Assembly Biosciences Reports Year End 2024 Financial Results and Recent Highlights

March 20, 2025

– Four development candidates in clinical studies with data anticipated this year, continuing rapid progress of antiviral pipeline –

– Interim Phase 1b proof-of-concept data, including initial efficacy measures, anticipated in fall 2025 for ABI-5366 and ABI-1179, long-acting helicase-primase inhibitor candidates for recurrent genital herpes –

SOUTH SAN FRANCISCO, Calif., March 20, 2025 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative therapeutics targeting serious viral diseases, today reported financial results for the year ended December 31, 2024, and recent highlights.

“We are well-positioned to deliver important clinical data on four of our novel antiviral candidates in 2025, including proof-of-concept efficacy data expected this fall from the Phase 1b studies of ABI-5366 and ABI-1179 for recurrent genital herpes,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “We anticipate that the rapid progress across our clinical pipeline we saw in 2024 will continue this year, reinforcing the exceptional execution of our R&D organization and our commitment to changing the treatment paradigm for individuals living with serious viral diseases.”

Fourth Quarter 2024 and Recent Highlights

- **Recurrent genital herpes**
  - Positive Phase 1a interim data released for ABI-1179
    - ABI-1179 was well-tolerated, with observed half-life and exposure supporting the potential for once-weekly oral dosing at a low dose
- **Hepatitis delta virus (HDV)**
  - Initiated dosing in the Phase 1a study for ABI-6250, an oral, small molecule entry inhibitor candidate for chronic HDV infection
- **Hepatitis B virus (HBV)**
  - Positive Phase 1b interim data released for ABI-4334, a next-generation highly potent capsid assembly modulator candidate for chronic HBV (cHBV) infection
    - ABI-4334 was well-tolerated, with an observed half-life supporting once-daily oral dosing
    - In the initial 150 mg dose cohort, a mean decline in HBV DNA of 2.9 $\log_{10}$ IU/mL was observed in a population of predominately hepatitis B e antigen (HBeAg) negative participants
- **Transplant-associated herpesviruses**
  - Advanced ABI-7423, an oral broad-spectrum non-nucleoside polymerase inhibitor candidate targeting transplant-associated herpesviruses, into IND/CTA-enabling studies
- **Partnership with Gilead Sciences, Inc. (Gilead)**
  - Received approximately $20.1 million equity investment and $10 million in accelerated funding from Gilead to advance clinical development programs

Anticipated Milestones and Events

- **Recurrent genital herpes (ABI-5366 and ABI-1179)**
  - In fall 2025, interim efficacy, safety and pharmacokinetic (PK) Phase 1b data 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 for ABI-4334 in participants with cHBV infection

ABI-1179 was contributed by Gilead under the collaboration between Assembly Bio and Gilead. ABI-5366, ABI-1179, ABI-6250, ABI-4334 and ABI-7423 are investigational product candidates that have not been approved anywhere globally, and their safety and efficacy have not been established.

Year End 2024 Financial Results

- **Cash, cash equivalents and marketable securities** were $112.1 million as of December 31, 2024, compared to $95.0 million as of September 30, 2024, and $130.2 million as of the year ended December 31, 2023. The company's cash position is projected to fund operations into mid-2026.
- **Revenues** from collaborative research were $28.5 million for the year ended December 31, 2024, compared to $7.2 million in 2023. The increase is primarily due to recognizing a full year of revenue in 2024 under the collaboration with Gilead.
- **Research and development expenses** were $55.9 million for the year ended December 31, 2024, compared to $48.9 million in 2023. The increase is attributable to having more candidates in development in 2024.
- **General and administrative expenses** were $18.0 million for the year ended December 31, 2024, compared to $22.9 million in 2023. The decrease is primarily due to decreases in legal and non-cash stock-based compensation expense.
- **Net loss attributable to common stockholders** was $40.2 million, or $6.69 per basic and diluted share, for the year ended December 31, 2024, compared to $61.2 million, or $13.38 per basic and diluted share, in 2023.

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 presented at conferences may not differentiate Assembly Bio's product candidates from other companies' candidates; 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.

CONSOLIDATED BALANCE SHEETS

(In thousands except for share amounts and par value)

	As of December 31,	
	2024	**2023**
ASSETS		
Current assets		
Cash and cash equivalents	$ 38,344	$ 19,841
Marketable securities	73,735	110,406
Accounts receivable from collaboration	—	43
Prepaid expenses and other current assets	3,424	3,497
Total current assets	115,503	133,787
Property and equipment, net	284	385
Operating lease right-of-use assets	3,069	2,339
Other assets	312	312
Total assets	**$ 119,168**	**$ 136,823**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 585	$ 461
Accrued research and development expenses	2,273	885
Other accrued expenses	6,862	5,744
Deferred revenue from a related party - short-term	37,622	30,915
Operating lease liabilities - short-term	461	1,220
Total current liabilities	47,803	39,225
Deferred revenue from a related party - long-term	35,378	55,379
Operating lease liabilities - long-term	2,628	1,122
Total liabilities	**85,809**	**95,726**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 7,457,240 and 5,482,752 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	7	5
Additional paid-in capital	859,488	826,921
Accumulated other comprehensive loss	(211)	(81)
Accumulated deficit	(825,925)	(785,748)
Total stockholders' equity	33,359	41,097
Total liabilities and stockholders' equity	**$ 119,168**	**$ 136,823**

ASSEMBLY BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands except for share and per share amounts)

	Year Ended December 31,	
	2024	2023
Collaboration revenue ($28,520 and $4,430 from a related party)	$ 28,520	$ 7,163
Operating expenses		
Research and development	55,933	48,900
General and administrative	18,007	22,909
Total operating expenses	73,940	71,809
Loss from operations	**(45,420)**	**(64,646)**
Other income		
Interest and other income, net	5,573	3,451
Total other income	5,573	3,451
Loss before income taxes	**(39,847)**	**(61,195)**
Income tax expense	330	33
Net loss	**$ (40,177)**	**$ (61,228)**
Other comprehensive loss		
Unrealized (loss) gain on marketable securities	(130)	722
Comprehensive loss	**$ (40,307)**	**$ (60,506)**
Net loss per share, basic and diluted	$ (6.69)	$ (13.38)
Weighted average common shares outstanding, basic and diluted	6,004,560	4,577,371