
**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): August 4, 2022

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 August 4, 2022, Generation Bio Co. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended June 30, 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

Exhibit No.	Description
99.1	Press Release Issued by Generation Bio Co. on August 4, 2022.
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: August 4, 2022

GENERATION BIO CO.

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: President and Chief Executive Officer

Generation Bio Reports Business Highlights and Second Quarter 2022 Financial Results

Cash balance of \$312.2M expected to fund operations into 2025

Cambridge, Mass. – Aug. 4, 2022 – Generation Bio Co. (Nasdaq: GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, reported business highlights and second quarter 2022 financial results.

“We are advancing our leading non-viral genetic medicine platform to unlock the potential of durable, redosable non-viral DNA therapeutics, and we have made significant progress in establishing the proprietary technologies necessary to realize our vision,” said Geoff McDonough, M.D., president and chief executive officer of Generation Bio. “This quarter, process development and scaling of rapid enzymatic synthesis (RES) for production of our closed-ended DNA (ceDNA) construct has allowed us to pursue a more flexible and capital efficient manufacturing strategy. In the remainder of the year, we plan to continue to develop our unique cell-targeted lipid nanoparticle (ctLNP) system for systemic delivery to hepatocytes, as well as for other therapeutic areas such as the retina and vaccines.”

Business Highlights

- **Announced update to Good Manufacturing Practice (GMP) manufacturing strategy:** In June 2022, Generation Bio announced advances in process development for RES production of ceDNA that enabled a new modular and more flexible manufacturing approach. The productivity, high purity yield and short cycle time of RES at scale is expected to supply portfolio programs for the next 10 years and requires a much smaller manufacturing footprint than previously anticipated. The company is therefore seeking to assign its lease or sublease the manufacturing facility it had planned to build out and will execute an alternative GMP strategy that provides control over personnel, quality, infrastructure and process know-how while enhancing capital efficiency. As a result of the decision to assign or sublease the property, Generation Bio is able to reallocate financial resources from the buildout to extend its projected cash runway into 2025.
- **Appointed Dannielle Appelhans to Board of Directors:** In July 2022, the company announced the appointment of Dannielle Appelhans to its Board of Directors. Appelhans is an experienced pharmaceutical executive who has built deep expertise in strategy, manufacturing, supply chain and operations, and is currently the Chief Operating Officer of Rubius Therapeutics.

Second Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$312.2 million as of June 30, 2022, compared with \$375.1 million in cash and cash equivalents as of December 31, 2021. The company believes that its cash position will fund its operating plan into 2025.

- **R&D Expenses:** Research and development (R&D) expenses were \$28.4 million for the quarter ended June 30, 2022, compared to \$22.7 million for the quarter ended June 30, 2021.
- **G&A Expenses:** General and administrative (G&A) expenses were \$10.1 million for the quarter ended June 30, 2022, compared to \$8.2 million for the quarter ended June 30, 2021.
- **Net Loss:** Net loss was \$37.9 million, or \$0.66 basic and diluted net loss per share, for the quarter ended June 30, 2022, compared to a net loss of \$30.8 million, or \$0.55 basic and diluted net loss per share, for the quarter ended June 30, 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.

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, manufacturing plans, cash resources, technology platform, including RES, 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; 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; uncertainties regarding the company's ability to assign or sublease its manufacturing property; whether the changes to the company's manufacturing strategy will achieve the anticipated savings; 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 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

Maren Killackey
Generation Bio
mkillackey@generationbio.com
857-371-4638

**GENERATION BIO CO.
CONSOLIDATED BALANCE SHEET DATA
(Unaudited)
(In thousands)**

<u>Earnings Release Balance Sheet</u>	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Cash, cash equivalents and marketable securities	\$ 312,204	\$ 375,145
Working capital	304,946	360,378
Total assets	418,994	476,771
Total stockholders' equity	324,874	381,746

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

	Three Months Ended June 30,	
	2022	2021
Operating expenses:		
Research and development	\$ 28,365	\$ 22,656
General and administrative	10,116	8,186
Total operating expenses	38,481	30,842
Loss from operations	(38,481)	(30,842)
Other income:		
Other income and interest income	552	51
Net loss and net loss attributable to common stockholders	\$ (37,929)	\$ (30,791)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.66)	\$ (0.55)
Weighted average common shares outstanding, basic and diluted	57,149,474	56,318,025
Comprehensive loss:		
Net loss	\$ (37,929)	\$ (30,791)
Other comprehensive loss:		
Unrealized losses on marketable securities	(339)	(6)
Comprehensive loss	\$ (38,268)	\$ (30,797)