# Assembly Biosciences Reports First Quarter 2024 Financial Results and Recent Highlights

May 8, 2024

- *Clinical trial application clearances received for a Phase 1a/1b trial for ABI-5366 targeting recurrent genital herpes, and a Phase 1b trial for ABI-4334 in chronic HBV infection; both studies on track to initiate by mid-2024*
- *ABI-5366 interim Phase 1a first-in-human data expected in Q3 2024 and ABI-4334 interim Phase 1b data expected by end of year*

SOUTH SAN FRANCISCO, Calif., May 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 highlights for the first quarter ended March 31, 2024.

“We are pleased that we now have regulatory clearance to initiate trials evaluating our promising investigational therapies ABI-5366 and ABI-4334 and look forward to sharing interim data from these studies later this year,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “These clearances are a significant step toward our goal of reaching key clinical inflection points for multiple programs in our antiviral pipeline by year end. Our continued clinical progress reflects the strength and agility of our highly experienced team and our singular focus of improving treatment options for those living with serious viral diseases.”

**First Quarter 2024 and Recent Highlights**

- Two clinical trial applications received clearance to proceed:
  - ABI-5366, a long-acting herpes simplex virus (HSV) helicase-primase inhibitor candidate, for initiation of Phase 1a/1b clinical studies in both healthy volunteers and in individuals with recurrent genital herpes
  - ABI-4334, a next-generation, highly potent capsid assembly modulator candidate, for initiation of a Phase 1b study in individuals with chronic hepatitis B virus (HBV) infection
- An abstract highlighting preclinical data for ABI-6250, an oral, small molecule HBV/hepatitis delta virus (HDV) entry inhibitor candidate, has been accepted for poster presentation at the European Association for the Study of the Liver (EASL) Congress™ 2024, June 5-8, 2024

**Anticipated 2024 Milestones**

- ABI-5366 and ABI-4334 studies expected to initiate by mid-2024:
  - ABI-5366 Phase 1a interim clinical data expected in Q3 2024 and interim Phase 1b data expected in the first half of 2025
  - ABI-4334 Phase 1b interim clinical data expected by the end of 2024
- Two additional candidates are anticipated to enter the clinic by the end of 2024:
  - ABI-1179, a long-acting HSV helicase-primase inhibitor contributed by Gilead Sciences, Inc. (Gilead) under the collaboration between Assembly Bio and Gilead
  - ABI-6250, a small molecule orally-bioavailable HDV entry inhibitor

**First Quarter 2024 Financial Results**

- **Cash, cash equivalents and marketable securities** were $113.0 million as of March 31, 2024, compared to $130.2 million as of December 31, 2023. Assembly Bio’s cash position is projected to fund operations into the second half of 2025.
- **Revenues** from collaborative research were $5.8 million for the three months ended March 31, 2024. There was no revenue recognized for the same period in 2023. Revenue for the three months ended March 31, 2024 consists of amounts recognized under the collaboration with Gilead.
- **Research and development expenses** were $11.9 million for the three months ended March 31, 2024, compared to $14.5 million for the same period in 2023. Increased expenses related to the development of ABI-1179 and ABI-6250 were more than offset by savings from the discontinuation of ABI-H3733 and vebicorvir as well as reduced employee and contractor-related expenses.
- **General and administrative expenses** were $4.6 million for the three months ended March 31, 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 $9.1 million, or $1.66 per basic and diluted share, for the three

months ended March 31, 2024, compared to $19.0 million, or $4.46 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)

| | March 31, 2024 (Unaudited) | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 18,749 | $ 19,841 |
| Marketable securities | 94,227 | 110,406 |

| | | |
|---|---|---|
| Accounts receivable from collaboration | 43 | 43 |
| Prepaid expenses and other current assets | 4,149 | 3,497 |
| Total current assets | 117,168 | 133,787 |
| | | |
| Property and equipment, net | 367 | 385 |
| Operating lease right-of-use assets | 2,036 | 2,339 |
| Other assets | 312 | 312 |
| **Total assets** | **$ 119,883** | **$ 136,823** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 727 | $ 461 |
| Accrued research and development expenses | 2,059 | 885 |
| Other accrued expenses | 2,051 | 5,744 |
| Deferred revenue from a related party - short-term | 32,771 | 30,915 |
| Operating lease liabilities - short-term | 1,145 | 1,220 |
| Total current liabilities | 38,753 | 39,225 |
| | | |
| Deferred revenue from a related party - long-term | 47,738 | 55,379 |
| Operating lease liabilities - long-term | 791 | 1,122 |
| **Total liabilities** | **87,282** | **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, $0.001 par value; 150,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 5,482,752 shares issued and outstanding as of March 31, 2024 and December 31, 2023 | 5 | 5 |
| Additional paid-in capital | 827,660 | 826,921 |
| Accumulated other comprehensive loss | (239) | (81) |
| Accumulated deficit | (794,825) | (785,748) |
| Total stockholders' equity | 32,601 | 41,097 |
| | | |
| **Total liabilities and stockholders' equity** | **$ 119,883** | **$ 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 March 31, | |
|---|---|---|
| | **2024** | **2023** |
| **Collaboration revenue from a related party** | $ 5,785 | $ — |
| | | |
| **Operating expenses** | | |
| Research and development | 11,879 | 14,547 |
| General and administrative | 4,635 | 5,012 |

| | | |
|---|---|---|
| Total operating expenses | 16,514 | 19,559 |
| **Loss from operations** | **(10,729)** | **(19,559)** |
| | | |
| **Other income** | | |
| Interest and other income, net | 1,652 | 609 |
| Total other income | 1,652 | 609 |
| | | |
| **Net loss** | **$ (9,077)** | **$ (18,950)** |
| | | |
| **Other comprehensive loss** | | |
| Unrealized (loss) gain on marketable securities | (158) | 290 |
| | | |
| **Comprehensive loss** | **$ (9,235)** | **$ (18,660)** |
| | | |
| Net loss per share, basic and diluted | $ (1.66) | $ (4.46) |
| Weighted average common shares outstanding, basic and diluted | 5,483,313 | 4,251,037 |