Assembly Biosciences Reports Third Quarter 2025 Financial Results and Recent Updates

November 10, 2025

– Released positive Phase 1b interim results for long-acting helicase-primase inhibitor candidate ABI-5366 showing significant reductions in viral shedding rate and genital lesion rate in recurrent genital herpes –

– Announced Phase 1a interim results for orally bioavailable HDV entry inhibitor candidate ABI-6250 supporting progression into Phase 2 evaluation –

– Additional interim Phase 1b data readouts from HSV program anticipated to include monthly oral dosing for ABI-5366 and two cohorts of weekly oral dosing for ABI-1179, with data now expected by end of year –

– Raised $175 million gross proceeds from equity financings –

SOUTH SAN FRANCISCO, Calif., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today reported financial results and recent updates for the third quarter ended September 30, 2025.

“Our third quarter was marked by significant progress across our pipeline and important data releases, particularly the impressive interim antiviral activity and clinical outcomes data from our Phase 1b study for ABI-5366 in participants with recurrent genital herpes,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “The $175 million equity investment we completed in August enables us to advance both our HSV and HDV programs into Phase 2 while continuing our efforts to discover and develop new programs. With enrollment in our Phase 1b study for ABI-5366 and two cohorts in our Phase 1b study for ABI-1179 now complete, we look forward to sharing additional data updates from our HSV program later this year.”

Third Quarter 2025 and Recent Highlights

- **Herpes Simplex Virus (HSV)**
  - Released positive interim results from a Phase 1b study of ABI-5366, a long-acting helicase-primase inhibitor development candidate, demonstrating significant reductions in HSV type 2 (HSV-2) shedding rate, high viral load shedding and genital lesion rates in participants with recurrent genital herpes
  - Completed enrollment in the ongoing Phase 1b study of ABI-5366 in participants with recurrent genital herpes
  - Completed enrollment in two cohorts of the ongoing Phase 1b study in participants with recurrent genital herpes for ABI-1179, a second long-acting helicase-primase inhibitor development candidate
  - Presented interim Phase 1b data for ABI-5366 in a late-breaking oral presentation at the 38th Congress of the International Union Against Sexually Transmitted Infections (IUSTI)-Europe
- **Hepatitis D Virus (HDV)**
  - Released interim results from a Phase 1a study of ABI-6250, an oral HDV entry inhibitor candidate, showing a pharmacokinetic profile supporting once-daily dosing, and dose-dependent increases in a biomarker of target engagement supporting progression to Phase 2 clinical evaluation in HDV
  - Completed enrollment and follow-up period in the Phase 1a study of ABI-6250 in healthy participants
  - Presented preclinical profiling of ABI-6250 in an oral presentation at the 2025 International HBV meeting
- **Hepatitis B Virus (HBV)**
  - Presented positive data from a Phase 1b study for ABI-4334, a next-generation, highly potent HBV capsid assembly modulator candidate, in a late-breaking poster presentation at the American Association for the Study of Liver Diseases (AASLD), The Liver Meeting®

- **Financing**
    - Raised $175 million in gross proceeds from equity financing with key institutional investors, strengthening financial position to support ongoing and future clinical development

Anticipated Milestones and Events

- Mr. Okazaki and Anuj Gaggar, MD, PhD, chief medical officer, will present in a fireside chat during the Guggenheim 2nd Annual Healthcare Innovation Conference on November 12, 2025
- Interim Phase 1b data readout for the HSV program in participants with recurrent genital herpes now anticipated by end of year from two cohorts of weekly dosing of ABI-1179 and one cohort of monthly dosing of ABI-5366. These datasets are expected to be announced together once all virology analyses are completed
- Initiation of a Phase 2 clinical study of ABI-5366 anticipated in mid-2026

ABI-1179 was contributed by Gilead Sciences, Inc. (Gilead) under the collaboration between Assembly Bio and Gilead. ABI-5366, ABI-1179, ABI-6250 and ABI-4334 are investigational product candidates that have not been approved anywhere globally, and their safety and efficacy have not been established.

