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

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**FORM 8-K**

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**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 10, 2023**

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**Generation Bio Co.**

(Exact Name of Registrant as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39319**  
(Commission  
File Number)

**81-4301284**  
(IRS Employer  
Identification No.)

**301 Binney Street  
Cambridge, MA**

(Address of Principal Executive Offices)

**02142**

(Zip Code)

**Registrant's telephone number, including area code: (617) 655-7500**

**Not applicable**

(Former Name or Former Address, if Changed Since Last Report)

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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 (see General Instruction A.2. below):

- 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**  
**Common Stock, \$0.0001 par value**  
**per share**

**Trading Symbol(s)**  
**GBIO**

**Name of each exchange on which registered**  
**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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 10, 2023, Generation Bio Co. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended March 31, 2023. A copy of this press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 on Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and 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 filing by the Company, under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release Issued by Generation Bio Co. on May 10, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**SIGNATURES**

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

Date: May 10, 2023

GENERATION BIO CO.

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: President and Chief Executive Officer

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## Generation Bio Reports Business Highlights and First Quarter 2023 Financial Results

*Company entered into strategic collaboration with Moderna to use Generation Bio's proprietary non-viral genetic medicine delivery system for two liver disease programs and to co-develop novel targeting for immune cells*

*Factor VIII expression data in non-human primates for wholly-owned hemophilia A program expected in 2023*

*First quarter 2023 cash balance of \$288.6 million expected to fund operations into 2025; additional \$47.5 million from Moderna collaboration received in second quarter 2023*

**CAMBRIDGE, MASS., May 10, 2023** -- Generation Bio Co. (Nasdaq: GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, reported business highlights and first quarter 2023 financial results.

“This year, we are focused on demonstrating proof-of-concept in non-human primates for hemophilia A, our lead program, which is the first step towards building a deep pipeline of rare and prevalent liver disease programs” said Geoff McDonough, M.D., chief executive officer of Generation Bio. “We believe our partnership with Moderna will expand the development of our liver portfolio beyond hemophilia A, and that our collaboration to develop novel targeting of our stealth lipid nanoparticle to address immune cells will accelerate our ambition to reach new therapeutic areas beyond the liver.”

### **Business Highlights:**

- **Announced Strategic Collaboration with Moderna:** In March 2023, Generation Bio announced a collaboration with Moderna that is intended to leverage the company's cell-targeted lipid nanoparticles (ctLNP) and closed-ended DNA (ceDNA) technologies to create genetic medicines for the treatment of liver and non-liver diseases. Moderna acquired the option to advance two liver programs, each using a ctLNP to deliver ceDNA. In addition, the two companies have agreed to jointly develop novel targeting for Generation Bio's stealth LNP to reach immune cells. Moderna has acquired the option to advance two immune cell programs, each using the collaboration ctLNP to deliver ceDNA. Moderna retains an additional option to license a third program either for the liver or for immune cells.

Generation Bio received an upfront payment of \$83.5 million, including \$40 million in cash, \$36 million in equity, and a \$7.5 million research prepayment, and is eligible to receive up to \$1.8 billion in milestone payments. Moderna will fund all research and development activities under the collaboration.

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- **Appointed Yalonda Howze, J.D. as Chief Legal Officer:** In April 2023, the company announced the appointment of Yalonda Howze as Chief Legal Officer. Howze brings nearly two decades of experience in strategy and operations across legal, corporate governance and compliance for life science companies. She earned her J.D. from the University of Virginia School of Law, M. Div. from Harvard University School of Divinity, and B.A. from the University of Michigan.

### **First Quarter 2023 Financial Results**

- **Cash Position:** Cash, cash equivalents, and marketable securities were \$288.6 million as of March 31, 2023, not including an additional \$47.5 million received in April 2023 from the collaboration with Moderna, compared to \$279.1 million in cash, cash equivalents, and marketable securities as of December 31, 2022. The company continues to believe that its cash position will fund its operating plan into 2025.
- **R&D Expenses:** Research and development (R&D) expenses were \$22.0 million for the quarter ended March 31, 2023, compared to \$25.6 million for the quarter ended March 31, 2022.
- **G&A Expenses:** General and administrative (G&A) expenses were \$12.9 million for the quarter ended March 31, 2023, compared to \$9.8 million for the quarter ended March 31, 2022.
- **Net Loss:** Net loss was \$32.1 million, or \$0.53 basic and diluted net loss per share, for the quarter ended March 31, 2023, compared to a net loss of \$35.0 million, or \$0.61 basic and diluted net loss per share, for the quarter ended March 31, 2022.

