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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to_____

Commission File Number: 001-39319

GENERATION BIO CO.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**81-4301284** **(I.R.S. Employer Identification Number)**
301 Binney Street **Cambridge, Massachusetts** **(Address of principal executive offices)**	**02142** **(Zip Code)**

(617) 655-7500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 Par Value	**GBIO**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 29, 2022 there were 57,087,958 shares of Common Stock, $0.0001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, of Generation Bio Co. contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs and preclinical studies and clinical trials;
- our estimates regarding expenses, future revenue, capital requirements, need for additional financing and the period over which we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- the timing of and our ability to complete the build-out and regulatory agency review of our manufacturing facility;
- our ability to operate our manufacturing facility to manufacture for clinical and commercial supply;
- the potential advantages of our non-viral genetic medicine platform;
- our plans to develop and, if approved, subsequently commercialize any product candidates we may develop;
- the timing of and our ability to submit applications and obtain and maintain regulatory approvals for any product candidates we may develop;
- our estimates regarding the potential addressable patient populations for our programs;
- our commercialization and marketing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the impact of the COVID-19 pandemic and our response to the pandemic;
- the impact of government laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- developments and expectations regarding developments and projections relating to our competitors and our industry; and

- our ability to maintain and establish collaborations or obtain additional funding.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and stockholders should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report, particularly in the "Risk Factors" section in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a competitive and rapidly changing environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures, or investments we may make or enter into.

Stockholders should read this Quarterly Report and the documents that we file with the SEC with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report are made as of the date of this Quarterly Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Except where the context otherwise requires or where otherwise indicated, the terms "we," "us," "our," "our company," "the company," and "our business" in this Quarterly Report refer to Generation Bio Co. and its consolidated subsidiary.

Generation Bio Co.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

Generation Bio Co.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 336,978	$ 375,145
Prepaid expenses and other current assets	4,585	4,041
Total current assets	341,563	379,186
Property and equipment, net	27,846	25,886
Operating lease right-of-use assets	62,882	65,143
Restricted cash	5,692	5,692
Deferred offering costs	461	461
Other long-term assets	5,582	403
Total assets	$ 444,026	$ 476,771
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,547	$ 2,023
Accrued expenses and other current liabilities	8,927	12,177
Operating lease liability	4,780	4,608
Total current liabilities	15,254	18,808
Operating lease liability, net of current portion	75,857	76,217
Total liabilities	91,111	95,025
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized at March 31, 2022 and December 31, 2021; 57,004,128 and 56,980,701 shares issued at March 31, 2022 and December 31, 2021, respectively; 57,004,128 and 56,969,618 shares outstanding at March 31, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	696,034	689,866
Accumulated other comprehensive income	—	—
Accumulated deficit	(343,125)	(308,126)
Total stockholders' equity	352,915	381,746
Total liabilities and stockholders' equity	$ 444,026	$ 476,771

The accompanying notes are an integral part of these condensed consolidated financial statements.

Generation Bio Co.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 25,554	$ 18,753
General and administrative	9,790	6,902
Total operating expenses	35,344	25,655
Loss from operations	(35,344)	(25,655)
Other income:		
Other income and interest income	345	93
Net loss and net loss attributable to common stockholders	$ (34,999)	$ (25,562)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (0.46)
Weighted average common shares outstanding, basic and diluted	56,996,495	55,366,238
Comprehensive loss:		
Net loss	$ (34,999)	$ (25,562)
Other comprehensive loss:		
Unrealized gains on marketable securities	—	1
Comprehensive loss	$ (34,999)	$ (25,561)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Generation Bio Co.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Three Months Ended March 31, 2022					
Balances at December 31, 2021	56,969,618	$ 6	$ 689,866	$ —	$ (308,126)	$ 381,746
Issuance of common stock upon exercise of stock options	21,787	—	102	—	—	102
Vesting of restricted common stock	12,723	—	—	—	—	—
Stock-based compensation expense	—	—	6,066	—	—	6,066
Unrealized gains on marketable securities	—	—	—	—	—	—
Net loss	—	—	—	—	(34,999)	(34,999)
Balances at March 31, 2022	57,004,128	$ 6	$ 696,034	$ —	$ (343,125)	$ 352,915

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Three Months Ended March 31, 2021					
Balances at December 31, 2020	46,291,877	$ 5	$ 456,974	$ 9	$ (188,975)	$ 268,013
Issuance of common stock upon public offering, net of issuance costs of $590	9,200,000	1	211,285	—	—	211,286
Issuance of common stock upon exercise of stock options	387,578	—	1,519	—	—	1,519
Vesting of restricted common stock	215,074	—	—	—	—	—
Stock-based compensation expense	—	—	3,479	—	—	3,479
Unrealized gains on marketable securities	—	—	—	1	—	1
Net loss	—	—	—	—	(25,562)	(25,562)
Balances at March 31, 2021	56,094,529	$ 6	$ 673,257	$ 10	$ (214,537)	$ 458,736

The accompanying notes are an integral part of these condensed consolidated financial statements.