Third Quarter 2025 Financial Results

- **Cash, cash equivalents and marketable securities** were $232.6 million as of September 30, 2025, compared to $75.0 million as of June 30, 2025. Assembly Bio's cash position is projected to fund operations into late 2027. This cash runway guidance does not include potential future payments to Assembly Bio under the collaboration with Gilead or from potential warrant exercises, which would further extend cash runway beyond 2028.
- **Revenue** from collaborative research with Gilead was $10.8 million for the three months ended September 30, 2025, compared to $6.8 million in the same period in 2024. The change reflects the increase in research and development incurred under the collaboration as well as an increase in collaboration funding.
- **Research and development expenses** were $16.6 million for the three months ended September 30, 2025, compared to $13.5 million for the same period in 2024. The increase is largely driven by an increase in spending on the Company's HSV program, as both ABI-1179 and ABI-5366 saw significant enrollment in their respective Phase 1b clinical studies during the current quarter.
- **General and administrative expenses** were $5.1 million for the three months ended September 30, 2025, compared to $4.3 million for the same period in 2024. The increase was primarily due to higher professional fees and increased stock-based compensation related to performance-based awards.
- **Net loss attributable to common stockholders** was $9.2 million, or $0.72 per basic and diluted share, for the three months ended September 30, 2025, compared to $9.6 million, or $1.51 per basic and diluted share, for the same period in 2024.

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 realize the potential benefits of its collaboration with 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 and secure additional funding necessary to continue its research activities, clinical studies, and other business operations; the U.S. federal government shutdown and potential effects of changes in government regulation, including as a result

of the change in U.S. administration in 2025; 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:

Investors:
Patrick Till
Meru Advisors
(484) 788-8560
investor_relations@assemblybio.com

Media:
Sam Brown LLC
Alyssa Kuciunas
(331) 481-3751
ASMBMedia@sambrown.com

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	September 30, 2025	December 31, 2024
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 22,534	$ 38,344
Marketable securities	210,023	73,735
Accounts receivable from collaboration with a related party	912	
Prepaid expenses and other current assets	3,343	3,424
Total current assets	236,812	115,503
Property and equipment, net	229	284
Operating lease right-of-use assets	2,644	3,069
Other assets	312	312
Total assets	**$ 239,997**	**$ 119,168**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,683	$ 585
Accrued research and development expenses	3,058	2,273
Other accrued expenses	5,728	6,862
Deferred revenue from a related party - short-term	42,363	37,622
Operating lease liabilities - short-term	548	461
Total current liabilities	53,380	47,803

Deferred revenue from a related party - long-term	1,715	35,378
Operating lease liabilities - long-term	2,207	2,628
Total liabilities	**57,302**	**85,809**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of September 30, 2025 and December 31, 2024; 15,816,987 and 7,457,240 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	16	7
Additional paid-in capital	1,036,906	859,488
Accumulated other comprehensive loss	(90)	(211)
Accumulated deficit	(854,137)	(825,925)
Total stockholders' equity	182,695	33,359
Total liabilities and stockholders' equity	**$ 239,997**	**$ 119,168**

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,	
	2025	**2024**	**2025**	**2024**
Collaboration revenue from a related party	$ 10,789	$ 6,845	$ 29,834	$ 21,163
Operating expenses				
Research and development	16,587	13,515	47,563	41,653
General and administrative	5,085	4,286	14,188	13,398
Total operating expenses	21,672	17,801	61,751	55,051
Loss from operations	**(10,883)**	**(10,956)**	**(31,917)**	**(33,888)**
Other income				
Interest and other income, net	1,687	1,343	3,705	4,452
Total other income	1,687	1,343	3,705	4,452
Loss before income taxes	**(9,196)**	**(9,613)**	**(28,212)**	**(29,436)**
Income tax expense	—	—	—	406
Net loss	**$ (9,196)**	**$ (9,613)**	**$ (28,212)**	**$ (29,842)**
Other comprehensive loss				
Unrealized gain (loss) on marketable securities	189	137	121	(75)
Comprehensive loss	**$ (9,007)**	**$ (9,476)**	**$ (28,091)**	**$ (29,917)**
Net loss per share, basic and diluted	$ (0.72)	$ (1.51)	$ (3.03)	$ (5.12)

Weighted average common shares outstanding, basic and diluted	12,686,122	6,351,431	9,301,740	5,827,750