Assembly Biosciences Reports First Quarter 2025 Financial Results and Recent Updates

May 8, 2025

– Ongoing clinical studies for four candidates on track with data expected in 2025, including interim Phase 1b data for long-acting helicase-primase inhibitors ABI-5366 and ABI-1179 anticipated in fall 2025 –

– New data from multiple programs highlighted at ICAR, ESCMID and EASL 2025 –

SOUTH SAN FRANCISCO, Calif., May 08, 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 first quarter ended March 31, 2025.

“We continue the strong progress across our antiviral portfolio and remain on track for the multiple key clinical data sets we plan to deliver in 2025,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “This includes proof-of-concept Phase 1b data we expect in the fall for ABI-5366 and ABI-1179 that will provide an initial look at antiviral activity for both candidates in participants with recurrent genital herpes. I’m proud of the accomplishments of our team as we focus on improving therapeutic options for those living with viral diseases where the need for treatment innovation is significant.”

First Quarter 2025 and Recent Highlights

- **ICAR 2025:** Presented three posters and one oral presentation describing the preclinical potency and pharmacokinetic (PK) profiles of ABI-5366 (poster), ABI-1179 (poster) and ABI-6250, an oral hepatitis D virus (HDV) entry inhibitor candidate (a poster and an oral presentation), at the International Conference on Antiviral Research (ICAR), March 17-21, 2025
- **ESCMID 2025:** Presented three posters highlighting new Phase 1a clinical data and preclinical data for therapeutic candidate ABI-5366 and claims data estimating U.S. genital herpes prevalence and treatment patterns at the 2025 Congress of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID), April 11-15, 2025
- **EASL 2025:** Presented two posters, including one late-breaker, highlighting new preclinical profile data for ABI-6250 (late-breaker) and results from *in vitro* studies of ABI-4334, a next-generation hepatitis B virus (HBV) capsid assembly modulator (poster), at the 2025 European Association for the Study of the Liver (EASL) Congress, May 7-10, 2025

Anticipated Milestones and Events

- **Recurrent genital herpes (ABI-5366 and ABI-1179)**
  - In fall 2025, interim efficacy, safety and PK data from Phase 1b studies for ABI-5366 and ABI-1179
  - Assembly Bio plans to run both studies concurrently and to evaluate weekly (and, for ABI-5366, monthly) oral dosing in participants with recurrent genital herpes over a 28-day dosing period
- **HDV (ABI-6250)**
  - In Q3 2025, data from a Phase 1a study in healthy participants for ABI-6250
  - Biomarker of ABI-6250 target engagement will be assessed in addition to safety and PK measures
- **HBV (ABI-4334)**
  - In the first half of 2025, efficacy, safety and PK data from the remaining 400 mg once-daily oral dosing cohort in a Phase 1b study in participants with chronic HBV infection for ABI-4334

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.

Upcoming Conferences

- Presentation by Mr. Okazaki and Anuj Gaggar, MD, PhD, chief medical officer of Assembly Bio, during the Jefferies Healthcare Conference, June 3-5, 2025
- Multiple abstracts accepted for presentation from Assembly Bio's herpes simplex virus (HSV) program at the STI & HIV World Congress, being held in Montreal, Canada, from July 26-30, 2025

First Quarter 2025 Financial Results

- **Cash, cash equivalents and marketable securities** were $91.0 million as of March 31, 2025, compared to $112.1 million as of December 31, 2024. Assembly Bio's cash position is projected to fund operations into mid-2026.

- **Revenue** from collaborative research with Gilead was $9.4 million for the three months ended March 31, 2025, compared to $5.8 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 from amending the agreement in December 2024.

- **Research and development expenses** were $14.9 million for the three months ended March 31, 2025, compared to $11.9 million for the same period in 2024. The increase is most largely due to increases in spending on ABI-6250 and ABI-5366.

- **General and administrative expenses** were $4.5 million for the three months ended March 31, 2025, compared to $4.6 million for the same period in 2024. The decrease is primarily due to a reduction in rent under Assembly Bio's amended corporate headquarters sublease.

- **Net loss attributable to common stockholders** was $8.8 million, or $1.17 per basic and diluted share, for the three months ended March 31, 2025, compared to $9.1 million, or $1.66 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 necessary to continue its research activities, clinical studies and other business operations; Assembly Bio's ability to realize the potential benefits of its collaboration with Gilead Sciences, Inc., 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)

	March 31, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 23,413	$ 38,344
Marketable securities	67,615	73,735
Prepaid expenses and other current assets	4,499	3,424
Total current assets	95,527	115,503
Property and equipment, net	251	284
Operating lease right-of-use assets	2,927	3,069
Other assets	312	312
Total assets	**$ 99,017**	**$ 119,168**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 875	$ 585
Accrued research and development expenses	2,106	2,273
Other accrued expenses	2,302	6,862
Deferred revenue from a related party - short-term	40,819	37,622
Operating lease liabilities - short-term	529	461
Total current liabilities	46,631	47,803
Deferred revenue from a related party - long-term	22,762	35,378
Operating lease liabilities - long-term	2,491	2,628
Total liabilities	**71,884**	**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 March 31, 2025 and December 31, 2024; 7,618,885 and 7,457,240 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	8	7
Additional paid-in capital	862,121	859,488
Accumulated other comprehensive loss	(253)	(211)
Accumulated deficit	(834,743)	(825,925)
Total stockholders' equity	27,133	33,359

Total liabilities and stockholders' equity	**$ 99,017**	**$ 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 March 31,	
	2025	**2024**
Collaboration revenue from a related party	$ 9,419	$ 5,785
Operating expenses		
Research and development	14,851	11,879
General and administrative	4,509	4,635
Total operating expenses	19,360	16,514
Loss from operations	**(9,941)**	**(10,729)**
Other income		
Interest and other income, net	1,123	1,652
Total other income	1,123	1,652
Net loss	**$ (8,818)**	**$ (9,077)**
Other comprehensive loss		
Unrealized loss on marketable securities	42	158
Comprehensive loss	**$ (8,860)**	**$ (9,235)**
Net loss per share, basic and diluted	$ (1.17)	$ (1.66)
Weighted average common shares outstanding, basic and diluted	7,506,321	5,483,313