Assembly Biosciences Reports Third Quarter 2023 Financial Results and Recent Updates

November 8, 2023

- *Established partnership with Gilead Sciences to advance differentiated treatments for herpesviruses, HBV, HDV and beyond*
- *Now anticipate four development candidates from expanded pipeline in clinical development by the end of 2024*
- *Named Anuj Gaggar, MD, PhD, as chief medical officer*
- *$100 million upfront payment and investment received from Gilead in October extends projected cash runway into 2H 2025*

SOUTH SAN FRANCISCO, Calif., Nov. 08, 2023 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a biotechnology company developing innovative antiviral therapeutics targeting serious viral diseases, today reported financial results for the third quarter ended September 30, 2023, and recent corporate updates.

“The Assembly Bio team has made exceptional progress in building a portfolio of promising antiviral candidates for herpesviruses, hepatitis B and hepatitis D,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “With our new long-term partnership with Gilead, a pioneer in virology, we are excited by the opportunity to accelerate progress on our antiviral pipeline to bring next-generation therapeutics to individuals living with serious viral infections. We believe that the financial and scientific resources provided by the collaboration position us well to reach critical short- and long-term milestones and deliver value for patients and our shareholders. We are also pleased to announce the addition of Dr. Anuj Gaggar to our leadership team as chief medical officer as we look ahead to having multiple antiviral candidates in the clinic next year.”

Third Quarter 2023 and Recent Updates

- Entered a long-term partnership with Gilead Sciences to advance discovery and development of novel antiviral therapies.
  - Collaboration combines Assembly Bio’s advanced virology research capabilities with Gilead’s established development and commercialization expertise in antiviral medicines to create a synergistic partnership focused on propelling scientific innovation and delivering new treatments to patients with significant unmet need.
  - Partnership includes Gilead opt-in rights on Assembly Bio’s current and future pipeline candidates, including two contributed Gilead herpesvirus programs.
  - $100 million upfront investment by Gilead, including equity investment, plus potential for future regulatory, commercial, opt-in and collaboration extension payments, provides runway to drive portfolio growth and support advancement of company’s current and future clinical and preclinical programs.
- Strengthened the leadership team with the naming of Anuj Gaggar, MD, PhD, as chief medical officer, as announced separately today. Dr. Gaggar is an infectious disease specialist who has focused on the development of new therapies in viral diseases including chronic hepatitis B virus (HBV), hepatitis C virus and hepatitis D virus (HDV) infections.
- Nominated first development candidate for the treatment of chronic HDV infection. ABI-6250, an orally bioavailable small molecule entry inhibitor, is moving toward IND-enabling studies with the goal of beginning clinical studies by the end of 2024.
- Presented preclinical data in two oral and one poster presentation highlighting the progress of multiple HBV and HDV pipeline programs at the 2023 International HBV Meeting held September 19-23, 2023.

Anticipated Milestones

Assembly Bio anticipates having four candidates in clinical studies by the end of 2024:

- ABI-5366, a long-acting helicase-primase inhibitor targeting high-recurrence genital herpes, is expected to enter the clinic by mid-2024.
- The herpes simplex virus (HSV) helicase-primase inhibitor candidate contributed by Gilead is expected to enter the clinic by the end of 2024.
- ABI-4334, a potent next-generation capsid assembly modulator for HBV, has completed Phase 1a development and is expected to enter Phase 1b by mid-2024.
- ABI-6250, a HDV entry inhibitor, is expected to enter the clinic by the end of 2024.

Upcoming Conferences

- Preclinical and clinical data from the company’s viral hepatitis portfolio will be highlighted in two presentations at the American Association for the Study of Liver Diseases (AASLD), The Liver Meeting®, taking place November 10-14, 2023,

in Boston.

Third Quarter 2023 Financial Results

- **Cash, cash equivalents and marketable securities** were $46.2 million as of September 30, 2023, compared to $59.8 million as of June 30, 2023. With the $100 million received from Gilead in October, Assembly Bio's cash position is projected to fund operations into the second half of 2025.
- **Research and development expenses** were $10.8 million for the three months ended September 30, 2023, compared to $18.1 million for the same period in 2022. The decrease is due to completion of the clinical trials for ABI-3733 and ABI-4334, discontinued development of vebicorvir and ABI-2158, and decreases in employee and contractor-related expenses.
- **General and administrative expenses** were $4.2 million for the three months ended September 30, 2023, compared to $5.3 million for the same period in 2022. The decrease is due to overall cost-saving initiatives.
- **Net loss attributable to common stockholders** was $14.4 million, or $0.27 per basic and diluted share, for the three months ended September 30, 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 realize the potential benefits of its collaboration with Gilead, 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; the occurrence of any event, change or other circumstance that could give rise to the termination of Assembly Bio's collaboration with Gilead; 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)

	September 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 26,656	$ 52,418
Marketable securities	19,554	39,192
Accounts receivable from collaboration	—	944
Prepaid expenses and other current assets	3,462	4,413
Total current assets	49,672	96,967
Property and equipment, net	561	743
Operating lease right-of-use assets	844	3,195
Other assets	552	889
Total assets	**$ 51,629**	**$ 101,794**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 758	$ 2,493
Accrued research and development expenses	1,619	3,122
Other accrued expenses	3,886	7,317
Operating lease liabilities - short-term	869	3,364
Total current liabilities	7,132	16,296
Deferred revenue	2,733	2,733
Operating lease liabilities - long-term	50	101
Total liabilities	**9,915**	**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, $0.001 par value; 150,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 52,614,194 and 48,894,973 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	53	49
Additional paid-in capital	816,722	807,938
Accumulated other comprehensive loss	(275)	(803)
Accumulated deficit	(774,786)	(724,520)
Total stockholders' equity	41,714	82,664
Total liabilities and stockholders' equity	**$ 51,629**	**$ 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	$ 10,824	$ 18,130	$ 37,894	$ 53,127
General and administrative	4,224	5,271	14,201	18,009
Total operating expenses	15,048	23,401	52,095	71,136
Loss from operations	**(15,048)**	**(23,401)**	**(52,095)**	**(71,136)**
Other income				
Interest and other income, net	628	256	1,829	439
Total other income	628	256	1,829	439
Net loss	**$ (14,420)**	**$ (23,145)**	**$ (50,266)**	**$ (70,697)**
Other comprehensive loss				
Unrealized gain (loss) on marketable securities	50	(1)	528	(580)
Comprehensive loss	**$ (14,370)**	**$ (23,146)**	**$ (49,738)**	**$ (71,277)**
Net loss per share, basic and diluted	$ (0.27)	$ (0.48)	$ (0.97)	$ (1.46)
Weighted average common shares outstanding, basic and diluted	52,565,333	48,448,399	51,951,123	48,289,501