Assembly Biosciences Reports Second Quarter 2024 Financial Results and Recent Updates

August 8, 2024

- *Dosing initiated in healthy participants in Phase 1a/b trial for ABI-5366 targeting recurrent genital herpes, with interim Phase 1a first-in-human data expected in Q3 2024 and interim Phase 1b data in participants with recurrent genital herpes expected in first half of 2025*
- *Dosing initiated in Phase 1b trial for ABI-4334 in participants with chronic HBV infection, with interim Phase 1b data expected by end of year*
- *Two additional pipeline candidates, ABI-1179 and ABI-6250, anticipated to enter clinic by end of year*

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2024 (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, 2024.

“Entering the second half of the year, I’m incredibly proud of our team’s accomplishments on our path to delivering novel therapeutics for individuals living with serious viral diseases,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “We are rapidly progressing toward key inflection points for our clinical development programs and remain on track with the data sets we plan to deliver in 2024. Specifically, in the third quarter, we look forward to sharing interim Phase 1a data for ABI-5366 in healthy participants. The pharmacokinetic data in this study will enable us to assess ABI-5366's ability to reach the target concentrations we have established for antiviral efficacy and to support our once-weekly oral dosing profile, while also informing dose selection in the Phase 1b part of the study in participants with recurrent genital herpes.”

Second Quarter 2024 and Recent Highlights

- First participants were dosed in two clinical trials:
  - The Phase 1a portion of a Phase 1a/b clinical study of ABI-5366, a long-acting herpes simplex virus (HSV) helicase-primase inhibitor candidate; the Phase 1a portion in healthy participants and the Phase 1b portion to be conducted in participants with recurrent genital herpes
  - A Phase 1b study of ABI-4334, a next-generation, highly potent capsid assembly modulator candidate, in participants with chronic hepatitis B virus (HBV) infection
- Scientific conference presentations highlighted:
  - Preclinical data for ABI-5366 (poster presentation) and ABI-1179 (poster and oral presentation) featured at the International Herpesvirus Workshop held July 13-17, 2024. ABI-1179 is the long-acting HSV helicase-primase inhibitor candidate contributed by Gilead Sciences, Inc. (Gilead) under the collaboration between Assembly Bio and Gilead
  - Preclinical data for ABI-6250, an oral, small molecule HBV/hepatitis delta virus (HDV) entry inhibitor candidate, featured in a poster presentation at the European Association for the Study of the Liver (EASL) Congress™ 2024 held June 5-8, 2024
  - Preclinical data for ABI-6250 featured in an oral presentation at the Science of HBV Cure Meeting 2024 held July 26-27, 2024
- Strengthened balance sheet with equity investments that resulted in aggregate gross proceeds to Assembly Bio of approximately $12.6 million, supporting advancement of antiviral portfolio and extending cash runway into Q1 2026

Upcoming Anticipated Milestones

- ABI-5366 Phase 1a interim clinical data in healthy participants expected in Q3 2024 and interim Phase 1b data in participants with recurrent genital herpes expected in the first half of 2025
- ABI-4334 Phase 1b interim clinical data expected by the end of 2024
- Two additional candidates, ABI-1179 and ABI-6250, are anticipated to enter the clinic by the end of 2024

Upcoming Conferences

- Abstract highlighting preclinical data for ABI-6250 accepted for poster presentation at the International HBV Meeting taking place September 11-15, 2024, in Chicago

Second Quarter 2024 Financial Results

- **Cash, cash equivalents and marketable securities** were $109.2 million as of June 30, 2024, compared to $113.0 million as of March 31, 2024. Assembly Bio's cash position is projected to fund operations into Q1 2026.
- **Revenue** from collaborative research was $8.5 million for the three months ended June 30, 2024. There was no revenue recognized for the same period in 2023. Revenue for the three months ended June 30, 2024, consists of amounts recognized under the collaboration with Gilead.
- **Research and development expenses** were $16.3 million for the three months ended June 30, 2024, compared to $12.5 million for the same period in 2023. The increase is attributable to having more candidates in development in 2024.
- **General and administrative expenses** were $4.5 million for the three months ended June 30, 2024, compared to $5.0 million for the same period in 2023. The decrease is primarily due to a decrease in non-cash stock-based compensation expense.
- **Net loss attributable to common stockholders** was $11.2 million, or $1.98 per basic and diluted share, for the three months ended June 30, 2024, compared to $16.9 million, or $3.88 per basic and diluted share, for the same period in 2023.

The investigational products and investigational product candidates referenced here have not been approved anywhere globally, and their safety and efficacy have not been established.

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

	June 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 19,208	$ 19,841
Marketable securities	90,011	110,406
Accounts receivable from collaboration	—	43
Prepaid expenses and other current assets	3,712	3,497
Total current assets	112,931	133,787
Property and equipment, net	349	385
Operating lease right-of-use assets	1,731	2,339
Other assets	312	312
Total assets	$ **115,323**	$ **136,823**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 801	$ 461
Accrued research and development expenses	2,531	885
Other accrued expenses	3,587	5,744
Deferred revenue from a related party - short-term	33,060	30,915
Operating lease liabilities - short-term	1,295	1,220
Total current liabilities	41,274	39,225
Deferred revenue from a related party - long-term	38,916	55,379
Operating lease liabilities - long-term	451	1,122
Total liabilities	**80,641**	**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 June 30, 2024 and December 31, 2023; 6,345,561 and 5,482,752 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	6	5
Additional paid-in capital	840,946	826,921
Accumulated other comprehensive loss	(293)	(81)
Accumulated deficit	(805,977)	(785,748)
Total stockholders' equity	34,682	41,097
Total liabilities and stockholders' equity	$ **115,323**	$ **136,823**

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,	
	2024	2023	2024	2023
Collaboration revenue from a related party	$ 8,533	$ —	$ 14,318	$ —
Operating expenses				
Research and development	16,259	12,523	28,138	27,070
General and administrative	4,477	4,965	9,112	9,977
Total operating expenses	20,736	17,488	37,250	37,047
Loss from operations	**(12,203)**	**(17,488)**	**(22,932)**	**(37,047)**
Other income				
Interest and other income, net	1,457	592	3,109	1,201
Total other income	1,457	592	3,109	1,201
Loss before income taxes	**(10,746)**	**(16,896)**	**(19,823)**	**(35,846)**
Income tax expense	406	—	406	—
Net loss	$ **(11,152)**	$ **(16,896)**	$ **(20,229)**	$ **(35,846)**
Other comprehensive loss				
Unrealized (loss) gain on marketable securities	(54)	188	(212)	478
Comprehensive loss	$ **(11,206)**	$ **(16,708)**	$ **(20,441)**	$ **(35,368)**
Net loss per share, basic and diluted	$ (1.98)	$ (3.88)	$ (3.64)	$ (8.33)
Weighted average common shares outstanding, basic and diluted	5,642,752	4,355,007	5,563,033	4,303,244