



Assembly Biosciences Reports First Quarter 2023 Financial Results and Recent Highlights

May 4, 2023

- *Herpesvirus candidate ABI-5366 progressing towards IND and planned to enter the clinic in the first half of 2024*
- *Additional development candidate nomination anticipated in 2023*
- *Multiple abstracts accepted for presentation at EASL 2023 in June*

SOUTH SAN FRANCISCO, Calif., May 04, 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 highlights for the first quarter ended March 31, 2023.

"Thanks to the depth and breadth of our team's virology drug development expertise, we were thrilled to nominate the first development candidate from our expanded virology pipeline, 5366, during the first quarter," said Jason Okazaki, chief executive officer and president of Assembly Bio. "With 5366 targeting high-recurrence genital herpes expected to enter the clinic in the first half of 2024 and nomination of a second pipeline candidate anticipated later this year, we look forward to advancing these new programs that are designed to address significant unmet medical needs with the potential for shorter paths to reaching key inflection points and clinical proof of concept."

"With respect to our core inhibitors, we reported promising additional clinical data for 4334 and made the strategic decision to evaluate partnering options for our core inhibitor portfolio," continued Mr. Okazaki. "We believe partnering the core inhibitors will enable opportunities for further clinical development aimed at achieving a functional cure for HBV, including through combination approaches. It also allows our teams to focus on accelerating 5366 and other compounds in our expanded virology portfolio, which offer us greater potential to have a near-term impact for patients and stockholders."

First Quarter 2023 and Recent Highlights

- Announced nomination of Assembly Bio's first herpesvirus development candidate, ABI-5366 (5366), a long-acting helicase inhibitor targeting high-recurrence genital herpes, for advancement to IND-enabling studies
- Reported data updates for two next-generation hepatitis B virus (HBV) core inhibitor candidates including Phase 1b data for ABI-H3733 (3733) in patients with chronic HBV infection and Phase 1a data of ABI-4334 (4334) in healthy subjects
- Announced the company's intention to prioritize resources on Assembly Bio's promising portfolio of antiviral programs with shorter paths to clinical proof of concept, including 5366, and evaluate partnering options for its core inhibitor portfolio prior to further clinical development of the mechanism for HBV cure

Anticipated Milestones and Events

- Nominate one additional development candidate from the expanded research portfolio in 2023
- Complete IND/CTA submission for 5366 and enter the clinic in the first half of 2024
- Advance one additional development candidate from a second program into clinical development by year end 2024

Upcoming Conferences

- Multiple abstracts accepted for presentation during the European Association for the Study of the Liver (EASL) International Liver Congress™, June 21-24, 2023, highlighting preclinical data for the company's oral, small molecule HBV/hepatitis delta virus (HDV) viral entry inhibitor program as well as results from 3733 and 4334 clinical and *in vitro* studies
- Presentation by Mr. Okazaki and William Delaney, PhD, chief scientific officer of Assembly Bio, during the Jefferies Healthcare Conference, June 7-9, 2023
- Presentation during the Science of HBV Cure meeting held June 2-3, 2023, on next-generation core inhibitors
- Submitting data on preclinical characterization of 5366 for scientific presentation during 2H 2023

First Quarter 2023 Financial Results

- **Cash, cash equivalents and marketable securities** were \$73.0 million as of March 31, 2023, compared to \$91.6 million as of December 31, 2022. Assembly Bio's cash position is projected to fund operations into the third quarter of 2024.
- **Research and development expenses** were \$14.5 million for the three months ended March 31, 2023, compared to \$17.2 million for the same period in 2022. The decrease is primarily due to the discontinued development of vebicorvir and

ABI-H2158 as well as decreases in employee and contractor-related expenses.

- **General and administrative expenses** were \$5.0 million for the three months ended March 31, 2023, compared to \$6.0 million for the same period in 2022. The decrease is primarily due to overall cost-saving initiatives.
- **Net loss attributable to common stockholders** was \$19.0 million, or \$0.37 per basic and diluted share, for the three months ended March 31, 2023, compared to \$23.1 million, or \$0.48 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)

	March 31, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 43,482	\$ 52,418
Marketable securities	29,534	39,192
Accounts receivable from collaboration	717	944

Prepaid expenses and other current assets	6,011	4,413
Total current assets	<u>79,744</u>	<u>96,967</u>
Property and equipment, net	619	743
Operating lease right-of-use (ROU) assets	2,419	3,195
Other assets	334	889
Total assets	<u>\$ 83,116</u>	<u>\$ 101,794</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,224	\$ 2,493
Accrued research and development expenses	3,046	3,122
Other accrued expenses	3,154	7,317
Operating lease liabilities - short-term	2,546	3,364
Total current liabilities	<u>9,970</u>	<u>16,296</u>
Deferred revenue	2,733	2,733
Operating lease liabilities - long-term	80	101
Total liabilities	<u>12,783</u>	<u>19,130</u>
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, 2023 and December 31, 2022; 52,015,268 and 48,894,973 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	52	49
Additional paid-in capital	814,264	807,938
Accumulated other comprehensive loss	(513)	(803)
Accumulated deficit	(743,470)	(724,560)
Total stockholders' equity	<u>70,333</u>	<u>82,624</u>
Total liabilities and stockholders' equity	<u>\$ 83,116</u>	<u>\$ 101,794</u>

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,	
	2023	2022
Operating expenses		
Research and development	\$ 14,547	\$ 17,205
General and administrative	5,012	5,957
Total operating expenses	<u>19,559</u>	<u>23,162</u>
Loss from operations	<u>(19,559)</u>	<u>(23,162)</u>
Other income		
Interest and other income, net	609	71
Total other income	<u>609</u>	<u>71</u>

Net loss	<u>\$ (18,950)</u>	<u>\$ (23,091)</u>
Other comprehensive loss		
Unrealized gain (loss) on marketable securities	<u>290</u>	<u>(489)</u>
Comprehensive loss	<u>\$ (18,660)</u>	<u>\$ (23,580)</u>
Net loss per share, basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.48)</u>
Weighted average common shares outstanding, basic and diluted	<u>51,012,450</u>	<u>48,123,930</u>