Assembly Biosciences Reports Second Quarter 2025 Financial Results and Recent Updates

August 6, 2025

– On track for proof-of-concept Phase 1b data no later than this fall in participants with recurrent genital herpes for long-acting herpes simplex virus (HSV) helicase-primase inhibitor candidates, ABI-5366 and ABI-1179 –

– Positive topline data reported for Phase 1b study of ABI-4334, a next-generation highly potent capsid assembly modulator candidate, in participants with chronic hepatitis B virus (HBV) –

– Interim data, including a biomarker for target engagement, reported from Phase 1a study in healthy volunteers of ABI-6250, an orally bioavailable, small molecule viral entry inhibitor candidate in development for chronic hepatitis delta virus (HDV) –

SOUTH SAN FRANCISCO, Calif., Aug. 06, 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 second quarter ended June 30, 2025.

“We are advancing toward our goal of generating impactful clinical datasets for four development candidates in 2025,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “We have delivered two important datasets already this year from our hepatitis programs, including positive topline data from our Phase 1b study of our most potent capsid assembly modulator, ABI-4334, in participants with chronic HBV, as well as interim data from a Phase 1a study of ABI-6250, including biomarker data supporting target engagement. Looking ahead, we remain on track to report key proof-of-concept Phase 1b data, including antiviral activity, no later than fall for ABI-5366 and ABI-1179 in participants with recurrent genital herpes, a chronic viral infection that significantly impacts the lives of millions of individuals.”

Second Quarter 2025 and Recent Highlights

- Initiated dosing in the Phase 1b portion of the ongoing Phase 1a/b trial for ABI-1179 and received clearance for an Investigational New Drug application to support expansion of this study to sites in the United States
- Released positive topline Phase 1b results for ABI-4334 that met Assembly Bio’s target clinical profile for the study, including strong antiviral activity in participants with chronic HBV infection
- Shared interim data from a Phase 1a study of ABI-6250 in healthy volunteers, including pharmacokinetics (PK) supportive of a once-daily oral dosing profile and biomarker data indicating engagement of its target, sodium taurocholate cotransporting polypeptide (NTCP), the receptor used by HDV to infect hepatocytes
- Presented four posters, including one late-breaker, highlighting Phase 1a clinical data for ABI-5366 and ABI-1179, preclinical data for ABI-5366, and claims data estimating U.S. genital herpes prevalence and treatment patterns at the STI & HIV 2025 World Congress, July 26-30, 2025
- Presented one oral and one poster presentation describing the Phase 1a clinical and preclinical profiles for ABI-5366 and ABI-1179 at the 49th Annual International Herpesvirus Workshop, July 26-30, 2025

Anticipated Milestones and Events

- **ABI-5366 and ABI-1179:** No later than fall 2025, interim efficacy, safety and PK data from Phase 1b studies for ABI-5366 and ABI-1179
    - Assembly Bio is running both studies concurrently and plans to evaluate weekly (and, for ABI-5366, monthly) oral dosing in participants with recurrent genital herpes over a 28-day dosing period
- **ABI-6250:** Abstract describing preclinical profiling of ABI-6250 accepted for oral presentation at the International HBV Meeting, September 8-12, 2025

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.

Second Quarter 2025 Financial Results

- **Cash, cash equivalents and marketable securities** were $75.0 million as of June 30, 2025, compared to $91.0 million as of March 31, 2025. Assembly Bio's cash position is projected to fund operations into mid-2026.

- **Revenue** from collaborative research with Gilead was $9.6 million for the three months ended June 30, 2025, compared to $8.5 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 from amending the agreement in December 2024.

- **Research and development expenses** were $16.1 million for the three months ended June 30, 2025, compared to $16.3 million for the same period in 2024. The decrease is most largely due to a decrease in spending on ABI-6250, which we had incurred significant preclinical and start-up activities for the Phase 1a study in 2024.

- **General and administrative expenses** were $4.6 million for the three months ended June 30, 2025, compared to $4.5 million for the same period in 2024, remaining essentially flat.

- **Net loss attributable to common stockholders** was $10.2 million, or $1.33 per basic and diluted share, for the three months ended June 30, 2025, compared to $11.2 million, or $1.98 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 maintain financial resources and secure additional funding necessary to continue its research activities, clinical studies, other business operations and continue as a going concern; 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; 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.

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

	June 30, 2025	December 31, 2024
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 24,006	$ 38,344
Marketable securities	50,974	73,735
Prepaid expenses and other current assets	2,487	3,424
Total current assets	77,467	115,503
Property and equipment, net	219	284
Operating lease right-of-use assets	2,782	3,069
Other assets	312	312
Total assets	**$ 80,780**	**$ 119,168**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 743	$ 585
Accrued research and development expenses	1,691	2,273
Other accrued expenses	3,407	6,862
Deferred revenue from a related party - short-term	40,917	37,622
Operating lease liabilities - short-term	533	461
Total current liabilities	47,291	47,803
Deferred revenue from a related party - long-term	13,038	35,378
Operating lease liabilities - long-term	2,351	2,628
Total liabilities	**62,680**	**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, $0.001 par value; 150,000,000 shares authorized as of June 30, 2025 and December 31, 2024; 7,672,249 and 7,457,240 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	8	7
Additional paid-in capital	863,312	859,488
Accumulated other comprehensive loss	(279)	(211)
Accumulated deficit	(844,941)	(825,925)
Total stockholders' equity	18,100	33,359
Total liabilities and stockholders' equity	**$ 80,780**	**$ 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Collaboration revenue from a related party	$ 9,626	$ 8,533	$ 19,045	$ 14,318
Operating expenses				
Research and development	16,125	16,259	30,976	28,138
General and administrative	4,594	4,477	9,103	9,112
Total operating expenses	20,719	20,736	40,079	37,250
Loss from operations	**(11,093)**	**(12,203)**	**(21,034)**	**(22,932)**
Other income				
Interest and other income, net	895	1,457	2,018	3,109
Total other income	895	1,457	2,018	3,109
Loss before income taxes	**(10,198)**	**(10,746)**	**(19,016)**	**(19,823)**
Income tax expense	—	406	—	406
Net loss	**$ (10,198)**	**$ (11,152)**	**$ (19,016)**	**$ (20,229)**
Other comprehensive loss				
Unrealized loss on marketable securities	26	54	68	212
Comprehensive loss	**$ (10,224)**	**$ (11,206)**	**$ (19,084)**	**$ (20,441)**
Net loss per share, basic and diluted	$ (1.33)	$ (1.98)	$ (2.51)	$ (3.64)
Weighted average common shares outstanding, basic and diluted	7,655,854	5,642,752	7,581,501	5,563,033