Assembly Biosciences Reports Second Quarter 2023 Financial Results and Recent Updates

August 9, 2023

- *Herpesvirus candidate ABI-5366 anticipated to enter clinic in first half of 2024*
- *New data for several pipeline programs presented at IHW and EASL 2023*
- *Additional development candidate nomination expected in 2023*

SOUTH SAN FRANCISCO, Calif., Aug. 09, 2023 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative antiviral therapeutics targeting serious viral diseases, today reported financial results and recent updates for the second quarter ended June 30, 2023.

“We are excited about the advancement of 5366, our long-acting helicase-primase inhibitor targeting high-recurrence genital herpes, into GLP toxicology studies and are working quickly to begin clinical trials for this candidate in the first half of next year,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “In parallel, our research organization continues to progress towards a second development candidate nomination, which we expect later this year. We are pleased with the progress of our expanded virology pipeline, for which strong preclinical data from multiple programs were highlighted at recent scientific meetings.”

Second Quarter 2023 and Recent Updates

- Continued IND-enabling studies, including initiation of GLP toxicology studies, for development candidate ABI-5366 (5366), a long-acting helicase-primase inhibitor targeting high-recurrence genital herpes
- Scientific conferences:
  - Presented data highlighting the preclinical characterization of 5366 in one oral presentation and one poster at the 47th Annual International Herpesvirus Workshop (IHW) held July 15-19, 2023
  - Presented five posters at the International Liver Congress^{TM}, the Annual Meeting of the European Association for the Study of the Liver (EASL), held June 21-24, 2023, including preclinical data for the company’s oral, small-molecule hepatitis B virus (HBV)/hepatitis delta virus (HDV) entry inhibitor program and results from *in vitro* and clinical studies of the next-generation core inhibitors ABI-4334 (4334) and ABI-H3733 (3733)
  - Presented during the Science of HBV Cure meeting held June 2-3, 2023, on 4334

Anticipated Milestones and Events

- Nominate an additional development candidate from the expanded research portfolio in 2023
- Complete IND/CTA submission for 5366 and initiate clinical studies in the first half of 2024
- Advance an additional development candidate into clinical studies by year-end 2024

Upcoming Conferences

- Three abstracts accepted for presentation at the 2023 International HBV Meeting taking place September 19-23, 2023, in Kobe, Japan, highlighting preclinical and *in vitro* data for the company’s oral, small-molecule HBV/HDV entry inhibitor program, small-molecule, liver-focused interferon alpha receptor agonist program and next-generation core inhibitor candidate 4334

Second Quarter 2023 Financial Results

- **Cash, cash equivalents and marketable securities** were $59.8 million as of June 30, 2023, compared to $73.0 million as of March 31, 2023. Assembly Bio’s cash position is projected to fund operations through the third quarter of 2024.
- **Research and development expenses** were $12.5 million for the three months ended June 30, 2023, compared to $17.8 million for the same period in 2022. The decrease is primarily due to prior year preclinical work and start-up costs preparing for the trials for 3733 and 4334 as well as the discontinued development of vebicorvir and ABI-H2158 and decreases in employee and contractor-related expenses.
- **General and administrative expenses** were $5.0 million for the three months ended June 30, 2023, compared to $6.8 million for the same period in 2022. The decrease is primarily due to overall cost-saving initiatives.
- **Net loss attributable to common stockholders** was $16.9 million, or $0.32 per basic and diluted share, for the three months ended June 30, 2023, compared to $24.5 million, or $0.51 per basic and diluted share, for the same period in 2022.

About Assembly Biosciences
Assembly Biosciences is a biotechnology company dedicated to the development of innovative small-molecule antiviral 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 clinical studies and fund business operations; Assembly Bio's ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's collaboration agreements, in the currently anticipated timeframes; 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, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 21,623	$ 52,418
Marketable securities	38,208	39,192
Accounts receivable from collaboration	342	944
Prepaid expenses and other current assets	3,908	4,413
Total current assets	64,081	96,967
Property and equipment, net	541	743
Operating lease right-of-use (ROU) assets	1,623	3,195

Other assets	332	889
Total assets	**$ 66,577**	**$ 101,794**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 904	$ 2,493
Accrued research and development expenses	2,037	3,122
Other accrued expenses	4,188	7,317
Operating lease liabilities - short-term	1,702	3,364
Total current liabilities	8,831	16,296
Deferred revenue	2,733	2,733
Operating lease liabilities - long-term	64	101
Total liabilities	**11,628**	**19,130**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 52,450,731 and 48,894,973 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	52	49
Additional paid-in capital	815,588	807,938
Accumulated other comprehensive loss	(325)	(803)
Accumulated deficit	(760,366)	(724,560)
Total stockholders' equity	54,949	82,624
Total liabilities and stockholders' equity	**$ 66,577**	**$ 101,794**

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,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	12,523	17,792	27,070	34,997
General and administrative	4,965	6,781	9,977	12,738
Total operating expenses	17,488	24,573	37,047	47,735
Loss from operations	**(17,488)**	**(24,573)**	**(37,047)**	**(47,735)**
Other income				
Interest and other income, net	592	112	1,201	183
Total other income	592	112	1,201	183
Net loss	**$ (16,896)**	**$ (24,461)**	**$ (35,846)**	**$ (47,552)**
Other comprehensive loss				
Unrealized gain (loss) on marketable securities	188	(90)	478	(579)

Comprehensive loss	**$ (16,708)**	**$ (24,551)**	**$ (35,368)**	**$ (48,131)**
Net loss per share, basic and diluted	$ (0.32)	$ (0.51)	$ (0.69)	$ (0.99)
Weighted average common shares outstanding, basic and diluted	52,260,088	48,293,495	51,638,928	48,208,735