Generation Bio Co.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (34,999)	$ (25,562)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,066	3,479
Depreciation and amortization expense	1,197	1,064
Amortization (accretion) of premium (discount) on marketable securities, net	—	260
Loss on sale of property and equipment	28	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(531)	704
Other noncurrent assets	(3,105)	(334)
Accounts payable	(684)	(145)
Accrued expenses and other current liabilities	(3,407)	(2,493)
Net cash used in operating activities	(35,435)	(23,027)
Cash flows from investing activities:		
Purchases of property and equipment	(2,784)	(915)
Maturities of marketable securities	—	114,400
Net cash (used in) provided by investing activities	(2,784)	113,485
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of underwriting discounts and commissions	—	211,876
Payment of offering costs	(50)	(438)
Proceeds from exercise of stock options and other types of equity, net	102	1,519
Net cash provided by financing activities	52	212,957
Net increase in cash, cash equivalents and restricted cash	(38,167)	303,415
Cash, cash equivalents and restricted cash at beginning of period	380,837	64,940
Cash, cash equivalents and restricted cash at end of period	$ 342,670	$ 368,355
Supplemental disclosure of noncash investing and financing information:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 1,928	$ 64
Offering costs included in accounts payable and accrued expenses	$ —	$ 111

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Nature of the Business and Basis of Presentation

Generation Bio Co., or Generation Bio, was incorporated on October 21, 2016 as Torus Therapeutics, Inc. and subsequently changed its name to Generation Bio Co. Generation Bio Co. and its consolidated subsidiary, or the company, we, our or us, are innovating genetic medicines to provide durable, redosable treatments for potentially hundreds of millions of patients living with rare and prevalent diseases. Our non-viral genetic medicines platform incorporates our high-capacity DNA construct called closed-ended DNA, or ceDNA; our cell-targeted lipid nanoparticle delivery system, or ctLNP; and our highly scalable capsid-free manufacturing process that uses our proprietary cell-free rapid enzymatic synthesis, or RES, to produce ceDNA. Using our approach, we are developing novel genetic medicines to provide targeted delivery of genetic payloads that include large and multiple genes to a range of cell types across a broad array of diseases. We are also engineering our genetic medicines to be redosable, which may enable individualized patient titration to reach the desired therapeutic expression and to maintain efficacy throughout a patient's life. We are headquartered in Cambridge, Massachusetts.

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainties regarding the timing and ability to complete the build-out of our manufacturing facility, the ability to establish clinical- and commercial-scale manufacturing processes and the ability to secure additional capital to fund operations. Programs currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization of a product. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales.

In June 2020, we completed our initial public offering, or IPO, pursuant to which we issued and sold 12,105,263 shares of our common stock, including 1,578,947 shares pursuant to the full exercise of the underwriters' option to purchase additional shares resulting in net proceeds of $210.7 million, after deducting underwriting discounts and commissions and other offering expenses. Upon the closing of the IPO, all of our outstanding convertible preferred stock automatically converted into shares of common stock. In January 2021, we issued and sold 9,200,000 shares of our common stock, including 1,200,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, in a follow-on public offering, resulting in net proceeds of $211.3 million after deducting underwriting discounts and commissions and other offering expenses.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, we have funded our operations with proceeds from the sale of instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the sales of convertible preferred stock (which converted into common stock in 2020), and most recently, the sale of common stock in underwritten public offerings. We have incurred recurring losses, including net losses of $35.0 million for the three months ended March 31, 2022 and $25.6 million for the three months ended March 31, 2021. As of March 31, 2022, we had an accumulated deficit of $343.1 million. We expect to continue to generate operating losses in the foreseeable future. As of May 5, 2022, the issuance date of these condensed consolidated financial statements, we expect that our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements for at least 12 months.

We will need to obtain additional funding through public or private equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. We may not be able to obtain financing on acceptable terms, or at all, and we may not be able to enter into collaborative or strategic alliances or licensing arrangements. The terms of any financing may adversely affect the holdings or the rights of our stockholders. Arrangements with collaborators or others may require us to relinquish rights to certain of our technologies or programs. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs, pipeline expansion or commercialization efforts, which could adversely affect our business prospects. Although management will continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations when needed or at all.

The accompanying condensed consolidated financial statements reflect the operations of Generation Bio and our wholly owned subsidiary, Generation Bio Securities Corporation. Intercompany balances and transactions have been eliminated in consolidation. The accompanying condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America, or GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB.

2. Summary of Significant Accounting Policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses and stock-based compensation expense. We base our estimates on historical experience, known trends and other market-specific or other relevant factors that we believe to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Unaudited interim financial information

The condensed consolidated balance sheet as of December 31, 2021 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of March 31, 2022 and for the three months ended March 31, 2022 and 2021 have been prepared by us pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These financial statements should be read in conjunction with our audited financial statements included in our Annual Report on Form 10-K that was most recently filed with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair presentation of our financial position as of March 31, 2022, the results of operations for the three months ended March 31, 2022 and 2021, and cash flows for the three months ended March 31, 2022 and 2021 have been made. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022 or any other period.

Our significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2021.

3. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	March 31, 2022	December 31, 2021
Accrued employee compensation and benefits	$ 3,392	$ 7,579
Accrued external research and development expenses	1,969	2,091
Property and equipment	1,720	869
Accrued professional fees	930	962
Other	916	676
Total	$ 8,927	$ 12,177

4. Equity

As of March 31, 2022, our amended and restated certificate of incorporation authorizes us to issue 150,000,000 shares of common stock, par value $0.0001 per share, and 5,000,000 shares of preferred stock, par value $0.0001 per share, all of which preferred stock is undesignated.

