Assembly Biosciences Reports Third Quarter 2026 Financial Results and Recent Updates

November 12, 2026

– Initiated Phase 2 clinical study of ABI-6250 in patients with chronic hepatitis delta virus infection –

– Exercised 40% U.S. Profit-Share option for the HSV helicase primase inhibitor program –

– Received first $75 million collaboration extension fee from Gilead; cash runway projected into 2029 –

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2026 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral and liver diseases, today reported financial results for the third quarter ended September 30, 2026, and recent business updates.

“This quarter, we rapidly advanced our liver disease program by initiating the Phase 2 study of ABI-6250 in chronic hepatitis delta virus and preparing for our Phase 2 study in cholestatic liver diseases, which we expect to begin in the first quarter next year,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “Alongside that progress, we elected to share U.S. costs and profits for the HSV helicase primase inhibitor program under our collaboration with Gilead, a decision we believe represents a significant opportunity to build long-term value. With a strong financial position, we look forward to the continued expansion of our pipeline and advancement of the herpesvirus and liver disease programs through their respective Phase 2 studies.”

Third Quarter 2026 and Recent Updates

- **Recurrent genital herpes**
  - Exercised the company’s option to participate in a 40% share of U.S. development costs and profits for the herpes simplex virus (HSV) helicase primase inhibitor (HPI) program under its collaboration with Gilead Sciences, Inc. (Gilead)
  - Final Phase 1b data for GS-1179 was presented at IDWeek 2026, supporting the continued development as a long-acting suppressive therapy for recurrent genital herpes
- **Liver disease programs**
  - Initiated dosing in a Phase 2 study evaluating ABI-6250 in participants with chronic hepatitis delta (HDV) infection
  - Received a Study May Proceed letter from the U.S. Food and Drug Administration (FDA) for the planned Phase 2 study of ABI-6250 in primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC) following the company’s pre-IND meeting regarding the development of 6250 in cholestatic liver diseases (CLD)
  - Initiated a Phase 1 hepatic impairment study to support potential future labeling for ABI-6250
  - Presented two posters featuring additional Phase 1a safety, tolerability, pharmacokinetic and target-engagement data for ABI-6250 at The Liver Meeting 2026, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). The pharmacodynamic analysis was recognized as a Poster of Distinction.
- **Research programs**
  - Nominated a new development candidate, ABI-8914, targeting the respiratory virus space, which is advancing into regulatory filing-enabling studies
- **Collaboration**
  - Received the first $75 million collaboration extension fee from Gilead following the third anniversary of the companies’ collaboration resulting in the cancellation of all outstanding Class B warrants issued in August 2025

Anticipated Milestones and Events

- Initiation by Gilead of a Phase 2 clinical study evaluating GS-1179 in participants with recurrent genital herpes by the end of 2026
- Initiation of a Phase 2 clinical study evaluating ABI-6250 in participants with cholestatic liver diseases, including PBC and PSC, in the first quarter of 2027

Third Quarter 2026 Financial Results

- **Cash, cash equivalents and marketable securities** were $314.3 million as of September 30, 2026, compared to $320.4 million as of June 30, 2026. The company's cash position, together with the $75 million collaboration extension fee received from Gilead in November 2026 following the third anniversary of the collaboration agreement, is projected to fund operations into 2029.
- **Revenue** from collaborative research with Gilead was $3.0 million for the three months ended September 30, 2026, compared to $10.8 million for the same period in 2025. The decrease was primarily due to an $11.3 million reduction in the transaction price of our HPI license, reflecting research and development costs under the Profit-Share that we estimate are probable of being reimbursed to Gilead, partially offset by an increase in research and development activities we performed under the Gilead Collaboration Agreement.
- **Research and development expenses** were $20.2 million for the three months ended September 30, 2026, compared to $16.6 million for the same period in 2025. The increase was primarily driven by higher external program expenses, reflecting the start-up of multiple clinical studies for ABI-6250 and increased research and discovery activities, as well as higher employee-related expenses. These increases were partially offset by lower external program expenses for GS-1179 and GS-5366 following completion of their Phase 1 clinical studies. Gilead now leads further development of the HSV HPI program, with Assembly Bio responsible for 40% of U.S. development costs.
- **General and administrative expenses** were $6.1 million for the three months ended September 30, 2026, compared to $5.1 million for the same period in 2025, primarily driven by higher stock-based compensation expense and increased commercial planning and market research expenses.
- **Net loss attributable to common stockholders** was $20.3 million, or $0.93 per basic and diluted share, for the three months ended September 30, 2026, compared to $9.2 million, or $0.72 per basic and diluted share, for the same period in 2025.

