000 to \$575,000. No changes were made to Mr. Okazaki’s target bonus or the other terms of his Amended and Restated Employment Agreement effective August 1, 2021.

There are no arrangements or understandings between Mr. Okazaki and any other person pursuant to which he was selected to serve as President, Chief Operating Officer and principal financial officer. There are also no family relationships between Mr. Okazaki and any

director or executive officer of the Company, and Mr. Okazaki has no direct or indirect interest in any transaction or proposed transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Item 7.01 Regulation FD Disclosure.

On July 20, 2022 the Company issued a press release entitled “Assembly Biosciences Announces Program Reprioritization and Organizational Update” announcing the Plan. The press release is attached hereto as Exhibit 99.1 and incorporated herein solely for purposes of this Item 7.01.

The information in this Item 7.01, including Exhibit 99.1 to this Current Report on Form 8-K, shall not be deemed “filed” for purposes of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing. This Current Report on Form 8-K shall not be deemed an admission as to the materiality of any information in the Current Report that is required to be disclosed solely by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated July 20, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Cautionary Note Regarding Forward-Looking Statements

The information in this Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the Plan, such as the number of positions affected by the Plan, the estimated costs associated with the Plan and the timeframe for completion of the Plan. Such forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties include: the Company’s ability to successfully execute the Plan, the expected costs associated with the Plan may exceed the Company’s forecasts; potential adverse legal, reputational, operational and financial effects on the Company resulting from the Plan; the Company’s ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by the Company’s collaboration agreements, in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of Company’s product candidates; clinical and nonclinical data presented at conferences may not differentiate the Company’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; continued development and commercialization of ABI-H3733, if successful, in the China territory will be dependent on, and subject to, the Company’s collaboration agreement governing this activity in the China territory; the Company’s ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on Company’s business and operations, including initiation, enrollment and continuation of its clinical studies or timing of discussions with regulatory authorities; and other risks identified from time to time in the Company’s reports filed with the SEC. 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. 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. More information about the Company’s risks and uncertainties are more fully detailed under the heading “Risk Factors” in the Company’s filings with the SEC, including its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. 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 thereunto duly authorized.

Assembly Biosciences, Inc.

Date: July 20, 2022

By: /s/ Jason A. Okazaki
Jason A. Okazaki
Chief Operating Officer

Assembly Biosciences Announces Program Reprioritization and Organizational Update

- *Discontinues clinical development of vebicorvir, Assembly Bio's first-generation core inhibitor, based on interim efficacy data from ongoing combination clinical studies*
- *Advancing next-generation, significantly more potent core inhibitors, ABI-H3733 and ABI-4334, in clinical studies*
- *Prioritizes research activities including small molecule HBV/HDV entry inhibitor, small molecule interferon- α receptor agonist and two additional undisclosed viral targets*
- *Reprioritized clinical programs and organizational restructuring extends cash runway into the first half of 2024*

SOUTH SAN FRANCISCO, Calif., July 20, 2022 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative, investigational therapeutics targeting hepatitis B virus (HBV) and other viral diseases, today announced that it is discontinuing further development of its first-generation core inhibitor, vebicorvir (VBR), as it prioritizes clinical development of its next-generation core inhibitors, ABI-H3733 (3733) and ABI-4334 (4334), and advances its research pipeline. Assembly Bio will restructure the organization and reduce its workforce to align with these strategic goals.

VBR Program Update

Assembly Biosciences will discontinue clinical development of its first-generation investigational core inhibitor, VBR, based on review of interim on-treatment efficacy from the two ongoing VBR triple combination studies. The data indicate that the triple combinations do not show a benefit in multiple key viral parameters compared to the dual combinations without VBR in either study.

"By combining VBR with NrtI therapy, we achieved a more rapid and a deeper level of viral suppression than with NrtI alone and we have continued to see a favorable safety and tolerability profile for VBR. Unfortunately, we do not believe, based on the interim data from our current studies, that either VBR triple combination is likely to achieve a meaningful rate of functional cure for patients with chronic HBV infection," said John McHutchison, AO, MD, chief executive officer and president of Assembly Bio. "Our strategy remains data driven, and, while data from our VBR program do not support conducting additional cure-focused clinical trials with this candidate, the work has greatly informed the clinical development programs for our next-generation core inhibitors and contributed to the HBV field. Those next-generation candidates, 3733 and 4334, are significantly more potent and provide the secondary mechanism against cccDNA that we believe will be critical to finite and curative treatments for HBV."

As a result of these data, Study 203, an open-label, Phase 2 study evaluating the triple combination of VBR + nucleos(t)ide analogue reverse transcriptase inhibitors (NrtI) + interferon (PEG-IFN α) versus the dual combinations of VBR + NrtI and NrtI + PEG-IFN α , will conclude immediately. No additional clinical studies of VBR are currently planned.