In January 2021, we issued and sold 9,200,000 shares of our common stock, including 1,200,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, in a follow-on public offering, resulting in net proceeds of $211.3 million after deducting underwriting discounts and commissions and other offering expenses. In August 2021, we entered into an "at-the-market" sales agreement pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $250.0 million. As of May 5, 2022, the issuance date of these condensed consolidated financial statements, we have not issued and sold any shares of our common stock pursuant to this sales agreement.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of our stockholders. Holders of common stock are not entitled to receive dividends, unless declared by the board of directors.

5. Stock-Based Compensation

Stock incentive plans

Our 2017 Stock Incentive Plan, or the 2017 Plan, provided for us to grant incentive stock options or nonstatutory stock options, restricted stock, restricted stock units and other equity awards to employees, non-employees, and directors. In January 2020, the number of shares of common stock authorized for issuance under the 2017 Plan was increased from 8,407,405 shares to 10,275,717 shares.

In May 2020, our board of directors adopted, and in June 2020, our stockholders approved, the 2020 Stock Incentive Plan, or the 2020 Plan, and, together with the 2017 Plan, the Plans, which became effective on June 11, 2020. The 2020 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of common stock reserved for issuance under the 2020 Plan is the sum of (1) 2,547,698 shares; plus (2) the number of shares (up to a maximum of 7,173,014 shares) as was equal to the sum of (x) the number of shares of common stock reserved for issuance under the 2017 Plan that remained available for grant under the 2017 Plan on June 11, 2020 and (y) the number of shares of common stock subject to outstanding awards granted under the 2017 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual

increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing until, and including, the fiscal year ending December 31, 2030, equal to the lesser of (i) 4% of the number of shares of common stock outstanding on such date, and (ii) an amount determined by the board of directors. In January 2021 and 2022, the number of shares of common stock authorized for issuance under the 2020 Plan was increased from 10,275,717 shares to 12,154,517 shares and from 12,154,517 shares to 14,433,745 shares, respectively. Upon the effectiveness of the 2020 Plan, we ceased granting additional awards under the 2017 Plan.

The Plans are administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions on any award under the Plans are determined at the discretion of the board of directors, or its committee if so delegated. Stock options granted under the Plans with service-based vesting conditions generally vest over four years and expire after ten years. The exercise price for stock options granted is not less than the fair value of common stock as of the date of grant. Prior to our IPO, fair value of common stock was determined by the board of directors. Subsequent to our IPO, fair value of common stock is based on quoted market prices.

As of March 31, 2022, 1,113,191 shares remained available for future issuance under the 2020 Plan. Shares subject to outstanding awards granted under the Plans that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right will be available for future awards under the 2020 Plan.

Grant of stock options

During the three months ended March 31, 2022, we granted service-based options to certain employees for the purchase of 2,537,390 shares of common stock with a weighted average grant date fair value of $4.77 per share that vest over a weighted average period of approximately four years.

Restricted stock units

During the three months ended March 31, 2022, we issued 1,604,809 restricted stock units with a fair value of $10.4 million that vest over a weighted average period of approximately 2.2 years.

Employee stock purchase plan

In May 2020, our board of directors adopted, and in June 2020, our stockholders approved, the 2020 Employee Stock Purchase Plan, or the 2020 ESPP, which became effective June 11, 2020. The 2020 ESPP is administered by our board of directors or by a committee appointed by the board of directors. The number of shares of common stock reserved for issuance under the 2020 ESPP automatically increases on the first day of each fiscal year, beginning with the fiscal year that commenced on January 1, 2021 and continuing for each fiscal year until, and including the fiscal year commencing on, January 1, 2030, in an amount equal to the lowest of (1) 1,302,157 shares of common stock, (2) 1% of the number of shares of common stock outstanding on such date, and (3) an amount determined by the board of directors. In January 2022, the number of shares of common stock authorized for issuance under the 2020 ESPP was increased from 950,931 shares to 1,520,738 shares. As of March 31, 2022, 1,482,231 shares remained available for issuance under the 2020 ESPP .

Stock-based compensation

Stock-based compensation expense was classified in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended March 31,	
(in thousands)	**2022**	**2021**
Research and development expenses	$ 3,151	$ 1,898
General and administrative expenses	2,915	1,581
Total	$ 6,066	$ 3,479

As of March 31, 2022, total unrecognized compensation cost related to unvested stock options and restricted common stock was $61.2 million, with $52.0 million expected to be recognized over a weighted average period of 2.8 years and $9.2 million expected to be recognized over a weighted average period of 2.0 years, respectively. Additionally, as of March 31, 2022, we had unrecognized compensation cost related to unvested stock options with performance-based vesting conditions for which performance has not been deemed probable of $1.8 million.

6. Commitments and Contingencies

401(k) Plan

We have a defined-contribution plan under Section 401(k) of the Internal Revenue Code of 1986, as amended, or the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to contribute a portion of their annual compensation on a pre-tax and/or after-tax basis. In September 2020, we adopted a match program, beginning on January 1, 2021, for employee contributions to the 401(k) Plan up to a maximum of four percent of the employee's salary, subject to the maximums established under the U.S. Internal Revenue Code of 1986, as amended.