About GS-1179
GS-1179, formerly ABI-1179, is an investigational helicase-primase inhibitor being developed for HSV infections. It was advanced through early clinical stage development under Assembly Bio's collaboration with Gilead. HSV helicase-primase inhibitors target an enzyme complex essential for viral replication and represent a mechanism distinct from currently available nucleoside analog therapies. GS-1179 was selected for advancement by Gilead in the HSV HPI program based on encouraging Phase 1b results and its potential to support once-weekly oral dosing.

About ABI-6250
ABI-6250 is an investigational first-in-class oral small-molecule inhibitor of the sodium taurocholate cotransporting polypeptide (NTCP), a membrane protein selectively expressed on hepatocytes that facilitates bile acid transport into hepatocytes and also serves as the receptor for hepatitis B virus (HBV) and hepatitis delta virus (HDV) to enter hepatocytes. Assembly Bio is developing ABI-6250 for the treatment of chronic HDV infection, where inhibition of NTCP blocks viral entry and represents a clinically validated therapeutic mechanism. ABI-6250 is also being evaluated in cholestatic liver diseases, such as primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC), where bile acid accumulation in the liver drives liver inflammation and liver injury.

About the Assembly Bio-Gilead Collaboration
In October 2023, Assembly Bio and Gilead entered into a 12-year collaboration to advance the research and development of novel antiviral therapies. Under the collaboration, Gilead has an option to obtain exclusive rights to each of Assembly Bio's current and future programs, and Assembly Bio is eligible to receive collaboration extension fees, option fees, milestone payments and royalties. Following Gilead's exercise of an option, Assembly Bio has the right to elect to share costs and profits in the U.S., as well as certain co-promotion rights for future programs.

To date, Gilead has exercised its option for Assembly Bio's helicase-primase inhibitor program for recurrent genital herpes, and

Assembly Bio has elected to participate in a 40% U.S. cost and profit share for the program.

About Assembly Biosciences
Assembly Biosciences is a biotechnology company dedicated to the development of innovative small-molecule therapeutics aimed at advancing the treatment paradigm of serious viral and liver diseases and improving the lives of patients worldwide. Led by an accomplished leadership team in antiviral and liver disease drug development, Assembly Bio is committed to improving outcomes for people living with the chronic impacts of herpesviruses, 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 initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's collaboration with Gilead, some of which will be conducted by Gilead, in the currently anticipated timeframes or at all; safety and efficacy data from clinical or nonclinical studies may not warrant further development of product candidates; clinical and nonclinical data may not differentiate product candidates from other companies' candidates; Assembly Bio's ability to realize the potential benefits of its collaboration with Gilead, including all financial aspects of the collaboration; Assembly Bio's ability to maintain financial resources and secure additional funding 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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ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	September 30, 2026	December 31, 2025
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 29,073	$ 58,450
Marketable securities	285,189	189,656
Accounts receivable from collaboration with a related party	582	974
Prepaid expenses and other current assets	6,316	5,469
Total current assets	321,160	254,549

Property and equipment, net	291	221
Operating lease right-of-use assets	2,081	2,508
Other assets	1,754	312
Total assets	**$ 325,286**	**$ 257,590**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,182	$ 1,171
Accrued research and development expenses	2,168	2,387
Other accrued expenses	5,194	7,749
Contract liability to a related party	13,742	36,904
Operating lease liabilities - short-term	635	569
Total current liabilities	24,921	48,780
Operating lease liabilities - long-term	1,572	2,059
Total liabilities	**26,493**	**50,839**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 20,368,351 and 15,855,329 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	20	16
Additional paid-in capital	1,165,001	1,038,823
Accumulated other comprehensive loss	(989)	(41)
Accumulated deficit	(865,239)	(832,047)
Total stockholders' equity	298,793	206,751
Total liabilities and stockholders' equity	**$ 325,286**	**$ 257,590**

ASSEMBLY BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands except for share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Collaboration revenue from a related party	$ 2,956	$ 10,789	$ 24,543	$ 29,834
Operating expenses				
Research and development	20,234	16,587	50,051	47,563
General and administrative	6,137	5,085	15,621	14,188
Total operating expenses	26,371	21,672	65,672	61,751
Loss from operations	**(23,415)**	**(10,883)**	**(41,129)**	**(31,917)**
Other income				
Interest and other income, net	3,159	1,687	7,937	3,705

Total other income	3,159	1,687	7,937	3,705
Net loss	**$ (20,256)**	**$ (9,196)**	**$ (33,192)**	**$ (28,212)**
Other comprehensive loss				
Unrealized gain (loss) on marketable securities	(366)	189	(948)	121
Comprehensive loss	**$ (20,622)**	**$ (9,007)**	**$ (34,140)**	**$ (28,091)**
Net loss per share, basic and diluted	$ (0.93)	$ (0.72)	$ (1.73)	$ (3.03)
Weighted average common shares outstanding, basic and diluted	21,780,874	12,686,122	19,196,128	9,301,740