
**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 18, 2021

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 March 18, 2021, Generation Bio Co. (the “Company”) issued a press release announcing the Company’s financial results for the quarter and year ended December 31, 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

Exhibit No.	Description
99.1	<u>Press Release Issued by Generation Bio Co. on March 18, 2021</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: March 18, 2021

By: /s/ Geoff McDonough

Name: Geoff McDonough, M.D.

Title: Chief Executive Officer



Generation Bio Reports Fourth Quarter and Full Year 2020 Financial Results

\$262.3 million cash balance at the end of 2020 bolstered by additional net proceeds of \$211.3 million from follow-on offering, funding key milestones into 2024

Ron Cooper appointed to Board of Directors

Company remains on track to begin IND-enabling studies for hemophilia A in 2021

CAMBRIDGE, MASS., March 18, 2021 — Generation Bio Co. (Nasdaq: GBIO), an innovative genetic medicines company creating a new class of non-viral gene therapy, reported recent business highlights and fourth quarter and full year 2020 financial results.

“2020 was a foundational year for Generation Bio in which we strengthened the leadership team, advanced our platform science, and added substantially to our balance sheet to fund our lead programs to human data,” said Geoff McDonough, M.D., president and chief executive officer of Generation Bio. “We entered 2021 with preclinical data in mice and non-human primates that we believe demonstrate our platform’s potential to go beyond what is currently possible with gene therapy for hemophilia A. We expect to announce additional data throughout the remainder of this year that will support the rapid expansion of our pipeline and showcase our differentiated approach to creating a new class of genetic medicine.”

Recent Business Highlights

- **Raised \$225.4 million in gross proceeds from follow-on offering:** In January 2021, Generation Bio closed a public offering of 9,200,000 shares of its common stock at a public offering price of \$24.50 per share, including 1,200,000 additional shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the offering, before deducting the underwriting discount and commissions and other offering expenses payable by Generation Bio, were approximately \$225.4 million.
- **Appointed Ron Cooper to Board of Directors:** In February 2021, Generation Bio announced the appointment of Ron Cooper to its Board of Directors. Mr. Cooper is a global biopharmaceutical executive who currently serves as president, chief executive officer and board member of Albireo Pharma, Inc.
- **Announced preclinical data that support development candidate selection for hemophilia A program:** Also in January 2021, the company reported data from a series of preclinical studies evaluating the expression of factor VIII in both mice and non-human primates (NHP). Data in mice showed that a single dose of a closed-ended DNA (ceDNA) construct delivered via the company’s novel, cell-targeted lipid nanoparticle (ctLNP) system led to mean human factor VIII expression levels from 9% to 23% of normal with a dose response across the three cohorts. In two additional separate studies, a mean 2:1 species translation ratio from mice to NHPs was observed, consistent with best-in-class translation ratios seen for other nucleic acids delivered via LNPs.

Selected Anticipated Company Milestones in 2021

- NHP factor VIII expression data for hemophilia A development candidate
- NHP factor IX expression, durability and redosing data
- Initiation of IND-enabling studies for phenylketonuria (PKU)
- Preclinical data for Gaucher disease and Wilson disease
- Preclinical data for expression of therapeutic antibodies

Fourth Quarter and Full Year 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$262.3 million as of December 31, 2020, compared with \$15.1 million as of December 31, 2019. Cash at December 31, 2020 does not include the \$211.3 million in net proceeds received from the follow-on public offering completed in January 2021.
- **R&D Expenses:** Research and development (R&D) expenses were \$16.4 million for the quarter ended December 31, 2020 and \$58.5 million for the year ended December 31, 2020, compared to \$12.7 million for the quarter ended December 31, 2019 and \$50.1 million for the year ended December 31, 2019.
- **G&A Expenses:** General and administrative (G&A) expenses were \$8.0 million for the quarter ended December 31, 2020 and \$22.6 million for the year ended December 31, 2020, compared to \$3.4 million for the quarter ended December 31, 2019 and \$12.2 million for the year ended December 31, 2019.
- **Net Loss:** Net loss was \$24.2 million, or \$0.53 basic and diluted net loss per share, for the quarter ended December 31, 2020 and \$80.5 million, or \$2.95 basic and diluted net loss per share, for the year ended December 31, 2020, compared to a net loss of \$16.1 million, or \$3.09 basic and diluted net loss per share, for the quarter ended December 31, 2019 and \$61.3 million, or \$12.96 basic and diluted net loss per share, for the year ended December 31, 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 engineered 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.

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 platforms, our research and clinical development plans, 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; 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 quarterly report on Form 10-Q, 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.

Contacts:

Investors

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

Media

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

Stephanie Simon
Ten Bridge Communications
617-581-9333
stephanie@tenbridgecommunications.com

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

	December 31,	
	2020	2019
Cash, cash equivalents and marketable securities	\$262,327	\$ 15,076
Working capital	256,515	8,998
Total assets	294,155	42,140
Convertible preferred stock	—	115,593
Total stockholders' equity (deficit)	268,013	(98,592)

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating expenses:				
Research and development	\$ 16,374	\$ 12,731	\$ 58,532	\$ 50,134
General and administrative	7,971	3,427	22,582	12,168
Total operating expenses	<u>24,345</u>	<u>16,158</u>	<u>81,114</u>	<u>62,302</u>
Loss from operations	(24,345)	(16,158)	(81,114)	(62,302)
Other income (expense):				
Interest income and other income (expense), net	119	95	591	985
Net loss and net loss attributable to common stockholders	<u>\$ (24,226)</u>	<u>\$ (16,063)</u>	<u>\$ (80,523)</u>	<u>\$ (61,317)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.53)</u>	<u>\$ (3.09)</u>	<u>\$ (2.95)</u>	<u>\$ (12.96)</u>
Weighted average common shares outstanding, basic and diluted	<u>45,855,896</u>	<u>5,205,942</u>	<u>27,256,494</u>	<u>4,731,519</u>
Comprehensive loss:				
Net loss	\$ (24,226)	\$ (16,063)	\$ (80,523)	\$ (61,317)
Other comprehensive income:				
Unrealized (loss) gain on marketable securities	(17)	(2)	9	9
Comprehensive loss	<u>\$ (24,243)</u>	<u>\$ (16,065)</u>	<u>\$ (80,514)</u>	<u>\$ (61,308)</u>