# Assembly Biosciences Reports Third Quarter 2024 Financial Results and Recent Updates

November 7, 2024

- *Positive Phase 1a interim data released for ABI-5366, a long-acting HSV helicase-primase inhibitor candidate for recurrent genital herpes, supporting potential for once-weekly and once-monthly oral dosing*
- *First participants dosed in Phase 1b trial evaluating ABI-5366 in individuals with recurrent genital herpes with interim data expected in first half of 2025*
- *Phase 1b trial for ABI-4334, a next-generation highly potent capsid assembly modulator candidate, ongoing in participants with chronic HBV with interim data expected by end of year*
- *ABI-1179 and ABI-6250 candidates on track to enter clinic by end of year*

SOUTH SAN FRANCISCO, Calif., Nov. 07, 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 third quarter ended September 30, 2024.

“I’m thrilled with the continued execution against our ambitious goal of advancing four candidates targeting serious viral diseases in the clinic and releasing two interim data sets by year end,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “We recently reported positive interim Phase 1a data for ABI-5366 that exceeded our expectations and supported the initiation of dosing in participants with recurrent genital herpes for the Phase 1b portion of the study. We look forward to adding two candidates to our clinical pipeline in the fourth quarter with the initiation of Phase 1 studies for ABI-1179 and ABI-6250."

**Third Quarter 2024 and Recent Highlights**

- Positive Phase 1a interim data were released for ABI-5366 and dosing was initiated in the Phase 1b portion of the ongoing Phase 1a/b trial
  - In Phase 1a interim data, ABI-5366 was well-tolerated with a favorable safety profile observed with exposures of up to 70 days and a half-life of approximately 20 days when dosed orally
  - The Phase 1b study portion in participants with recurrent genital herpes is expected to explore both once-weekly and once-monthly oral dosing; interim data are expected in the first half of 2025
- Regulatory clearance was received for a Phase 1a/b study for ABI-1179, a long-acting herpes simplex virus (HSV) helicase-primase inhibitor contributed by Gilead Sciences, Inc. (Gilead) under the collaboration between Assembly Bio and Gilead
- Anuj Gaggar, MD, PhD, chief medical officer, and William Delaney, PhD, chief scientific officer, presented during the H.C. Wainwright 5th Annual Viral Hepatitis Virtual Conference held October 8, 2024
- Preclinical data for ABI-6250, an oral, small molecule hepatitis B virus (HBV)/hepatitis delta virus (HDV) entry inhibitor candidate, were highlighted in a poster presentation at the International HBV Meeting held September 11-15, 2024

**Upcoming Anticipated Milestones**

- ABI-5366 Phase 1b interim clinical data in participants with recurrent genital herpes expected in the first half of 2025
- ABI-4334 Phase 1b interim clinical data in participants with chronic HBV expected by the end of 2024
- ABI-1179 and ABI-6250 both on track to enter the clinic by the end of 2024

**Third Quarter 2024 Financial Results**

- **Cash, cash equivalents and marketable securities** were $95.0 million as of September 30, 2024, compared to $109.2 million as of June 30, 2024. Assembly Bio’s cash position is projected to fund operations into Q1 2026.
- **Revenue** from collaborative research was $6.8 million for the three months ended September 30, 2024. There was no revenue recognized for the same period in 2023. Revenue for the three months ended September 30, 2024 consists of amounts recognized under the collaboration with Gilead.
- **Research and development expenses** were $13.5 million for the three months ended September 30, 2024, compared to $10.8 million for the same period in 2023. The increase is attributable to having more candidates in development in 2024.
- **General and administrative expenses** remained essentially flat year over year, totaling $4.3 million for the three months ended September 30, 2024, compared to $4.2 million for the same period in 2023.
- **Net loss attributable to common stockholders** was $9.6 million, or $1.51 per basic and diluted share, for the three months ended September 30, 2024, compared to $14.4 million, or $3.29 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 maintain financial resources necessary to continue its research activities, clinical studies and other business operations; 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.

**Contacts**

**Investor and Corporate:**
Shannon Ryan
SVP, Investor Relations, Corporate Affairs and Alliance Management
(415) 738-2992
investor_relations@assemblybio.com

**Media:**
Sam Brown Inc.
Hannah Hurdle
(805) 338-4752
ASMBMedia@sambrown.com

**ASSEMBLY BIOSCIENCES, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
(In thousands except for share amounts and par value)

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| Current assets | | |

| | | |
|---|---|---|
| Cash and cash equivalents | $ 28,452 | $ 19,841 |
| Marketable securities | 66,502 | 110,406 |
| Accounts receivable from collaboration | — | 43 |
| Prepaid expenses and other current assets | 3,259 | 3,497 |
| Total current assets | 98,213 | 133,787 |
| Property and equipment, net | 316 | 385 |
| Operating lease right-of-use assets | 1,421 | 2,339 |
| Other assets | 312 | 312 |
| **Total assets** | **$ 100,262** | **$ 136,823** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 1,335 | $ 461 |
| Accrued research and development expenses | 1,586 | 885 |
| Other accrued expenses | 4,765 | 5,744 |
| Deferred revenue from a related party - short-term | 32,620 | 30,915 |
| Operating lease liabilities - short-term | 1,329 | 1,220 |
| Total current liabilities | 41,635 | 39,225 |
| Deferred revenue from a related party - long-term | 32,511 | 55,379 |
| Operating lease liabilities - long-term | 113 | 1,122 |
| **Total liabilities** | **74,259** | **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, $0.001 par value; 150,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 6,354,414 and 5,482,752 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | 6 | 5 |
| Additional paid-in capital | 841,743 | 826,921 |
| Accumulated other comprehensive loss | (156) | (81) |
| Accumulated deficit | (815,590) | (785,748) |
| Total stockholders' equity | 26,003 | 41,097 |
| **Total liabilities and stockholders' equity** | **$ 100,262** | **$ 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| **Collaboration revenue from a related party** | $ 6,845 | $ — | $ 21,163 | $ — |

| | | | | |
|---|---|---|---|---|
| **Operating expenses** | | | | |
| Research and development | 13,515 | 10,824 | 41,653 | 37,894 |
| General and administrative | 4,286 | 4,224 | 13,398 | 14,201 |
| Total operating expenses | 17,801 | 15,048 | 55,051 | 52,095 |
| **Loss from operations** | **(10,956)** | **(15,048)** | **(33,888)** | **(52,095)** |
| **Other income** | | | | |
| Interest and other income, net | 1,343 | 628 | 4,452 | 1,829 |
| Total other income | 1,343 | 628 | 4,452 | 1,829 |
| **Loss before income taxes** | **(9,613)** | **(14,420)** | **(29,436)** | **(50,266)** |
| Income tax expense | — | — | 406 | — |
| **Net loss** | **$ (9,613)** | **$ (14,420)** | **$ (29,842)** | **$ (50,266)** |
| **Other comprehensive loss** | | | | |
| Unrealized gain (loss) on marketable securities | 137 | 50 | (75) | 528 |
| **Comprehensive loss** | **$ (9,476)** | **$ (14,370)** | **$ (29,917)** | **$ (49,738)** |
| Net loss per share, basic and diluted | $ (1.51) | $ (3.29) | $ (5.12) | $ (11.61) |
| Weighted average common shares outstanding, basic and diluted | 6,351,431 | 4,380,444 | 5,827,750 | 4,329,260 |