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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 10, 2021**

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**Generation Bio Co.**

(Exact Name of Registrant as Specified in Charter)

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**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)

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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.

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

On November 10, 2021, Generation Bio Co. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended September 30, 2021. 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release Issued by Generation Bio Co. on November 10, 2021</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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## 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: November 10, 2021

GENERATION BIO CO.

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: President and Chief Executive Officer

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# Generation Bio Reports Business Highlights and Third Quarter 2021 Financial Results

*New preclinical retinal data illustrating potential for expansive therapeutic applications of ctLNP delivery presented at ESGCT 2021 Annual Virtual Congress*

**CAMBRIDGE, MASS., Nov. 10, 2021** -- Generation Bio Co. (Nasdaq: GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, reported recent business highlights and third quarter 2021 financial results.

“We are building a leading non-viral genetic medicine company with the potential to transform treatments within multiple therapeutic areas,” said Geoff McDonough, M.D., chief executive officer of Generation Bio. “We continue to advance our ceDNA, and next-generation rapid enzymatic synthesis technologies, and plan to provide data on factor VIII expression in non-human primates for our hemophilia A program by year-end. We also continue to develop our ctLNP delivery platform, and with the data recently presented at the ESGCT Congress, demonstrated a breakthrough for the retinal field, potentially paving the way for a wave of novel retinal therapies.”

## Business Highlights

- **Reported Preclinical Data Demonstrating Broad Delivery of ceDNA and mRNA to Photoreceptors using ctLNP:** In October 2021, Generation Bio presented preclinical data at the European Society of Gene and Cell Therapy (ESGCT) Annual Virtual Congress showing that sub-retinal delivery of closed-ended DNA using cell-targeted lipid nanoparticle (ctLNP-ceDNA) in rodents demonstrated broad distribution and durable expression that was comparable to that achieved with adeno-associated virus Type 5 (AAV5) (the current standard of delivery) in rodents, and tolerability. These findings support the use of ctLNP-ceDNA to potentially achieve full gene replacement for inherited retinal diseases. Similar results were observed for sub-retinal delivery of mRNA using ctLNP in both rodents and non-human primates. This first-ever demonstration of species translation with comparable tolerability and uniform photoreceptor expression across species using ctLNP suggests ctLNP could be a best-in-class non-viral delivery system for mRNA to the retina, potentially enabling gene editing in the retina.

## Third Quarter 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$398.4 million as of September 30, 2021, compared with \$262.3 million as of December 31, 2020.
- **R&D Expenses:** Research and development (R&D) expenses were \$22.0 million for the quarter ended September 30, 2021, compared to \$15.3 million for the quarter ended September 30, 2020.
- **G&A Expenses:** General and administrative (G&A) expenses were \$9.7 million for the quarter ended September 30, 2021, compared to \$5.7 million for the quarter ended September 30, 2020.

- **Net Loss:** Net loss was \$31.9 million, or \$0.56 basic and diluted net loss per share, for the quarter ended September 30, 2021, compared to a net loss of \$20.8 million for the quarter ended September 30, 2020.

### **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 tissues, 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](http://www.generationbio.com).

### **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the company, including statements about our strategic plans or objectives, our technology platform, our research and clinical development plans, the expected timing of the submission of investigational new drug, or IND, applications and preclinical data, our manufacturing plans, our expectations regarding our new facility 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 preclinical studies will be predictive of the results of later preclinical studies and clinical trials; uncertainties regarding the timing and ability to complete the build-out of the company's manufacturing facility and regarding the new manufacturing process; expectations regarding the timing of submission of IND applications; expectations for regulatory approvals to conduct trials or to market products; 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; as well as the other risks and uncertainties set forth in the "Risk Factors" section of our 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.

**Contacts:**

**Investors**

Maren Killackey  
Generation Bio  
541-646-2420  
mkillackey@generationbio.com

**Media**

Alicia Webb  
Generation Bio  
847-254-4275  
awebb@generationbio.com

Lisa Raffensperger  
Ten Bridge Communications  
617-903-8783  
lisa@tenbridgecommunications.com

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

<u>Earnings Release Balance Sheet</u>	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Cash, cash equivalents and marketable securities	\$ 398,363	\$ 262,327
Working capital	388,764	256,515
Total assets	464,033	294,155
Total stockholders' equity	407,210	268,013

**GENERATION BIO CO.  
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS  
(Unaudited)**

(in thousands, except share and per share data)

	<b>Three Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Operating expenses:		
Research and development	\$ 21,991	\$ 15,308
General and administrative	9,667	5,661
Total operating expenses	31,658	20,969
Loss from operations	(31,658)	(20,969)
Other (expense) income:		
Other (expense) and interest income, net	(197)	120
Net loss and net loss attributable to common stockholders	\$ (31,855)	\$ (20,849)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.56)	\$ (0.46)
Weighted average common shares outstanding, basic and diluted	56,629,193	45,468,838
Comprehensive loss:		
Net loss	\$ (31,855)	\$ (20,849)
Other comprehensive loss:		
Unrealized (losses) gains on marketable securities	(3)	30
Comprehensive loss	\$ (31,858)	\$ (20,819)