### **About Generation Bio**

Generation Bio is innovating genetic medicines to provide durable, redosable treatments for people living with rare and prevalent diseases. The company's non-viral genetic medicine platform incorporates a novel DNA construct called closed-ended DNA, or ceDNA; a unique cell-targeted lipid nanoparticle delivery system, or ctLNP; and a highly scalable capsid-free manufacturing process that uses proprietary cell-free rapid enzymatic synthesis, or RES, to produce ceDNA. The platform is designed to enable multi-year durability from a single dose, to deliver large genetic payloads, including multiple genes, to specific tissues and cell types, and to allow titration and redosing to adjust or extend expression levels in each patient. RES has the potential to expand Generation Bio's manufacturing scale to hundreds of millions of doses to support its mission to extend the reach of genetic medicine to more people, living with more diseases, around the world.

For more information, please visit [www.generationbio.com](http://www.generationbio.com).

### **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the company, including statements about the company's strategic plans or objectives, cash resources, technology platform, research and clinical development plans, the terms of the research

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collaboration between Moderna and Generation Bio to develop novel nucleic acid therapeutics, including the potential to target immune cells with diverse nucleic acid cargos and the liver for gene replacement, the targets to be developed under the collaboration, the funding to be paid by Moderna upon reaching certain milestones, and the potential benefits and results that may be achieved through other preclinical data, and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: that the receipt of milestone and other payments under the collaboration with Moderna, and the other anticipated benefits of the collaboration with Moderna, may not be achieved on the anticipated timeline, or at all; that data may not support further development of the therapies subject to the collaboration with Moderna due to safety, efficacy, or other reasons; uncertainties inherent in the identification and development of product candidates, including the conduct of research activities, the initiation and completion of preclinical studies and clinical trials and clinical development of the company’s product candidates; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; whether results from earlier preclinical studies will be predictive of the results of later preclinical studies and clinical trials; uncertainties regarding the RES manufacturing process; uncertainties regarding the company’s ability to assign or sublease its manufacturing property; challenges in the manufacture of genetic medicine products; whether the company’s cash resources are sufficient to fund the company’s operating expenses and capital expenditure requirements for the period anticipated; the impact of the COVID-19 pandemic on the company’s business and operations; expectations for regulatory approvals to conduct trials or to market products; as well as the other risks and uncertainties set forth in the “Risk Factors” section of the company’s most recent annual report on Form 10-K, which is on file with the Securities and Exchange Commission, and in subsequent filings the company may make with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the company’s views as of the date hereof. The company anticipates that subsequent events and developments will cause the company’s views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the company’s views as of any date subsequent to the date on which they were made.

**Investors and Media Contact**

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**GENERATION BIO CO.  
CONSOLIDATED BALANCE SHEET DATA  
(Unaudited)  
(In thousands)**

<u>Earnings Release Balance Sheet</u>	<u>March 31, 2023</u>	<u>December 31, 2022</u>
Cash, cash equivalents and marketable securities	\$ 288,649	\$ 279,091
Working capital	321,996	267,866
Total assets	431,417	376,264
Total stockholders' equity	279,139	282,493

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**GENERATION BIO CO.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
**(in thousands, except share and per share data)**

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development	\$ 22,000	\$ 25,554
General and administrative	12,866	9,790
Total operating expenses	34,866	35,344
Loss from operations	(34,866)	(35,344)
Other income:		
Other income and interest income, net	2,772	345
Net loss and net loss attributable to common stockholders	\$ (32,094)	\$ (34,999)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.53)	\$ (0.61)
Weighted average common shares outstanding, basic and diluted	60,230,077	56,996,495
Comprehensive loss:		
Net loss	\$ (32,094)	\$ (34,999)
Other comprehensive loss:		
Unrealized gains on marketable securities	117	—
Comprehensive loss	\$ (31,977)	\$ (34,999)

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