Indemnification agreements

In the ordinary course of business, we may provide indemnification of varying scope and terms to vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with members of our board of directors and our officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments we could be required to make under these indemnification agreements is, in many cases, unlimited. We have not incurred any material costs as a result of such indemnifications and are not currently aware of any indemnification claims.

Legal proceedings

We, from time to time, may be party to litigation arising in the ordinary course of business. We were not subject to any material legal proceedings during the three months ended March 31, 2022.

7**. Net Loss per Share**

We have generated a net loss in all periods presented, therefore the basic and diluted net loss per share attributable to common stockholders are the same as the inclusion of the potentially dilutive securities would be anti-dilutive. We excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated:

	March 31,	
	2022	2021
Unvested restricted common stock	—	482,728
Unvested restricted common stock units	1,537,744	18,040
Stock options to purchase common stock	8,473,696	5,801,170
Total	10,011,440	6,301,938

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations are meant to provide material information relevant to an assessment of the financial condition and results of operations of our company, including an evaluation of the amounts and uncertainties of cash flows from operations and from outside resources, so as to allow investors to better view our company from management's perspective. It should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our consolidated financial statements and related notes appearing in our most recently filed Annual Report on Form 10-K, or Annual Report, with the Securities and Exchange Commission, or SEC. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, in our Annual Report and in the other documents filed with the SEC, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are innovating genetic medicines to provide durable, redosable treatments for potentially hundreds of millions of patients living with rare and prevalent diseases. Our non-viral genetic medicine platform incorporates our high-capacity ceDNA; our ctLNP delivery system; and our highly scalable capsid-free manufacturing process that uses our proprietary cell-free rapid enzymatic synthesis, or RES, to produce ceDNA. Using our approach, we are developing novel genetic medicines to provide targeted delivery of genetic payloads that include large and multiple genes to a range of cell types across a broad array of diseases. We are also engineering our genetic medicines to be redosable, which may enable individualized patient titration to reach the desired level of therapeutic expression and to maintain efficacy throughout a patient's life.

We are advancing a broad and expansive portfolio of programs, including programs for rare and prevalent diseases of the liver and retina. We are focused on diseases with significant unmet need for which our non-viral genetic medicine platform may substantially improve clinical efficacy relative to current gene therapy approaches. We are initially prioritizing rare monogenic diseases of the liver and retina, which are diseases that result from mutations in a single gene, that have well-established biomarkers and clear clinical and regulatory pathways.

In addition, we believe that our non-viral genetic medicine platform may be used to develop therapies that deliver antibody genes to direct the liver to produce antibody therapies from patients' own cells for years at a time from a single dose in a process we refer to as endogenous therapeutic antibody production, or ETAP. We plan to advance ETAP programs across multiple therapeutic areas, including prevalent indications.

We also believe that our platform may be used to develop other therapeutic modalities and are exploring ways to apply our platform technologies. For example, we are conducting early research into the development of potential messenger RNA-, or mRNA-, based vaccines and ceDNA-based vaccines, in each case, using our proprietary ctLNPs for vaccines. We believe mRNA-ctLNP and ceDNA-ctLNP vaccines could meet or exceed the benchmark for efficacy and duration of current mRNA-LNP vaccines in use. In particular, we believe ceDNA-ctLNP vaccines could enable more durable antigen expression, and could be stored at ambient temperatures, potentially allowing for greater shelf stability than currently approved mRNA-LNP vaccines, which currently must be stored at very low temperatures, limiting distribution.

Furthermore, we plan to expand our portfolio to include rare and prevalent diseases of the skeletal muscle, the central nervous system and oncology by developing discrete ctLNPs, each engineered to reach a different tissue.

Since our inception in October 2016, we have focused substantially all of our resources on building our non-viral genetic medicine platform, establishing and protecting our intellectual property portfolio, conducting research and development activities, developing our manufacturing process, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations with proceeds from the sale of instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the

sales of convertible preferred stock (which converted into common stock in 2020) and, most recently, the sale of common stock in our public offerings. In June 2020, we completed our initial public offering, or IPO, pursuant to which we issued and sold 12,105,263 shares of our common stock, including 1,578,947 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares. We received net proceeds of $210.7 million, after deducting underwriting discounts and commissions and other offering expenses. In January 2021, we issued and sold 9,200,000 shares of our common stock, including 1,200,000 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares, in a follow-on public offering, resulting in net proceeds of $211.3 million after deducting underwriting discounts and commissions and other offering expenses.

Historically, we have incurred significant operating losses. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more product candidates we may develop. For the three months ended March 31, 2022 and 2021, we reported net losses of $35.0 million and $25.6 million, respectively. As of March 31, 2022, we had an accumulated deficit of $343.1 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- continue our current research programs and conduct additional research programs;
- expand the capabilities of our proprietary non-viral genetic medicine platform;
- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development, future commercialization efforts and operations as a public company;
- hire additional clinical, regulatory and scientific personnel;
- advance any product candidates we identify into preclinical and clinical development;
- build out and maintain a commercial-scale current Good Manufacturing Practice-compliant manufacturing facility;
- establish additional commercial manufacturing sources and secure supply chain capacity sufficient to provide necessary quantities of any product candidates we may develop for clinical or commercial use;
- seek marketing approvals for any product candidates that successfully complete clinical trials; and
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for any product candidates we may develop. If we obtain regulatory approval for any product candidates we may develop, we expect to incur significant expenses related to developing our commercial capability to support product sales, marketing and distribution. Further, we expect to continue to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditures into 2024. We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong. We could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. See "—Liquidity and Capital Resources."

