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): January 6, 2025

Generation Bio Co.

(Exact Name of Registrant as Specified in Charter)

001-39319

Delaware

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 Office	es)	(Zip Code)
Registrant's teleph	one number, including area co	de: (617) 655-7500
(Former Nam	Not applicable e or Former Address, if Changed Since	e Last Report)
Check the appropriate box below if the Forr registrant under any of the following provision	_	, , , ,
☐ Written communications pursuant to Ru	ale 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 pu	irsuant to Rule 14d-2(b) under th	ne Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pu	irsuant to Rule 13e-4(c) under th	e 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 registran of 1933 (§230.405 of this chapter) or Rule 12		y as defined in Rule 405 of the Securities Act act of 1934 (§240.12b-2 of this chapter).
		Emerging growth company \square
If an emerging growth company, indicate by period for complying with any new or revise Exchange Act. □		

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

Departure of Matthew Norkunas, Chief Financial Officer

On January 6, 2025, Generation Bio Co. (the "Company") and Matthew Norkunas, MD, MBA agreed that they will enter into a separation agreement (the "Norkunas Separation Agreement") for Dr. Norkunas's departure as the Company's Chief Financial Officer, effective as of January 10, 2025 (the "Effective Date").

Pursuant to the Norkunas Separation Agreement, the Company will agree to provide Dr. Norkunas with separation benefits consisting of (i) cash severance of approximately \$100,000, which is an amount equal to three months of his base salary in effect on the Effective Date, less applicable taxes and withholdings, payable in equal installments over a three-month period, (ii) temporary healthcare coverage for up to three months to the extent he is eligible for and elects such coverage, (iii) acceleration of vesting of his outstanding unvested equity awards on the Effective Date such that such equity awards shall be deemed vested to the extent that they would have been deemed vested as of April 10, 2025 as if he continued as an employee of the Company, and (iv) the extension of the post-termination exercise period of his stock options with an exercise price of less than \$20.00 per share to January 29, 2026, subject to the terms of the Company's 2020 Stock Incentive Plan (the "Plan"). The Norkunas Separation Agreement would also include a general release of claims by Dr. Norkunas.

The foregoing description of the Norkunas Separation Agreement is qualified in its entirety by reference to the full text of the Norkunas Separation Agreement, a copy of which the Company intends to file as an exhibit to its Annual Report on Form 10-K for the year ended December 31, 2024.

Departure of Matthew Stanton, Chief Scientific Officer

On January 6, 2025, the Company and Matthew Stanton, Ph.D. agreed that they will enter into a separation agreement (the "Stanton Separation Agreement") for Dr. Stanton's departure as the Company's Chief Scientific Officer, effective as of the Effective Date.

Pursuant to the Stanton Separation Agreement, the Company will agree to provide Dr. Stanton with separation benefits consisting of (i) cash severance of approximately \$400,000, which is an amount equal to nine months of his base salary in effect on the Effective Date, less applicable taxes and withholdings, payable in equal installments over a nine-month period, (ii) temporary healthcare coverage for up to nine months to the extent he is eligible for and elects such coverage, (iii) full acceleration of vesting as to 25% of his outstanding unvested equity awards on the Effective Date, and (iv) the extension of the post-termination exercise period of his stock options with an exercise price of less than \$20.00 per share to January 29, 2026, subject to the terms of the Plan. The Stanton Separation Agreement would also include a general release of claims by Dr. Stanton.

Concurrent with entering into the Stanton Separation Agreement, the Company plans to enter into a consulting agreement (the "Consulting Agreement") with Dr. Stanton, pursuant to which Dr. Stanton will agree to provide advisory and other consulting services to the Company following the Effective Date until July 10, 2025. The Company expects that it will pay Dr. Stanton an hourly consulting fee equal to \$400 per hour for any hours in excess of 10 hours per month for his services under the Consulting Agreement.

The foregoing descriptions of the Stanton Separation Agreement and the Consulting Agreement are qualified in their entirety by reference to the full text of the Stanton Separation Agreement and the Consulting Agreement, copies of which the Company intends to file as exhibits to its Annual Report on Form 10-K for the year ended December 31, 2024.

