

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 28, 2024

Assembly Biosciences, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35005
(Commission File Number)

20-8729264
(IRS Employer
Identification No.)

Two Tower Place, 7th Floor,
South San Francisco, California
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's Telephone Number, Including Area Code: (833) 509-4583

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	ASMB	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 28, 2024, Assembly Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2023. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished with this Item 2.02, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit Number	Description
99.1	Press Release dated March 28, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: March 28, 2024

Assembly Biosciences, Inc.

By: /s/ John O. Gunderson

John O. Gunderson

VP, General Counsel and Corporate Secretary

Assembly Biosciences Reports Fourth Quarter and Year End 2023 Financial Results and Recent Highlights

- *Four candidates planned to be in clinical development in 2024 with interim data from two studies anticipated by year end*
- *Clinical development timelines accelerated for ABI-5366; now anticipating interim data from Phase 1a available in 3Q2024, initiation of Phase 1b in individuals with recurrent genital herpes by end of 2024 and interim Phase 1b data available in 1H2025*
- *Gilead Sciences, Inc. partnership supports advancement and strengthening of antiviral pipeline targeting serious viral diseases*

SOUTH SAN FRANCISCO, Calif., March 28, 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 fourth quarter and year ended December 31, 2023.

“Our progress in 2023 demonstrated our capacity to drive our expanded antiviral pipeline forward and our commitment to individuals suffering from life-impacting viral diseases,” said Jason Okazaki, chief executive officer and president of Assembly Bio. “With our long-term partnership in place with Gilead and the addition of Dr. Anuj Gaggar to our management team as CMO, we are well-positioned to make critical progress clinically across multiple programs in 2024 and look forward to sharing preliminary data on 5366 and 4334 later this year.”

Fourth Quarter 2023 and Recent Highlights

- Entered a long-term partnership with Gilead to advance discovery and development of novel antiviral therapies
- Strengthened the leadership team with the naming of Anuj Gaggar, MD, PhD, as chief medical officer
- Filed a clinical trial application for ABI-5366 to support initiation of Phase 1a/1b clinical studies

Anticipated Milestones and Events**By mid-year 2024:**

- ABI-5366, a long-acting herpes simplex virus (HSV) helicase-primase inhibitor targeting recurrent genital herpes, is expected to enter a Phase 1a/1b study
- ABI-4334, a next-generation, highly potent capsid assembly modulator, is anticipated to enter a Phase 1b study in individuals with chronic hepatitis B virus infection

Q3 2024:

- Interim clinical data from the ABI-5366 Phase 1a study portion expected to be available

By the end of 2024:

- Interim clinical data from the ABI-4334 Phase 1b study expected to be available
 - The Phase 1b portion of the ABI-5366 study, in individuals with recurrent genital herpes, is anticipated to be underway
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- Two additional candidates are anticipated to enter the clinic:
 - ABI-1179, a long-acting HSV helicase-primase inhibitor contributed by Gilead under the collaboration between Assembly Bio and Gilead
 - ABI-6250, a small molecule orally-bioavailable hepatitis delta virus entry inhibitor

First half 2025:

- Interim clinical data from the Phase 1b portion of the ABI-5366 study expected to be available

Fourth Quarter 2023 and Year End Financial Results

- **Cash, cash equivalents and marketable securities** were \$130.2 million as of December 31, 2023, compared to \$46.2 million as of September 30, 2023, and \$91.6 million as of the year ended December 31, 2022. The company's cash position is projected to fund operations into the second half of 2025.
- **Revenues** from collaborative research were \$7.2 million for the year ended December 31, 2023. There was no revenue recognized for the same period in 2022. Revenue for the year ended December 31, 2023, consists of \$4.4 million recognized under the collaboration with Gilead and the remaining deferred revenue balance of \$2.7 million under the collaboration agreement with BeiGene following Assembly Bio's decision to discontinue further development of ABI-H3733 in conjunction with entering into the Gilead collaboration, following the previous prioritization of ABI-4334 over ABI-H3733.
- **Research and development expenses** were \$48.9 million for the year ended December 31, 2023, compared to \$70.0 million in 2022. The decrease is due to completion of the clinical trials for ABI-H3733 and ABI-4334, discontinued development of vecicorvir and ABI-H2158, and decreases in employee and contractor-related expenses.
- **General and administrative expenses** were \$22.9 million for the year ended December 31, 2023, compared to \$24.1 million in 2022. The decrease is due to overall cost-saving initiatives.
- **Net loss attributable to common stockholders** was \$61.2 million, or \$13.38 per basic and diluted share, for the year ended December 31, 2023, compared to \$93.1 million, or \$23.08 per basic and diluted share in 2022.

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.

Contacts

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

	As of December 31,	
	2023	2022
ASSETS		
Current assets		
Cash and cash equivalents	\$ 19,841	\$ 52,418
Marketable securities	110,406	39,192
Accounts receivable from collaboration	43	944
Prepaid expenses and other current assets	3,497	4,413
Total current assets	133,787	96,967
Property and equipment, net	385	743
Operating lease right-of-use assets	2,339	3,195
Other assets	312	889
Total assets	\$ 136,823	\$ 101,794
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 461	\$ 2,493
Accrued research and development expenses	885	3,122
Other accrued expenses	5,744	7,317
Deferred revenue - short-term (\$30,915 and \$- to a related party)	30,915	—
Operating lease liabilities - short-term	1,220	3,364
Total current liabilities	39,225	16,296
Deferred revenue - long-term (\$55,379 and \$- to a related party)	55,379	2,733
Operating lease liabilities - long-term	1,122	101
Total liabilities	95,726	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 December 31, 2023 and December 31, 2022; 5,482,752 and 4,074,552 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	5	4
Additional paid-in capital	826,921	807,983
Accumulated other comprehensive loss	(81)	(803)
Accumulated deficit	(785,748)	(724,520)
Total stockholders' equity	41,097	82,664
Total liabilities and stockholders' equity	\$ 136,823	\$ 101,794

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands except for share and per share amounts)

	Year Ended December 31,	
	2023	2022
Collaboration revenue (\$4,430 and \$- from a related party)	\$ 7,163	\$ —
Operating expenses		
Research and development	48,900	69,980
General and administrative	22,909	24,134
Total operating expenses	71,809	94,114
Loss from operations	(64,646)	(94,114)
Other income		
Interest and other income, net	3,451	1,022
Total other income	3,451	1,022
Loss before income taxes	(61,195)	(93,092)
Income tax expense	(33)	—
Net loss	\$ (61,228)	\$ (93,092)
Other comprehensive loss		
Unrealized gain (loss) on marketable securities	722	(384)
Comprehensive loss	\$ (60,506)	\$ (93,476)
Net loss per share, basic and diluted	\$ (13.38)	\$ (23.08)
Weighted average common shares outstanding, basic and diluted	4,577,371	4,034,105