COVID-19

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and to date, the COVID-19 pandemic continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and difficult to predict. We, our contract development and manufacturing organizations, or CDMOs, and our contract research organizations, or CROs, experienced temporary reductions in the capacity to undertake research-scale production and to execute some preclinical studies. While these operations have since normalized, we, together with our CDMOs and CROs, are closely monitoring the impact of the COVID-19 pandemic on these operations. In addition, shortages, delays and governmental restrictions arising from the COVID-19 pandemic have disrupted and may continue to disrupt global supply chains and our vendors' ability to procure items, such as raw materials, that are essential for the manufacturing of our product candidates or needed to build out our manufacturing facility. We have taken steps to monitor and strengthen our supply chain to maintain an uninterrupted supply of our critical products and services.

We plan to continue to closely monitor the ongoing impact of the COVID-19 pandemic on our employees and our other business operations. In an effort to provide a safe work environment for our employees, we are continuing to maintain our increased cadence of sanitization of our office and lab facilities, implementation of various social distancing measures in our office and lab facilities, and provision of personal protective equipment for our employees present in our office and lab facilities. We are continuing to monitor the impact and effects of the COVID-19 pandemic and our response to it and, in accordance with updated federal and state guidelines, we have relaxed some of our COVID-19 related restrictions. For example, we are permitting on-site presence in our office and lab facilities. Additionally, we implemented a new company policy concerning COVID-19 vaccinations effective during the first quarter of 2022, which includes mandatory vaccination requirements for all employees, with certain limited exceptions.

We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of the pandemic.

Components of Our Results of Operations

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our programs, which include:

- personnel-related costs, including salaries, benefits and stock-based compensation expense, for employees engaged in research and development functions;

- expenses incurred in connection with our research programs, including under agreements with third parties, such as consultants, contractors and CROs, and regulatory agency fees;
- the cost of developing and scaling our manufacturing process and manufacturing drug substance and drug product for use in our research and preclinical studies, including under agreements with third parties, such as consultants, contractors and CDMOs;
- laboratory supplies and research materials;
- facilities, depreciation and amortization and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our external research and development expenses consist of costs that include fees and other costs paid to consultants, contractors, CDMOs and CROs in connection with our research, preclinical and manufacturing activities. We do not allocate our research and development costs to specific programs because costs are deployed across multiple programs and our platform and, as such, are not separately classified. We expect that our research and development expenses will increase substantially as we advance our programs into clinical development and expand our discovery, research and preclinical activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any product candidates we may develop. The successful development of any of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development, including the following:

- the timing and progress of preclinical studies, including investigational new drug, or IND , -enabling studies;
- the number and scope of preclinical and clinical programs we decide to pursue;
- raising additional funds necessary to complete preclinical and clinical development of our product candidates;
- the timing of the submission and acceptance of IND applications or comparable foreign applications that allow commencement of future clinical trials for our product candidates;
- the successful initiation, enrollment and completion of clinical trials, including under Good Clinical Practices;
- our ability to achieve positive results from our future clinical programs that support a finding of safety and effectiveness and an acceptable risk-benefit profile in the intended patient populations of any product candidates we may develop;
- our ability to build out our manufacturing facility and scale RES to produce clinical and initial commercial supply;
- our ability to establish arrangements with third-party manufacturers for preclinical and clinical supply;
- the availability of specialty raw materials for use in production of our product candidates;
- our ability to establish new licensing or collaboration arrangements;
- the receipt and related terms of regulatory approvals from the U.S. Food and Drug Administration and other applicable regulatory authorities;

- our ability to establish, obtain, maintain, enforce and defend patent, trademark, trade secret protection and other intellectual property rights or regulatory exclusivity for any product candidates we may develop and our technology; and

- our ability to maintain a continued acceptable safety, tolerability and efficacy profile of our product candidates following approval.

A change in the outcome of any of these variables with respect to any product candidates we may develop could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidates we may develop.

General and administrative expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, benefits and stock-based compensation, for employees engaged in executive, legal, finance and accounting and other administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, investor and public relations and accounting and audit services as well as direct and allocated facility-related costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our programs and platform. We also anticipate that we will continue to incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs and investor and public relations expenses associated with operating as a public company.

Other income and interest income

Other income and interest income consists of interest income earned on our invested cash balances and other miscellaneous income unrelated to our core operations.