Election of Kevin Conway as Chief Financial Officer

On January 6, 2025, the Board of Directors (the "Board") of the Company elected Kevin Conway to serve as the Company's Chief Financial Officer, principal financial officer and principal accounting officer, effective as of the Effective Date.

Prior to being appointed as the Company's Chief Financial Officer, Mr. Conway, age 37, served as the Company's Vice President, Finance, from March 2022 to January 2025, its Senior Director, Corporate Controller, from April 2021 to March 2022, its Corporate Controller from April 2020 to April 2021 and its Assistant Corporate Controller from July

2019 to April 2020. Before joining the Company, Mr. Conway served as the Assistant Controller to Solid Biosciences Inc., a life sciences company, from August 2018 to July 2019. Mr. Conway received his Bachelor of Science in communications from Ithaca College and his masters of science in accounting from the University of Massachusetts, Boston. Mr. Conway is a Certified Public Accountant in the state of Massachusetts.

In connection with his election as Chief Financial Officer, Mr. Conway will receive an annual base salary of \$420,000 and his annual target bonus will be 40% of his annual base salary, prorated for 2025. The Company will also grant Mr. Conway an option to purchase 290,960 shares of the Company's common stock under the Plan. The option will have an exercise price equal to the closing price of the Company's common stock on the Nasdaq Global Select Market on January 10, 2025, and a term of 10 years. The option will vest as to 25% of the shares underlying the option on January 10, 2026, and, as to the remainder, an additional 6.25% of the underlying shares quarterly thereafter until January 10, 2029.

Mr. Conway entered into the Company's standard indemnification agreement, a copy of which was filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-238608) filed with the Securities and Exchange Commission on May 22, 2020. Pursuant to the terms of the indemnification agreement, the Company may be required, among other things, to indemnify Mr. Conway for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him in any action or proceeding arising out of his service as an officer of the Company.

Election of Phillip Samayoa as Chief Scientific Officer

On January 6, 2025, the Board of the Company elected Phillip Samayoa, Ph.D., to serve as the Company's Chief Scientific Officer, effective as of the Effective Date.

Dr. Samayoa has served as the Company's Chief Strategy Officer since September 2022. Previously, Dr. Samayoa served as the Company's Senior Vice President, Head of Corporate Development, from April 2021 to September 2022, the Company's Vice President, Strategy and Portfolio Development from December 2018 to April 2021 and the Company's Senior Director, Strategy and Portfolio Development from December 2017 to December 2018. Prior to joining the Company, Dr. Samayoa served as a Principal at Atlas Ventures, a venture capital firm. Dr. Samayoa received dual B.S. degrees in biological engineering and physics from the Massachusetts Institute of Technology and his Ph.D. in bioinformatics and systems biology from the University of California, San Diego.

In connection with his election as Chief Scientific Officer, Dr. Samayoa will receive an annual base salary of \$510,000 and his annual target bonus will be 40% of his annual base salary.

Item 7.01 Regulation FD.

On January 6, 2025, the Company issued a press release announcing the Company's new focus on applying its cell-targeted lipid nanoparticle ("ctLNP") delivery technology to develop siRNA therapeutics for T cell-driven autoimmune diseases (as described below), and the management changes described in Item 5.02 above. 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 filing.

Item 8.01 Other Events.

On January 6, 2025, the Board approved a reduction in the Company's workforce (the "RIF") by approximately 20%. The Company expects to complete the RIF by the second quarter of 2025. The reorganization is intended to support the Company's new focus on applying its ctLNP delivery technology to develop siRNA therapeutics to silence disease-driving targets in T cells. The Company plans to submit its first investigational new drug application in the second half of 2026 and to enter the clinic within its cash runway, which the Company expects to last into the second half of 2027.

As a result of the RIF, the Company estimates that it will incur severance-, termination- and retention-related costs of approximately \$1.0 million to \$2.0 million, which the Company expects to recognize by the second quarter of 2025.

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 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.

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 Company's reorganization and associated costs, the Company's expected timeline for submitting its first investigational new drug application and the Company's strategic plans or objectives, cash resources and expected cash runway, technology platform, research and clinical development plans and preclinical data, and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forwardlooking 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 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 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 forwardlooking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forwardlooking 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 <u>Press Release Issued by Generation Bio Co. on January 6, 2025.</u>

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: January 6, 2025

GENERATION BIO CO.

