

**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): May 4, 2023

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.)

**331 Oyster Point Blvd., Fourth 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 May 4, 2023, Assembly Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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 May 4, 2023.
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.

Assembly Biosciences, Inc.

Date: May 4, 2023

By: /s/ John O. Gunderson

John O. Gunderson

VP, General Counsel and Corporate Secretary

Assembly Biosciences Reports First Quarter 2023 Financial Results and Recent Highlights

- *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 4, 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
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- 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.

Contacts

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

	March 31, 2023 <u>(Unaudited)</u>	December 31, 2022
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	79,744	96,967
Property and equipment, net	619	743
Operating lease right-of-use (ROU) assets	2,419	3,195
Other assets	334	889
Total assets	\$ 83,116	\$ 101,794
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	9,970	16,296
Deferred revenue	2,733	2,733
Operating lease liabilities - long-term	80	101
Total liabilities	12,783	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 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	70,333	82,624
Total liabilities and stockholders' equity	\$ 83,116	\$ 101,794

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

	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	19,559	23,162
Loss from operations	(19,559)	(23,162)
Other income		
Interest and other income, net	609	71
Total other income	609	71
Net loss	\$ (18,950)	\$ (23,091)
Other comprehensive loss		
Unrealized gain (loss) on marketable securities	290	(489)
Comprehensive loss	\$ (18,660)	\$ (23,580)
Net loss per share, basic and diluted	\$ (0.37)	\$ (0.48)
Weighted average common shares outstanding, basic and diluted	51,012,450	48,123,930