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021:

(in thousands)	Three Months Ended March 31, 2022	2021	Change 2022 vs 2021
Operating expenses:			
Research and development	$ 25,554	$ 18,753	$ 6,801
General and administrative	9,790	6,902	2,888
Total operating expenses	35,344	25,655	9,689
Loss from operations	(35,344)	(25,655)	(9,689)
Other income:			
Other income and interest income	345	93	252
Net loss	$ (34,999)	$ (25,562)	$ (9,437)

Research and development expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2022 and 2021:

(in thousands)	Three Months Ended March 31, 2022	2021	Change 2022 vs 2021
Personnel-related	$ 7,746	$ 5,388	$ 2,358
Preclinical and manufacturing	4,641	5,829	(1,188)
Facilities	5,339	2,220	3,119
Stock-based compensation	3,151	1,898	1,253
Lab supplies	1,479	1,630	(151)
Consulting and professional services	1,010	458	552
Other	2,188	1,330	858
Total research and development expenses	$ 25,554	$ 18,753	$ 6,801

Research and development expenses were $25.6 million for the three months ended March 31, 2022, compared to $18.8 million for the three months ended March 31, 2021. The increase in facilities costs of $3.1 million was primarily driven by the recognition of rent expense related to the lease of our manufacturing facility. The increases in personnel-related costs of $2.4 million and stock-based compensation costs of $1.3 million were primarily due to increased headcount in our research and development function. These increases were partially offset by a decrease in preclinical and manufacturing costs of $1.2 million primarily due to a decrease in costs as we transitioned to our in-house RES manufacturing process in the second half of 2021.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2022 and 2021:

(in thousands)	Three Months Ended March 31, 2022	2021	Change 2022 vs 2021
Personnel-related	$ 4,057	$ 3,038	$ 1,019
Stock-based compensation	2,915	1,581	1,334
Professional and consultant fees	2,049	1,416	633
Facilities	126	446	(320)
Other	643	421	222
Total general and administrative expenses	$ 9,790	$ 6,902	$ 2,888

General and administrative expenses were $9.8 million for the three months ended March 31, 2022, compared to $6.9 million for the three months ended March 31, 2021. The increase in stock-based compensation costs and personnel-related costs of $1.3 million and $1.0 million, respectively, were primarily a result of an increase in headcount in our general and administrative function.

Other income and interest income

Other income and interest income for the three months ended March 31, 2022 was $0.3 million as compared to $0.1 million for the three months ended March 31, 2021. The increase in other income and interest income was primarily due to a nonrecurring gain recognized during the three months ended March 31, 2022 related to an amendment of our Cambridge, Massachusetts office and laboratory space lease, partially offset by a decrease in interest income earned on our invested cash balances.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we support our continued research activities and development of our programs and platform. We have not yet commercialized any product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. To date, we have funded our operations with proceeds from instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the sale of convertible preferred stock (which converted into common stock in 2020) and with proceeds from the sale of common stock in our public offerings. In June 2020, we completed our IPO, pursuant to which we issued and sold 12,105,263 shares of our common stock, including 1,578,947 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares. We received net proceeds of $210.7 million, after deducting underwriting discounts and commissions and other offering expenses. In January 2021, we issued and sold 9,200,000 shares of our common stock, including 1,200,000 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares, in a follow-on public offering, resulting in net proceeds of $211.3 million, after deducting underwriting discounts and commissions and other offering expenses. In August 2021, we entered into an "at-the-market" sales agreement pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $250.0 million. As of May 5, 2022, the issuance date of the condensed consolidated financial statements, we have not issued and sold any shares of our common stock pursuant to this sales agreement. As of March 31, 2022, we had cash and cash equivalents of $337.0 million.

Cash flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Three Months Ended March 31,	
(in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (35,435)	$ (23,027)
Net cash (used in) provided by investing activities	(2,784)	113,485
Net cash provided by financing activities	52	212,957
Net increase in cash, cash equivalents and restricted cash	$ (38,167)	$ 303,415

Operating activities

During the three months ended March 31, 2022, operating activities used $35.4 million of cash, primarily resulting from our net loss of $35.0 million, offset by non-cash charges of $7.3 million and changes in our operating assets and liabilities of $7.7 million. Net cash used by changes in our operating assets and liabilities for the three months ended March 31, 2022 consisted of a $4.1 million decrease of accrued expense and other current liabilities and accounts payable, $3.1 million increase in other noncurrent assets and a $0.5 million increase in prepaid expenses and other current assets.

During the three months ended March 31, 2021, operating activities used $23.0 million of cash, primarily resulting from our net loss of $25.6 million and changes in our operating assets and liabilities of $2.3 million, both partially offset by non-cash charges of $4.8 million. Net cash used by changes in our operating assets and liabilities for the three months ended March 31, 2021 consisted primarily of a $2.5 million decrease in accrued expenses and other current liabilities and a $0.3 million increase in other noncurrent assets, partially offset by a $0.7 million decrease in prepaid expenses and other current assets.

Changes in accounts payable, accrued expenses and other current liabilities, prepaid expenses, and other long term assets in the periods were generally due to growth in our business and the timing of vendor invoicing and payments.

Investing activities

During the three months ended March 31, 2022, net cash used in investing activities was $2.8 million, due to an increase in purchases of property and equipment during the period. During the three months ended March 31, 2021, net cash provided by investing activities was $113.5 million, due to the maturities of marketable securities of $114.4 million, partially offset by a $0.9 million increase in purchases of property and equipment during the period.

Property and equipment purchases during the three months ended March 31, 2022 and 2021 were primarily related to leasehold improvements and lab equipment for our facility in Cambridge, Massachusetts.

