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 27, 2023

Generation Bio Co.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39319**	**81-4301284**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

301 Binney Street Cambridge, MA	**02142**
(Address of Principal Executive Offices)	**(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	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**GBIO**	**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 2.05 Costs Associated with Exit or Disposal Activities.

On November 27, 2023, the Board of Directors (the "Board") of Generation Bio Co. (the "Company") approved a reduction of the Company's workforce by approximately 40% (the "RIF"). The Company expects to complete the RIF by the end of the second quarter of 2024. The RIF was implemented following a review of strategic priorities and a determination by the Company's management and Board to implement a strategic reorganization to invest in the Company's highly selective cell-targeted lipid nanoparticle (ctLNP) delivery platform to develop wholly-owned programs for extrahepatic cell types and to develop its immune-quiet DNA (iqDNA) platform for its lead program in hemophilia A and other programs.

The RIF, together with reductions in operational expenditures including Good Manufacturing Practice readiness and manufacturing expenses, is expected to yield savings of approximately $120 million over the next three years. The Company expects its cash runway will be extended into the second half of 2027.

In connection with the RIF, affected employees will be eligible to receive severance benefits, including cash severance, temporary healthcare coverage to the extent they are eligible for and elect such coverage, and transition support services, subject to each such employee entering into an effective separation agreement, which will include a general release of claims against the Company. The Company is also offering a retention bonus to certain of the affected employees if such employees remain in continuous employment with the Company through their respective separation dates and execute a general release of claims against the Company.

As a result of the RIF, the Company estimates that it will incur severance-, termination- and retention-related costs of approximately $7 million to $8 million, which the Company expects to recognize in the fourth quarter of 2023 and the first quarter of 2024. The estimates of costs and expenses that the Company expects to incur in connection with the RIF are subject to a number of assumptions and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the RIF.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

As part of the RIF described above in Item 2.05, the Company will terminate the employment of Douglas Kerr, M.D., Ph.D., M.B.A., the Company's Chief Medical Officer, and Tracy Zimmermann, Ph.D., the Company's Chief Development Officer, effective as of January 28, 2024 (the "Separation Date").

The Company anticipates that it will enter into a separation and release agreement with each of Dr. Kerr and Dr. Zimmermann at the time of their separation (collectively, the "Separation Agreements"), pursuant to which Dr. Kerr and Dr. Zimmermann will be entitled to receive severance benefits, including cash severance in an amount equal to nine months of their base salary in effect on the Separation Date, in the total gross amount of $0.4 million and $0.3 million, respectively, less applicable taxes and withholdings, payable in equal installments over a nine-month period, temporary healthcare coverage for up to nine months to the extent they are eligible for and elect such coverage, and transition support services. In addition, the Company expects that under the terms of the Separation Agreements, 25% of Dr. Kerr and Dr. Zimmermann's outstanding unvested equity awards will become fully vested on the Separation Date. The Separation Agreements will also contain a general release of claims by each of Dr. Kerr and Dr. Zimmermann.

The foregoing description of the Separation Agreements are qualified in their entirety by reference to the full text of the Separation Agreements, copies of which the Company intends to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024.

Item 7.01 Regulation FD.

On November 29, 2023, the Company issued a press release announcing the strategic reorganization and RIF. A copy of this press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 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 filling.

Forward-Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans and prospects for the Company, including statements about the strategic reorganization, the potential cost savings from the strategic reorganization and the impact of the strategic reorganization on the Company's cash runway, and the Company's strategic plans or objectives, cash resources, technology platform, 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 as to whether the strategic reorganization will result in the cost savings expected or the extension of the Company's cash runway for the period anticipated or have other impacts on the Company's ability to achieve its strategic goals; 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 technologies; 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; 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 Current Report on Form 8-K 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by Generation Bio Co. on November 29, 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GENERATION BIO CO.

Date: November 29, 2023

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: President and Chief Executive Officer

Generation Bio Announces Strategic Reorganization to Extend Cash Runway for Development of ctLNP and iqDNA Platforms

- *Company to invest in highly selective cell-targeted lipid nanoparticle (ctLNP) delivery platform to develop wholly-owned programs for extrahepatic cell types*

- *Development of immune-quiet DNA (iqDNA) platform for lead hemophilia A program to continue*

- *Strategic reorganization will result in a 40% reduction of workforce*

- *Anticipated cost savings to extend cash runway into 2H 2027*

CAMBRIDGE, MASS., Nov. 29, 2023 -- Generation Bio Co. (Nasdaq: GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, announced a strategic reorganization to prioritize investment in the development of its cell-targeted lipid nanoparticle (ctLNP) delivery system for wholly-owned programs in extrahepatic cell types. Generation Bio intends to continue to develop ctLNP for immune cells as part of its collaboration with Moderna and to develop its immune-quiet DNA (iqDNA) for its lead hemophilia A and other programs.

"Our ctLNP platform has demonstrated uniquely selective ligand-targeted delivery to T cells with minimal off-target uptake. We believe there is a clear path to developing our own programs using ctLNP to reach extrahepatic targets and are realigning our investments to support this," said Geoff McDonough, M.D., chief executive officer of Generation Bio. "We also remain focused on developing the iqDNA platform for our lead program in hemophilia A as well as for other programs in the liver and beyond. To allow us to reach critical development milestones for these platforms under current market conditions, we are taking the difficult but necessary steps to align our investments with our strategy and to extend our cash runway."

Dr. McDonough continued: "We are deeply grateful to all our employees who have demonstrated incredible dedication to each other, to our community, and to the millions of people whose lives we aim to significantly improve by pursuing our mission. We are focused on supporting our departing employees through this difficult transition, and on beginning the next stage of our journey."

The reorganization actions and financial impacts are as follows:

- Streamlining R&D to develop wholly-owned ctLNP programs for extrahepatic cell types
- Continuing to develop immune cell programs with Moderna
- Continuing to develop the iqDNA platform for its lead hemophilia A and other programs
- Extending cash runway into the second half of 2027

The company will reduce its total workforce by 40%, while preserving core R&D capacity. Several of Generation Bio's leadership team members will also depart as part of the reorganization.

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 novel iqDNA; a unique ctLNP delivery system; and a highly scalable capsid-free manufacturing process that uses proprietary cell-free rapid enzymatic synthesis, or RES, to produce iqDNA. This approach 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.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the company, including statements about the strategic reorganization, the potential cost savings from the strategic reorganization and the impact of the strategic reorganization on the company's cash runway, and the company's strategic plans or objectives, cash resources, technology platform, 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 as to whether the strategic reorganization will result in the cost savings expected or the extension of the company's cash runway for the period anticipated or have other impacts on the company's ability to achieve its strategic goals; 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 technologies; 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; 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.

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