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): March 23, 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 1.01 Entry Into a Material Definitive Agreement.

On March 23, 2023 (the "Effective Date"), Generation Bio Co. (the "Company") entered into a Collaboration and License Agreement (the "Collaboration Agreement") with ModernaTX, Inc. ("Moderna") to collaborate on developing treatments for certain diseases by targeting delivery of nucleic acids to liver cells and certain cells outside of the liver. Additionally, on the Effective Date, the Company entered into a Share Purchase Agreement (the "Share Purchase Agreement") with Moderna, pursuant to which the Company agreed to sell and issue shares of its common stock to Moderna.

Collaboration and License Agreement

Under the Collaboration Agreement, the parties have agreed to collaborate on three preclinical research programs relating to lipid nanoparticle ("LNP") delivery systems and nucleic acid payloads, with each party obtaining certain rights to intellectual property used in and arising out of such research programs. Each party will be solely responsible for its own clinical development and commercialization of products under the Collaboration Agreement.

The first research program (the "Non-Liver ctLNP Program") will be focused on the discovery and development of cell-targeted LNPs ("ctLNPs") directed to agreed-upon immune cell types (the "Cell Target Types"). The second research program will be focused on the use of ctLNPs developed under the Non-Liver ctLNP Program to discover and develop products (which the parties anticipate will incorporate the Company's closed-ended DNA ("ceDNA") constructs) directed to agreed-upon targets outside of the liver (the "Non-Liver Targets"). The third research program will be focused on the discovery and development of products (which the parties anticipate will comprise ceDNA constructs and the Company's liver-targeted ctLNPs) directed to specified indications to be targeted in the liver (the "Liver Targets"), including rare (which may include Phenylketonuria and Wilson disease) and prevalent indications.

The research programs will be conducted pursuant to research plans and associated research budgets established by governance committees formed by the parties. Moderna will reimburse the Company for the internal and external costs incurred by the Company in conducting the research programs, to the extent consistent with such research plans and budgets.

Moderna has exclusive options, upon payment of option exercise fees, to obtain worldwide, exclusive, sublicensable licenses under specified Company intellectual property to develop, manufacture and commercialize (a) products comprising LNP delivery systems and nucleic acid payloads that are directed to (i) up to two of the Liver Targets, (ii) up to two of the Non-Liver Targets and (iii) a third Liver Target or Non-Liver Target and (b) Independent Program Products (as defined below) that include mRNA that are directed to gene and protein targets in any of the Cell Target Types ("Exclusive Targets"). Subject to the Company's exclusivity obligations described below, each party has granted to the other a worldwide, non-exclusive, sublicensable license under certain LNP-related intellectual property arising out of the Non-Liver ctLNP Program (the "Joint Collaboration ctLNP Intellectual Property"), to develop, manufacture and commercialize products comprising LNP delivery systems and nucleic acid payloads directed to gene and protein targets in any of the Cell Target Types ("Independent Program Products").

Each party is obligated to use commercially reasonable efforts to complete the activities assigned to it under the research plans, and Moderna is further obligated to use commercially reasonable efforts to develop, seek regulatory approval for and commercialize at least one product directed to each target for which Moderna exercises its exclusive license option in at least one indication in the United States and in specified European countries.

The Company has agreed not to, directly or indirectly, alone or with, for or through any third party, develop, manufacture, commercialize or exploit (a) products containing mRNA that are directed to any of the Cell Target Types, during an agreed-upon exclusivity period, which may be extended by payment of extension fees, (b) products directed to any Liver Target or Non-Liver Target during the option periods for those targets, (c) products directed to any Liver Target or Non-Liver for which Moderna has exercised its exclusive license option or (d) products containing mRNA that are directed to any Exclusive Target for which Moderna has exercised its exclusive license option.