Financing activities

During the three months ended March 31, 2022, net cash provided by financing activities was $0.1 million, consisting of proceeds from the exercise of common stock options during the period. During the three months ended March 31, 2021, net cash provided by financing activities was $213.0 million, consisting primarily of proceeds from our follow-on public offering of common stock of $211.9 million, net of underwriting discounts and commissions, and proceeds of $1.5 million from the exercise of common stock options, partially offset by the payment of $0.4 million of public offering costs.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and initiate clinical trials for our product candidates in development. The timing and amount of our operating expenditures will depend largely on:

- the identification of additional research programs and product candidates;
- the scope, progress, costs and results of preclinical and clinical development for any product candidates we may develop;
- the costs, timing and outcome of regulatory review of any product candidates we may develop;
- the cost and timing of clinical and commercial-scale manufacturing activities, including the build-out of our manufacturing facility;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidates we may develop for which we receive marketing approval;
- the costs and scope of the continued development of our non-viral genetic medicine platform;
- the costs of satisfying any post-marketing requirements;
- the revenue, if any, received from commercial sales of product candidates we may develop for which we receive marketing approval;

- the costs and timing of preparing, filing and prosecuting applications for patents, obtaining, maintaining, defending and enforcing our intellectual property rights and defending against any intellectual property-related claims, including claims of infringement, misappropriation or other violation of third-party intellectual property;

- the costs of operational, financial and management information systems and associated personnel;

- the associated costs in connection with any acquisition of in-licensed products, intellectual property and technologies; and

- the costs of operating as a public company.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditures into 2024. The net decrease in cash and cash equivalents during the three months ended March 31, 2022 includes cash outflows for seasonal and one-time expenditures, which are not expected to recur during the remainder of the 2022 fiscal year. We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong. We could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We do not have any committed external source of funds. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter would result in fixed payment obligations and may involve agreements that include grants of security interests on our assets and restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, granting liens over our assets, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. Any debt financing or additional equity that we raise may contain terms that could adversely affect the holdings or the rights of our common stockholders.

If we are unable to raise sufficient capital as and when needed, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate we may develop, or be unable to expand our operations or otherwise capitalize on our business opportunities. If we raise additional funds through collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

See the “Risk Factors” section of this Quarterly Report and in our Annual Report for additional risks associated with our substantial capital requirements.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses and related disclosures and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ significantly from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report, we believe that the accounting policies related to accrued research and development expenses and stock-based compensation are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements. There have been no material changes to our critical accounting policies and estimates from those disclosed in our financial statements and the related notes included in our Annual Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risks.

Interest Rate Market Risk

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of $337.0 million as of March 31, 2022. We did not have marketable securities as of March 31, 2022, and we did not record any impairment charges to our marketable debt securities during the three months ended March 31, 2022. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a majority of our investments are in short-term securities, which in previous reporting periods had included marketable debt securities. Interest rate changes would result in a change in the net fair value of these financial instruments due to the difference between the current market interest rate and the market interest rate at the date of purchase of the financial instrument. We currently do not seek to hedge this exposure to fluctuations in interest rates. We have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

Counterparty Credit Risk

Our investment portfolio is subject counterparty credit risk due to potential changes in the credit ratings of the issuers. A downgrade in the credit rating of an issuer of a debt security or further deterioration of the credit markets could result in a decline in the fair value of the debt instruments. Our investment guidelines prohibit investment in auction rate securities and we do not believe we have any direct exposure to losses relating from mortgage-based securities or derivatives related thereto such as credit-default swaps.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our President and Chief Executive Officer and our Chief Financial Officer, our principal executive officer and principal financial and accounting officer, respectively, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2022, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no other changes in our internal control over financial reporting (as defined in Rules 13a–15(f) and 15d–15(f) under the Exchange Act) during the three months ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report, you should carefully consider the factors discussed in Part I, Item 1A Risk Factors in our Annual Report, which could materially affect our business, financial condition, or future results.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
10.1+	Offer letter, dated October 11, 2018, by and between the registrant and Antionette Paone, as amended (incorporated by reference to Exhibit 10.21 to the registrant's Annual Report on Form 10-K, File No. 001-39319, filed February 24, 2022).
10.2*	Third Amendment to Lease, dated February 24, 2022, by and between the registrant and BMR-Rogers Street LLC.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

\+ Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENERATION BIO CO.

Date: May 5, 2022

By: /s/ Geoff McDonough
Geoff McDonough, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 5, 2022

By: /s/ Matthew Norkunas
Matthew Norkunas, M.D., M.B.A.
Chief Financial Officer
(Principal Financial and Accounting Officer)

THIRD AMENDMENT TO LEASE

THIS THIRD AMENDMENT TO LEASE (this "Amendment") is entered into as of this 24th day of February, 2022 (the "Effective Date"), by and between BMR-ROGERS STREET LLC, a Delaware limited liability company ("Landlord"), and GENERATION BIO CO., a Delaware corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant are parties to that certain Lease dated as of August 2, 2018, as amended by that certain First Amendment to Lease dated as of July 12, 2019 (the "First Amendment"), as further amended by that certain Second Amendment to Lease dated as of June 17, 2020 (the "Second Amendment") (as amended, the "Existing Lease"), whereby Tenant leases certain Premises from Landlord located at 301 Binney Street, Cambridge, Massachusetts;

B. WHEREAS, Tenant has requested and Landlord has agreed that Tenant surrender a portion of its mechanical space within the First Floor Premises (as defined in the First Amendment) as shown on Exhibit A, for a total aggregate area of 404 RSF (collectively, the "Surrender Premises") for use by another tenant, to substitute the Premises plans attached to the Existing Lease accordingly, and to adjust the Base Rent for the First Floor Premises accordingly; and

C. WHEREAS, Landlord and Tenant desire to modify and amend the Existing Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Amendment, capitalized terms shall have the meanings ascribed to them in the Existing Lease unless otherwise defined herein. The Existing Lease, as amended by this Amendment, is referred to collectively herein as the "Lease." From and after the Effective Date, the term "Lease," as used in the Existing Lease, shall mean the Existing Lease, as amended by this Amendment.

