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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 5, 2022**

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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                                   | Trading Symbol(s) | Name of each exchange on which registered |
|---|-------------------|---|
| <b>Common Stock, \$0.0001 par value<br/>per share</b> | <b>GBIO</b>       | <b>Nasdaq Global Select Market</b>        |

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 5, 2022, Generation Bio Co. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended March 31, 2022. 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<br/>No.</b> | <b>Description</b>   |
|------------------------|--|
| 99.1                   | <a href="#">Press Release Issued by Generation Bio Co. on May 5, 2022.</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 5, 2022

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 2022 Financial Results**

*Company continues to optimize cell-targeted lipid nanoparticle (ctLNP) delivery system for nonviral genetic medicine applications in liver, retina and vaccines*

*Cash balance of \$337.0M expected to fund operations into 2024*

**CAMBRIDGE, MASS., May 05, 2022** -- 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 2022 financial results.

“We are making steady advances in optimizing our cell-targeted lipid nanoparticles, or ctLNPs, for use in our liver and retina programs as well as in developing our platform technologies for novel vaccine applications,” said Geoff McDonough, M.D., president and chief executive officer of Generation Bio. “We believe our approach to genetic medicine has the potential to create highly differentiated therapies capable of fulfilling significant unmet need, and we look forward to providing updates on our progress.”

**Key priorities across core therapeutic areas:**

- ***Liver:*** Generation Bio is developing a liver optimized ctLNP to deliver a factor VIII closed-ended DNA (ceDNA) construct for the treatment of hemophilia A. The company is in the process of optimizing the biodistribution profile of its liver optimized ctLNP in non-human primates (NHP) to support the selection of a ctLNP for its hemophilia A program and for use in additional liver disease programs. Hemophilia A is a serious bleeding disorder for which existing therapeutic options face significant limitations. Generation Bio’s nonviral genetic medicine approach aims to enable a durable, redosable clinical profile that could be administered early in childhood and repeated as needed over a lifetime.
- ***Retina:*** Generation Bio’s approach to treating inherited and other retinal diseases involves a retina optimized ctLNP and disease specific nucleic acid cargos. The company plans to evaluate more advanced generations of its retina optimized ctLNP in NHPs for its lead retina program in Stargardt disease, as well as for use in subsequent retina programs. Over 200 million people suffer from retinal diseases, many of which are caused by a gene mutation that is too large to be delivered using existing gene therapy approaches. Generation Bio aims to leverage the capacity of ceDNA and favorable biodistribution profile of its retina optimized ctLNP in the eye to deliver large genes to address previously untreatable retinal diseases.
- ***Vaccines:*** Generation Bio is building a novel platform to create vaccines that use a vaccine optimized ctLNP to deliver ceDNA or messenger RNA (mRNA) and that are intended to meet or exceed the efficacy of existing mRNA vaccines. The company has

established the efficacy of its vaccine optimized ctLNP with mRNA in mice and NHP and is conducting additional studies of its vaccine optimized ctLNP with ceDNA in NHPs. The company is evaluating the potential of a ceDNA vaccine to achieve a differentiated profile with respect to the durability, kinetics, and magnitude of the humoral and T-cell responses relative to current mRNA vaccines.

### First Quarter 2022 Financial Results

- **Cash Position:** Cash and cash equivalents were \$337.0 million as of March 31, 2022, compared to \$375.1 million in cash and cash equivalents as of December 31, 2021. The company continues to believe that its cash position will fund its operating plan into 2024. The net decrease in cash and cash equivalents during the first quarter of 2022 includes cash outflows for seasonal and one-time expenditures, which are not expected to recur during the remainder of 2022.
- **R&D Expenses:** Research and development (R&D) expenses were \$25.6 million for the quarter ended March 31, 2022, compared to \$18.8 million for the quarter ended March 31, 2021.
- **G&A Expenses:** General and administrative (G&A) expenses were \$9.8 million for the quarter ended March 31, 2022, compared to \$6.9 million for the quarter ended March 31, 2021.
- **Net Loss:** Net loss was \$35.0 million, or \$0.61 basic and diluted net loss per share, for the quarter ended March 31, 2022, compared to a net loss of \$25.6 million, or \$0.46 basic and diluted net loss per share, for the quarter ended March 31, 2021.

### 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 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 our strategic plans or objectives, our technology platform, our research and clinical development plans, applications and 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: 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 timing and ability to complete the build-out of the company's manufacturing facility and regarding the RES manufacturing process; 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 our 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  
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**GENERATION BIO CO.  
CONSOLIDATED BALANCE SHEET DATA  
(Unaudited)  
(In thousands)**

|                            | <b>March 31,</b> | <b>December 31,</b> |
|----------------------------|------------------|---------------------|
|                            | <b>2022</b>      | <b>2021</b>         |
| Cash and cash equivalents  | \$ 336,978       | \$ 375,145          |
| Working capital            | 326,309          | 360,378             |
| Total assets               | 444,026          | 476,771             |
| Total stockholders' equity | 352,915          | 381,746             |

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

|   | Three Months Ended March 31, |             |
|---|------------------------------|-------------|
|   | 2022                         | 2021        |
| Operating expenses:   |                              |             |
| Research and development  | \$ 25,554                    | \$ 18,753   |
| General and administrative  | 9,790                        | 6,902       |
| Total operating expenses  | 35,344                       | 25,655      |
| Loss from operations  | (35,344)                     | (25,655)    |
| Other income:   |                              |             |
| Other income and interest income  | 345                          | 93          |
| Net loss and net loss attributable to common stockholders                 | \$ (34,999)                  | \$ (25,562) |
| Net loss per share attributable to common stockholders, basic and diluted | \$ (0.61)                    | \$ (0.46)   |
| Weighted average common shares outstanding, basic and diluted             | 56,996,495                   | 55,366,238  |
| Comprehensive loss:   |                              |             |
| Net loss  | \$ (34,999)                  | \$ (25,562) |
| Other comprehensive income:   |                              |             |
| Unrealized gains on marketable securities                                 | —                            | 1           |
| Comprehensive loss  | \$ (34,999)                  | \$ (25,561) |