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): May 22, 2026

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 7.01 Regulation FD Disclosure.

On May 22, 2026, Assembly Biosciences, Inc. (the "Company") issued a press release announcing its plans to expand the clinical development of ABI-6250 ("6250"), its oral entry inhibitor candidate for chronic hepatitis delta virus ("HDV") infection, into primary biliary cholangitis ("PBC") and primary sclerosing cholangitis ("PSC"), broadening the program into cholestatic liver diseases. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of Section 18, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

The Company has plans to expand the clinical development of 6250, its oral entry inhibitor candidate for chronic HDV infection, into PBC and PSC, broadening the program into cholestatic liver diseases.

6250 is currently being evaluated for chronic HDV infection and has completed a Phase 1a clinical trial in healthy participants. It is an investigational oral small-molecule inhibitor of the sodium taurocholate co-transporting polypeptide ("NTCP"), a membrane protein selectively expressed on hepatocytes that facilitates bile acid transport into cells and also serves as the entry receptor for HDV infection. By inhibiting NTCP, 6250 blocks the uptake of bile acids into liver cells, a mechanism directly relevant to cholestatic liver diseases, where bile acid accumulation drives liver inflammation and liver injury.

The Company believes the expansion of 6250 into PBC and PSC is supported by preclinical data, the compound’s pharmacologic profile, and clinical findings from the Phase 1a study. These data demonstrated target engagement, including dose-dependent elevations in plasma total bile acids, consistent with NTCP inhibition. In addition, chronic toxicology studies have been completed and support the potential for longer-term dosing in planned Phase 2 trials. The Company plans to initiate a Phase 2 clinical study of 6250 in HDV in the fourth quarter of 2026. In addition, a Phase 2 basket study in cholestatic liver diseases, focused on PBC and PSC, is expected to begin in the first quarter of 2027, subject to regulatory feedback.

The Company recently conducted a pre-IND meeting with the U.S. Food and Drug Administration to discuss the planned development of 6250 in cholestatic liver diseases. While official meeting minutes are pending, the Company believes the discussion was constructive and provided helpful guidance to support advancement of the program.

PBC and PSC are chronic, autoimmune cholestatic liver diseases characterized by impaired bile flow, accumulation of bile acids in the liver and progressive liver damage. Clinical symptoms for both PBC and PSC include itch and fatigue, with development of fibrosis and cirrhosis as the diseases progress. There are multiple therapies available for the treatment of PBC; however, a significant percentage of individuals have an inadequate response to these treatments, and there remains an unmet medical need for improved treatment of PBC. There is a significant unmet medical need for the management of PSC as there are currently no approved therapies.

6250 is an investigational product candidate that has not been approved anywhere globally, and its safety and efficacy have not been established.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated May 22, 2026.
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: May 22, 2026

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

Exhibit 99.1

Assembly Biosciences Announces Expansion of ABI-6250 Clinical Development Into Cholestatic Liver Diseases

– Phase 2 study in cholestatic liver diseases, focused on PBC and PSC, anticipated to initiate in Q1 2027 –
– Builds on completed Phase 1a study and ongoing development in HDV –

SOUTH SAN FRANCISCO, Calif. – May 22, 2026 – Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today announced plans to expand the clinical development of ABI-6250, its oral entry inhibitor candidate for chronic hepatitis delta virus (HDV) infection, into primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC), broadening the program into cholestatic liver diseases.

“We are excited to expand the ABI-6250 program into PBC and PSC, where there remains significant unmet medical need despite existing PBC therapies, and in the case of PSC, no approved treatments,” said Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio. “The NTCP receptor plays an integral role in both HDV entry and bile acid transport into liver cells, making it a compelling target across multiple liver diseases. We believe ABI-6250 has the potential to address key drivers of disease pathology in these conditions and look forward to advancing clinical evaluation in these populations.”

ABI-6250 is currently being evaluated for chronic HDV infection and has completed a Phase 1a clinical trial in healthy participants. It is an investigational oral small-molecule inhibitor of the sodium taurocholate co-transporting polypeptide (NTCP), a membrane protein selectively expressed on hepatocytes that facilitates bile acid transport into cells and also serves as the entry receptor for HDV infection. By inhibiting NTCP, ABI-6250 blocks the uptake of bile acids into liver cells, a mechanism directly relevant to cholestatic liver diseases, where bile acid accumulation drives liver inflammation and liver injury.

“Treatment options for cholestatic liver diseases have expanded in recent years, but important gaps remain, particularly for patients with PSC for whom no treatments currently are approved and for those with PBC who do not adequately respond to the current therapies,” said Christopher Bowlus, MD, Lena Valente Professor and Chief, Division of Gastroenterology and Hepatology, University of California, Davis. “Targeting NTCP represents a mechanistically distinct approach compared to currently approved therapies, given its central role in bile acid transport. An oral agent like ABI-6250 that modulates this pathway could offer a differentiated strategy to impact disease biology and patient symptoms.”

The company believes the expansion of ABI-6250 into PBC and PSC is supported by preclinical data, the compound’s pharmacologic profile, and clinical findings from the Phase 1a study. These data demonstrated target engagement, including dose-dependent elevations in plasma total bile acids, consistent with NTCP inhibition. In addition, chronic toxicology studies have

been completed and support the potential for longer-term dosing in planned Phase 2 trials. The company plans to initiate a Phase 2 clinical study of ABI-6250 in HDV in the fourth quarter of 2026. In addition, a Phase 2 basket study in cholestatic liver diseases, focused on PBC and PSC, is expected to begin in the first quarter of 2027, subject to regulatory feedback.

Assembly Bio recently conducted a pre-IND meeting with the U.S. Food and Drug Administration to discuss the planned development of ABI-6250 in cholestatic liver diseases. While official meeting minutes are pending, the company believes the discussion was constructive and provided helpful guidance to support advancement of the program.

PBC and PSC are chronic, autoimmune cholestatic liver diseases characterized by impaired bile flow, accumulation of bile acids in the liver and progressive liver damage. Clinical symptoms for both PBC and PSC include itch and fatigue, with development of fibrosis and cirrhosis as the diseases progress. There are multiple therapies available for the treatment of PBC; however, a significant percentage of individuals have an inadequate response to these treatments, and there remains an unmet medical need for improved treatment of PBC. There is a significant unmet medical need for the management of PSC as there are currently no approved therapies.

ABI-6250 is an investigational product candidate that has not been approved anywhere globally, and its safety and efficacy have not been established.

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 and liver diseases and improve the lives of patients worldwide. Led by an accomplished team of leaders in antiviral and liver disease drug development, Assembly Bio is committed to improving outcomes for patients struggling with the serious, chronic impacts of herpesvirus, hepatitis delta virus (HDV) infections, cholestatic liver diseases and hepatitis B virus (HBV). 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 realize the potential benefits of its collaboration with Gilead Sciences, Inc. (Gilead), 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 may not differentiate Assembly Bio’s product candidates from other companies’ candidates; Assembly Bio’s ability to maintain financial resources necessary to continue its research activities, clinical studies and other business operations; potential effects of changes in government regulation;

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.

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