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: President and Chief Executive Officer



Generation Bio to Apply ctLNP Delivery Technology to Develop siRNA Therapeutics for T Cell-Driven Autoimmune Diseases

- Novel programs will combine validated cell-targeted LNP (ctLNP) delivery with siRNA to selectively modulate T cells in vivo
- Programs to focus on silencing hard-to-drug targets of high therapeutic value in T cell-driven autoimmune diseases
- Company reorganization supports evolution of ctLNP-enabled strategy and buildout of clinical capabilities ahead of first IND expected in 2H 2026

CAMBRIDGE, Mass. – Jan. 6, 2025 (GLOBE NEWSWIRE) -- Generation Bio Co. (Nasdaq:GBIO) a biotechnology company working to change what is possible for people living with T cell-driven autoimmune diseases, announced it is leveraging its validated T cell-directed lipid nanoparticle (ctLNP) to develop siRNA therapeutics to silence disease-driving targets in T cells.

"We are excited to move Generation Bio toward the clinic by deploying our ctLNP to deliver siRNA to T cells. By precisely modulating T cell activity *in vivo* we believe we can address high-value, currently undruggable targets involved in the inflammation and tissue damage associated with T cell-driven autoimmune diseases," said Geoff McDonough, M.D., chief executive officer of Generation Bio. "Our aim is to silence therapeutic T cell targets without impacting other immune cell types, unlocking a powerful new application for siRNA in the field. We plan to submit our first IND in the second half of 2026 and to enter the clinic within our cash runway, which is into the second half of 2027."

siRNA delivery to T cells has historically been limited by the inability to achieve selective cell targeting combined with efficient access to the cytoplasm where siRNA operates, challenges that Generation Bio has designed its ctLNP to overcome. The company recently presented non-human primate data demonstrating that its ctLNPs work by targeting T cells through a target receptor of interest with a strong selectivity for CD8+ and CD4+ effector T cells and NK cells, all of which are involved in auto-reactive tissue damage in a number of autoimmune diseases.

siRNA delivered with ctLNP aims to modulate T cell function without impacting the function of the broader immune system. ctLNP-siRNA could reach targets that change how auto-reactive T cells activate, differentiate, migrate, and damage tissues. Generation Bio will provide further details about its lead ctLNP-siRNA programs in upcoming quarters and expects to submit its first IND in the second half of 2026.

The company is reorganizing to support the clinical development of T cell-directed medicines. In addition, the company is announcing changes to its executive leadership team. Phillip Samayoa,

Ph.D., chief strategy officer, will succeed Matthew Stanton, Ph.D. as chief scientific officer. Dr. Stanton will remain with the company through mid-2025 and transition to its Scientific Advisory Board thereafter. Kevin Conway, the company's head of finance, has been elected chief financial officer to succeed Matthew Norkunas, M.D. Generation Bio also expects to appoint a chief medical officer in 2025.

"I am grateful for the passion and expertise each person at Generation Bio has contributed to enable our transition toward the clinic," said Dr. McDonough. "Matt Stanton has been instrumental in the invention of our technologies, and I look forward to our continued work together. Likewise, Matt Norkunas has built a terrific team here, which Kevin will continue to build upon. With a strong foundation in place, we are well-positioned to execute on our mission to bring highly differentiated T cell-directed therapies to patients."

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, strategic reorganization, cash resources, technology platforms, research and clinical development plans and timelines, 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: the potential impact of the strategic reorganization on the company's operations and development timeline; 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 forwardlooking 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.

About Generation Bio

Generation Bio is a biotechnology company changing what is possible for people living with T cell-driven autoimmune diseases. The company is developing a new modality of therapeutics leveraging its T cell selective cell-targeted lipid nanoparticle (ctLNP) to deliver siRNA *in vivo*, enabling modulation of T cell activity that causes inflammation and auto-reactive tissue destruction. By selectively modulating T cells that drive disease pathology, ctLNP-siRNA therapeutics could potently block target function with sequence-level specificity while sparing the broader immune system. This potent new modality is designed to reach targets that are poorly drugged by other approaches, opening a broad indication space of T cell driven autoimmune diseases.

For more information, please visit www.generationbio.com.

Investors and Media Contact

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