Study 204, which is fully enrolled and conducted in collaboration with Arbutus Biopharma, is an open-label Phase 2 triple combination study evaluating VBR + NrtI + Arbutus' investigational RNAi (AB-729) versus VBR + NrtI and NrtI + AB-729. In consultation with Arbutus, the companies intend to continue the study and evaluate the primary endpoints of safety and tolerability of the combination regimen.

Pipeline Program Updates

Assembly Bio will now focus on advancing clinical development programs for the company's next-generation investigational core inhibitors, 3733 and 4334, which have demonstrated >35-fold and >900-fold higher potency, respectively, than VBR in inhibiting the formation of new cccDNA in preclinical studies. A randomized, multi-center, double-blind and placebo-controlled Phase 1b trial of 3733 is underway, evaluating the safety, pharmacokinetics (PK) and antiviral activity of 3733 in adults with chronic HBV (cHBV) infection. Initial data are anticipated during the second half of 2022. Additionally, during the second half of 2022, Assembly Bio intends to initiate a Phase 1a trial of 4334 to evaluate safety, tolerability and PK following single ascending dose and multiple ascending dose administrations in healthy participants.

The company will also prioritize its small molecule research programs, including the oral HBV/hepatitis D virus (HDV) entry inhibitor and oral, liver-focused interferon- α receptor (IFNAR) agonist programs announced earlier this year and two additional viral targets to be introduced during the third quarter of 2022. The IFNAR agonist program will be described in more detail during a research webcast on July 26. Registration for this webcast is available at <https://investor.assemblybio.com/events/event-details/ifnar-interferon-receptor-agonist-research-webcast>.

"Given the extensive experience of our team in advancing novel antivirals, we have leveraged our world class virology expertise to build upon our core inhibitor portfolio, expanding our research focus into new novel targets for HBV and other related and unrelated viruses," noted Dr. McHutchison. "We look forward to unveiling these additional programs and highlighting the expansion of our portfolio in our planned research webcasts over the coming months."

Organizational Updates

Assembly Bio will align the organization to reflect its refocused pipeline. The company workforce will be reduced by approximately 30%, to approximately 70 full-time employees, to support clinical development of 3733 and 4334 and the company's novel research pipeline, and to optimize manufacturing of all candidates.

Luisa Stamm, MD, PhD, the current Assembly Bio chief medical officer, will leave the company at the end of this month. Michele Anderson, SVP of development operations at Assembly Bio, has been appointed as chief development officer effective August 1, 2022, and will assume responsibility for the company's development organization.

Additionally, Michael Samar, currently the chief financial officer, will leave the organization effective August 12, 2022.

Jason Okazaki, Assembly Bio's current chief operating officer, will oversee all general and administrative functions, including finance. Due to these increased departmental responsibilities, Mr. Okazaki has been appointed as president and chief operating officer effective August 1, 2022. John McHutchison, AO, MD, will continue as chief executive officer at Assembly Bio.

The reprioritization and restructuring activities are expected to extend Assembly Bio's estimated cash runway into the first half of 2024 after incurring a one-time charge for severance and other reorganization costs.

Dr. McHutchison concluded, "I want to personally thank my colleagues who have supported Assembly Bio's progress to this point, particularly those responsible for advancing VBR into Phase 2 studies and who are impacted by today's announcement. The decision to realign our resources and restructure our organization is a difficult one, but refocusing our organization is essential to delivering on Assembly Bio's mission of advancing next-generation compounds for patients suffering from HBV, HDV and other viruses."

About Assembly Biosciences

Assembly Bio is a clinical-stage biotechnology company pioneering the development of therapeutics for viral diseases, including pursuing finite and potentially curative therapies for the 296 million people living with hepatitis B virus (HBV) worldwide. Assembly Bio is advancing a leading portfolio of more potent, next-generation core inhibitor drug candidates that aim to break the complex viral replication cycle of HBV and research programs focused on the discovery of additional novel antiviral mechanisms for HBV and other viral diseases. 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 successfully execute its reprioritization and restructuring activities; potential adverse legal, reputational, operational and financial effects on Assembly Bio resulting from the reprioritization and restructuring activities; Assembly Bio's ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's 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; 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; continued development and commercialization of ABI-H3733, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing this activity in the China territory; Assembly Bio's ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation, enrollment 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.

Contacts

Investor and Corporate:

Shannon Ryan

SVP, Investor Relations, Corporate Affairs and Alliance Management

(415) 738-2992

sryan@assemblybio.com

Media:

Sam Brown Inc.

Hannah Hurdle

(805) 338-4752

ASMBMedia@sambrown.com