
**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): November 5, 2020

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 2.02 Results of Operations and Financial Condition.

On November 10, 2020, Generation Bio Co. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended September 30, 2020. 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 5, 2020, the Board of Directors of the Company appointed Dr. Douglas Kerr as Chief Medical Officer of the Company, effective as of November 9, 2020. Prior to being appointed the Company’s Chief Medical Officer, Dr. Kerr served as the Company’s Chief Development Officer. In connection with his appointment as Chief Medical Officer, Dr. Kerr will be replaced as Chief Development Officer by Dr. Tracy Zimmermann.

On November 5, 2020, Mark Angelino informed the Company of his intention to resign from his role as the Chief Operating Officer of the Company, effective as of early February 2021.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release Issued by Generation Bio Co. on November 10, 2020</u>

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: November 10, 2020

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: Chief Executive Officer



Generation Bio Reports Third Quarter 2020 Business Updates and Financial Results

On Track to Advance Lead Programs into Pre-Clinical Development in 2021 Supported by Key Leadership Team Appointments

Cambridge, Mass. – Nov. 10, 2020 – Generation Bio Co. (Nasdaq: GBIO) is an innovative genetic medicines company creating a new class of non-viral gene therapy. Today the company reported recent business highlights and third quarter financial results.

“2020 continues to be a year of progress and execution for Generation Bio as we advance our non-viral gene therapy approach,” said Geoff McDonough, M.D., president and chief executive officer of Generation Bio. “Despite the challenges of the COVID-19 pandemic, we remain on-track to advance our lead programs into IND-enabling preclinical development next year. We believe our strong cash balance positions us well to execute on our ambitions into 2023.”

Recent Business Highlights

“This period marks an expansion of our focus beyond our platform to include preclinical development and readiness for the clinic. To support this effort, I am pleased to announce the appointment of Tracy Zimmermann to chief development officer. Tracy will lead our pre-clinical development programs across the portfolio, building on the excellent foundation she has created since joining Generation Bio in 2018. Tracy’s new role allows for Doug Kerr to focus on building our clinical development capabilities as chief medical officer. Together with Matt Stanton, our chief scientific officer, Tracy and Doug make a terrific, complementary leadership team for our R&D work,” Dr. McDonough said. A summary of the leadership appointments follows.

- **Tracy Zimmermann, Ph.D., Appointed as Chief Development Officer:** Tracy previously served as vice president, preclinical research and translational biology. Prior to joining the company, Dr. Zimmermann held a variety of R&D roles over a 15-year tenure at Alnylam Pharmaceuticals. She received her Ph.D. from the University of Colorado at Boulder.
- **Doug Kerr, M.D., Ph.D., MBA, Appointed as Chief Medical Officer:** Doug joined Generation Bio in 2017 and has led R&D operations and strategic development of the company’s portfolio. He received his M.D. and Ph.D. from Jefferson Medical College and his MBA from Princeton University.

Dr. McDonough continued, “Separately, Mark Angelino, our chief operating officer and co-founder, will undertake a planned transition from Generation Bio to return to early stage company formation work in early 2021. Although too soon for farewells, we are indebted to Mark for his vision and leadership in forming and building our community here.”

Selected Anticipated Company Milestones

- Development candidate selection for hemophilia A and PKU in 2021
- Initiation of IND-enabling studies for hemophilia A and PKU in 2021

Upcoming Investor Conference Presentations

Management will present at two upcoming investor conferences:

- Dr. McDonough will present at the Stifel Virtual Healthcare Conference on Monday, Nov. 16, 2020 at 8:00 a.m. ET; and,
- Matthew Norkunas, M.D., MBA, chief financial officer, will participate in a fireside chat during the Jefferies Virtual London Healthcare Conference on Wednesday, Nov. 18, 2020 at 11:50 a.m. ET.

Live webcasts of the presentation and the fireside chat will be available in the investor section of the company's website at www.generationbio.com. The webcasts will be archived for 60 days following the presentations.

Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$280.4 million as of September 30, 2020.
- **R&D Expenses:** Research and development (R&D) expenses were \$15.3 million for the quarter ended September 30, 2020 compared to \$13.4 million for the same period of 2019.
- **G&A Expenses:** General and administrative (G&A) expenses were \$5.7 million for the quarter ended September 30, 2020 compared to \$2.9 million for the same period of 2019.
- **Net Loss:** Net loss was \$20.8 million for the quarter ended September 30, 2020 compared to \$16.1 million for the same period of 2019.

About Generation Bio

Generation Bio is an innovative genetic medicines company focused on creating a new class of non-viral gene therapy to provide durable, redosable treatments for people living with rare and prevalent diseases. The company's non-viral platform incorporates a proprietary, high-capacity DNA construct called closed-ended DNA, or ceDNA; a cell-targeted lipid nanoparticle delivery

system, or ctLNP; and an established, scalable capsid-free manufacturing process. The platform is designed to enable multi-year durability from a single dose of ceDNA and to allow titration and redosing if needed. The ctLNP is designed to deliver large genetic payloads, including multiple genes, to specific tissues to address a wide range of indications. The company's efficient, scalable manufacturing process supports Generation Bio's mission to extend the reach of gene therapy to more people, living with more diseases, in more places 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 its strategic plans or objectives, 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; expectations for regulatory approvals to conduct trials or to market products; challenges in the manufacture of genetic medicine products; the Company's ability to obtain sufficient cash resources to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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 the Company's most recent quarterly report on Form 10-Q, 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

Chelcie Lister
THRUST Strategic Communications
chelcie@thrustsc.com
910-777-3049

Media

Stephanie Simon

Ten Bridge Communications

stephanie@tenbridgecommunications.com

617-581-9333

GENERATION BIO CO.
CONSOLIDATED BALANCE SHEET DATA
(unaudited)
(in thousands)

	September 30, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	\$ 280,366	\$ 15,076
Working capital	276,650	8,998
Total assets	310,922	42,140
Convertible preferred stock	—	115,593
Total stockholders' equity (deficit)	286,539	(98,592)

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

	Three Months Ended September 30,	
	2020	2019
Operating expenses:		
Research and development	\$ 15,308	\$ 13,447
General and administrative	5,661	2,886
Total operating expenses	20,969	16,333
Loss from operations	(20,969)	(16,333)
Other income (expense):		
Interest income and other income (expense), net	120	205
Net loss and net loss attributable to common stockholders	\$ (20,849)	\$ (16,128)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.46)	\$ (3.31)
Weighted average common shares outstanding, basic and diluted	45,468,838	4,866,830