
**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): November 6, 2024

Generation Bio Co.

(Exact Name of Registrant as Specified in Charter)

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)

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.

Item 2.02 Results of Operations and Financial Condition.

On November 6, 2024, Generation Bio Co. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended September 30, 2024. 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

| Exhibit No. | Description |
|------------------------|---|
| 99.1 | Press Release Issued by Generation Bio Co. on November 6, 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 6, 2024

GENERATION BIO CO.

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: President and Chief Executive Officer

Generation Bio Reports Recent Business Highlights and Third Quarter 2024 Financial Results

- *Non-human primate data presented at ESGCT demonstrated selective in vivo delivery of mRNA with T cell-targeted lipid nanoparticle (ctLNP)*
- *Cash balance of \$199.8 million expected to fund operations into 2H 2027*

CAMBRIDGE, MASS., Nov. 6, 2024 -- Generation Bio Co. (Nasdaq:GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, reported business highlights and third quarter 2024 financial results.

“There is immense potential for a new class of redosable, selectively targeted *in vivo* genetic medicines to fulfill the needs of people living with diseases that remain unaddressed by existing treatment options,” said Geoff McDonough, chief executive officer of Generation Bio. “Our cell-targeted lipid nanoparticle (ctLNP) platform has recently demonstrated highly selective *in vivo* delivery of mRNA to T cells in non-human primates (NHPs), a key milestone on the path to developing *in vivo* programs for T cell-mediated autoimmune diseases.”

Generation Bio recently presented data at the European Society of Gene and Cell Therapy (ESGCT) 31st Annual Congress from an NHP study showing that a single IV dose of a ctLNP delivering mRNA selectively to T cells transduced most circulating T cells with balanced distribution to CD4+ and CD8+ cells. These data confirm and improve on the potency and biodistribution profiles seen in previous murine and NHP studies, which have shown minimal off-target distribution to LNP clearance tissues. The NHP study was conducted as part of the company’s collaboration with Moderna, Inc.

Third Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities were \$199.8 million as of September 30, 2024, compared to \$264.4 million in cash, cash equivalents, and marketable securities as of December 31, 2023. The company continues to believe that its cash, cash equivalents, and marketable securities will fund its operating expenses and capital expenditures into the second half of 2027.
- **R&D Expenses:** Research and development (R&D) expenses were \$15.1 million for the quarter ended September 30, 2024, compared to \$21.9 million for the quarter ended September 30, 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were \$9.2 million for the quarter ended September 30, 2024, compared to \$11.6 million for the quarter ended September 30, 2023.
- **Net Loss:** Net loss was \$15.3 million, or \$0.23 basic and diluted net loss per share, for the quarter ended September 30, 2024, compared to a net loss of \$28.3 million, or \$0.43 basic and diluted net loss per share, for the quarter ended September 30, 2023.

About Generation Bio

Generation Bio is innovating non-viral genetic medicines to provide durable and redosable treatments for hundreds of millions of patients living with rare and prevalent diseases. The company is developing two distinct and complementary platforms: a potent, highly selective cell-targeted lipid nanoparticle (ctLNP) delivery system and a novel immune-quiet DNA (iqDNA) cargo produced by a scalable capsid-free manufacturing process that uses proprietary cell-free rapid enzymatic synthesis (RES). With these platforms, Generation Bio aims to develop the next wave of non-viral genetic medicines 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.

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 platforms, research and clinical development plans, 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; uncertainties regarding the company's novel platforms and related technologies; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; 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; 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 and quarterly report on Form 10-Q, which are 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)**

| <u>Earnings Release Balance Sheet</u> | <u>September 30, 2024</u> | <u>December 31, 2023</u> |
|--|---------------------------|--------------------------|
| Cash, cash equivalents and marketable securities | \$ 199,812 | \$ 264,364 |
| Working capital | 161,089 | 232,704 |
| Total assets | 248,784 | 374,758 |
| Total stockholders' equity | 104,442 | 203,128 |

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

| | Three Months Ended September 30, | |
|---|---|-------------|
| | 2024 | 2023 |
| Revenues: | | |
| Collaboration Revenue | \$ 7,554 | \$ 2,146 |
| Operating expenses: | | |
| Research and development | 15,088 | 21,862 |
| General and administrative | 9,181 | 11,641 |
| Loss on lease termination | 1,169 | — |
| Total operating expenses | 25,438 | 33,503 |
| Loss from operations | (17,884) | (31,357) |
| Other income: | | |
| Other income and interest income, net | 2,571 | 3,091 |
| Net loss | \$ (15,313) | \$ (28,266) |
| Net loss per share, basic and diluted | \$ (0.23) | \$ (0.43) |
| Weighted average common shares outstanding, basic and diluted | 66,738,468 | 65,907,000 |
| Comprehensive loss: | | |
| Net loss | \$ (15,313) | \$ (28,266) |
| Other comprehensive loss: | | |
| Unrealized gains on marketable securities | 599 | 19 |
| Comprehensive loss | \$ (14,714) | \$ (28,247) |