# 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 7, 2024

# 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	none number, including area co	ode: (617) 655-7500			
	(Former Nam	Not applicable ne or Former Address, if Changed Sinc	e Last Report)			
	eck the appropriate box below if the Form istrant under any of the following provision					
	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))					
Sec	curities registered pursuant to Section 12(b)	) of the Act:				
C	Title of each class ommon Stock, \$0.0001 par value per share	Trading Symbol(s) GBIO	Name of each exchange on which registered Nasdaq Global Select Market			
	icate by check mark whether the registrant 1933 (§230.405 of this chapter) or Rule 12th		as defined in Rule 405 of the Securities Act act of 1934 (§240.12b-2 of this chapter).			
			Emerging growth company			
for			lected not to use the extended transition period d pursuant to Section 13(a) of the Exchange			

#### Item 2.02 Results of Operations and Financial Condition.

On August 7, 2024, Generation Bio Co. (the "Company") issued a press release announcing the Company's financial results for the quarter ended June 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 filling.

#### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits

Exhibit

No. Description

99.1 Press Release Issued by Generation Bio Co. on August 7, 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: August 7, 2024

GENERATION BIO CO.

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: President and Chief Executive Officer



#### **Generation Bio Reports Second Quarter 2024 Financial Results**

• Cash balance of \$217 million still expected to fund operations into 2H 2027

**CAMBRIDGE, MASS., Aug. 7, 2024** -- 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 2024 financial results.

"We continue to apply our proprietary cell-targeted LNP delivery system to develop *in vivo* genetic medicines for T cells, hematopoietic stem cells and hepatocytes," said Geoff McDonough, chief executive officer of Generation Bio. "We believe our delivery platform has the potential to create uniquely differentiated *in vivo* therapeutics that are redosable, delivered at point-of-care, and scalable at low cost, thereby addressing challenges of current *ex vivo* genetic medicine approaches, creating new market opportunities, and significantly expanding access for patients."

Generation Bio's novel, proprietary cell-targeted lipid nanoparticle (ctLNP) delivery system is engineered to have an extended half-life in systemic circulation compared to current LNP technologies that enables the biologic targeting ligands on the company's ctLNPs to engage with receptors on specific cell types and tissues to achieve selective, potent, and efficient cargo expression. ctLNPs can deliver a variety of cargos, including Generation Bio's proprietary immune-quiet form of DNA (iqDNA). iqDNA is designed to express or replace large genes to achieve years-long expression of therapeutic proteins. Generation Bio is focused on developing a range of differentiated, redosable therapeutics: *in vivo* T cell therapies for autoimmune indications, *in vivo* hematopoietic stem cells (HSC) therapies for sickle cell disease and beta-thalassemia, and systemic delivery to the liver for hemophilia A.

#### **Second Quarter 2024 Financial Results**

- Cash Position: Cash, cash equivalents, and marketable securities were \$216.9 million as of June 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 \$16.4 million for the quarter ended June 30, 2024, compared to \$21.8 million for the quarter ended June 30, 2023.
- **G&A Expenses**: General and administrative (G&A) expenses were \$9.5 million for the quarter ended June 30, 2024, compared to \$13.0 million for the quarter ended June 30, 2023
- **Net Loss:** Net loss was \$20.4 million, or \$0.31 basic and diluted net loss per share, for the quarter ended June 30, 2024, compared to a net loss of \$31.1 million, or \$0.47 basic and diluted net loss per share, for the quarter ended June 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, which is 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)

(Unaudited) (In thousands)

Earnings Release Balance Sheet		e 30, 2024	December 31, 2023	
Cash, cash equivalents and marketable securities	\$	216,942	\$ 264,36	54
Working capital		193,178	232,70	)4
Total assets		265,264	374,75	58
al stockholders' equity		115,407	203,12	28

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### GENERATION BIO CO. CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited) (in thousands, except share and per share data)

	Three Months Ended June 30,				
		2024		2023	
Revenues:		_		_	
Collaboration Revenue	\$	4,091	\$	880	
Operating expenses:					
Research and development		16,388		21,832	
General and administrative		9,515		12,967	
Loss on lease termination		1,497			
Total operating expenses		27,400		34,799	
Loss from operations		(23,309)		(33,919)	
Other income:					
Other income and interest income, net		2,877		2,853	
Net loss	\$	(20,432)	\$	(31,066)	
Net loss per share, basic and diluted	\$	(0.31)	\$	(0.47)	
Weighted average common shares outstanding, basic and diluted		66,531,000		65,656,151	
Comprehensive loss:					
Net loss	\$	(20,432)	\$	(31,066)	
Other comprehensive loss:					
Unrealized losses on marketable securities		(83)		(57)	
Comprehensive loss	\$	(20,515)	\$	(31,123)	

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