Under the terms of the Collaboration Agreement, Moderna has agreed to pay the Company an upfront payment of $40 million and a $36 million equity investment pursuant to the Share Purchase Agreement, as well as an upfront payment of certain research costs. In addition, the Company is eligible to receive up to an aggregate of $1.8 billion in milestone payments upon the achievement of specified development, regulatory, commercial, and sales milestone events, research term extensions fees and exclusivity extension fees. Subject to reductions in specified circumstances, the Company will also be entitled to receive tiered royalties: (i) ranging from high-single-digits to low-double-digits on sales of licensed

products that are directed to any Liver Target or Non-Liver Target with respect to which Moderna has exercised its exclusive license option, and (ii) in the single digits on sales of Independent Program Products, including the exclusively licensed Independent Program Products directed to the Exclusive Targets. In consideration for the non-exclusive license granted by Moderna to the Company under the Joint Collaboration ctLNP Intellectual Property, the Company has agreed to pay Moderna tiered royalties in the single digits on sales of Independent Program Products that include mRNA, subject to reductions in specified circumstances. Royalties will be paid by each party, on a licensed product-by-licensed product and country-by-country basis, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; or (iii) ten (10) years after the first commercial sale of the applicable licensed product.

Unless earlier terminated, the Collaboration Agreement will expire upon the expiration of the last royalty term for the last licensed product. The Collaboration Agreement may be terminated by Moderna, on a target-by-target and country-by-country basis or in its entirety, upon 90 days' prior written notice. Either party may, subject to specified cure periods, terminate the Collaboration Agreement in the event of the other party's uncured material breach. Either party may also terminate the Collaboration Agreement under specified circumstances relating to the other party's insolvency.

The foregoing description of the terms of the Collaboration Agreement is qualified in its entirety by reference to the full text of the Collaboration Agreement, a copy of which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2023.

Share Purchase Agreement

In connection with the execution of the Collaboration Agreement, the Company and Moderna also entered into the Share Purchase Agreement for the sale and issuance of 5,859,375 shares of the Company's common stock (the "Shares") to Moderna at an aggregate purchase price of $36.0 million. The sale of the Shares closed on the Effective Date. The Share Purchase Agreement contains customary representations, warranties and covenants of each of the Company and Moderna. In addition, under the Share Purchase Agreement Moderna has the right, subject to certain terms and conditions, to purchase up to 3.06% of the outstanding shares of the Company's common stock (on a post-closing basis) in connection with a future equity financing of at least $25.0 million by the Company.

Pursuant to the terms of the Share Purchase Agreement, Moderna may not, for a period beginning on the Effective Date and ending on the eighteen (18) month anniversary of the Effective Date, without the prior written approval of the Company and subject to specified conditions, directly or indirectly, (i) acquire shares of the Company's common stock, (ii) solicit proxies or consents with respect to any matter, (iii) effect, offer or propose a merger, tender or exchange offer or other business combination, any recapitalization, restructuring, liquidation, dissolution or other similar extraordinary transaction, or a purchase of the Company's assets or businesses, or (iv) undertake other specified actions related to the potential acquisition of additional equity interests in, or change of control of, the Company (the "Standstill Restrictions"). The Standstill Restrictions terminate upon the occurrence of certain trigger events, including a change of control of the Company.

Under the Share Purchase Agreement, the Company has granted certain resale registration rights to Moderna with respect to the Shares that Moderna may exercise beginning six months following the Effective Date and subject to certain restrictions.

The foregoing description of the terms of the Share Purchase Agreement is qualified in its entirety by reference to the full text of the Share Purchase Agreement, a copy of which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2023.

Item 3.02 Unregistered Sales of Equity Securities.

The information set forth in Item 1.01 above under the caption "Share Purchase Agreement" is incorporated herein by reference. The Shares were issued in reliance on the exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act") based on the Investor's representations in the Share Purchase Agreement. The Shares have not been registered under the Securities Act or any state securities laws and may not be offered or sold in the United States absent registration under the Securities Act or an applicable exemption from the registration requirements.

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: March 23, 2023

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: President and Chief Executive Officer