2. Surrender Premises. The parties acknowledge and agree that Tenant shall be deemed to have surrendered the Surrender Premises effective as of September 1, 2020. The table set forth in Section 2.2 of the Original Lease is hereby deleted and replaced with the following, effective as of September 1, 2020:

Definition or Provision	Means the Following
Approximate Rentable Area of Fourth Floor Premises	52,252 square feet
Approximate Rentable Area of First Floor Premises	18,906 square feet
Approximate Rentable Area of Premises (total)	71,158 square feet
Approximate Rentable Area of Building	417,290 square feet
Tenant's Pro Rata Share of Building	17.05%

3. Premises. The parties acknowledge and agree that the Premises plans attached to the Second Amendment as Exhibit A are hereby deleted in their entirety and replaced with the plans attached hereto and incorporated herein as Exhibit B.

4. Base Rent for First Floor Premises. Notwithstanding anything to the contrary set forth in the Existing Lease, from and after January 1, 2022, monthly and annual installments of Base Rent for the First Floor Premises as of January 1, 2022 and through the Term of the Lease shall be as set forth in the chart below, which chart shall replace the corresponding rows in the chart set forth in Section 2 of the First Amendment. Furthermore, the provisions of Article 8 of the Existing Lease shall not apply to the Base Rent for the First Floor Premises for the period commencing on January 1, 2022 and ending on April 30, 2029. Tenant acknowledges that notwithstanding the fact that the Surrender Premises shall be deemed surrendered by Tenant as of September 1, 2020, there shall be no adjustments made to Base Rent or Tenant's Adjusted Share with respect to the First Floor Premises previously payable by Tenant prior to January 1, 2022.

Dates	Square Feet of Rentable Area	Base Rent per Square Foot of Rentable Area	Monthly Base Rent	Annual (or Annualized) Base Rent
1/1/2022-7/17/2022	18,906	$94.23 annually	$148,459.37	$1,781,512.38
7/18/2022-7/17/2023	18,906	$96.88 annually	$152,634.44	$1,831,613.28

7/18/2023-7/17/2024	18,906	$99.60 annually	$156,919.80	$1,883,037.60
7/18/2024-7/17/2025	18,906	$102.40 annually	$161,331.20	$1,935,974.40
7/18/2025-7/17/2026	18,906	$105.28 annually	$165,868.64	$1,990,423.68
7/18/2026-7/17/2027	18,906	$108.26 annually	$170,563.63	$2,046,763.56
7/18/2027-7/17/2028	18,906	$111.32 annually	$175,384.66	$2,104,615.92
7/18/2028-4/30/2029	18,906	$114.48 annually	$180,363.24*	$2,164,358.88*

**Tenant to pay pro-rated amount for partial month/year*

5. Notices. Landlord and Tenant confirm that, notwithstanding anything in the Lease to the contrary, notices delivered to each party pursuant to the Lease should be sent to:

Landlord: BMR-Rogers Street LLC
4570 Executive Drive, Suite 400 San Diego, California 92121
Attn: Legal Department
Email: [**]

Tenant: Generation Bio Co.
301 Binney Street
Cambridge, Massachusetts 02142
Attn: Chief Financial Officer

6. Broker. Tenant represents and warrants to Landlord that Tenant has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment, and agrees to reimburse, indemnify, save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord, at Tenant's sole cost and expense) and hold harmless the Landlord Parties for, from and against any and all cost or liability for compensation claimed by any such broker or agent employed or engaged by Tenant or claiming to have been employed or engaged by Tenant. Landlord represents and warrants to Tenant that Landlord has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment and agrees to reimburse, indemnify, save, defend (at Tenant's option and with counsel reasonably acceptable to Tenant, at Landlord's sole cost and expense) and hold harmless the Tenant Parties for, from and against any and all cost or liability for compensation claimed by any such broker or agent employed or engaged by Landlord or claiming to have been employed or engaged by Landlord.

7. Effect of Amendment. Except as modified by this Amendment, the Existing Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. In the event of any conflict between the terms contained in this Amendment and the Existing Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties.

8. Successors and Assigns. Each of the covenants, conditions and agreements contained in this Amendment shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns and sublessees. Nothing in this section shall in any way alter the provisions of the Lease restricting assignment or subletting.

9. Miscellaneous. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are inserted and included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease, lease amendment or otherwise until execution by and delivery to both Landlord and Tenant.

10. Authority. Tenant guarantees, warrants and represents that the individual or individuals signing this Amendment on Tenant's behalf have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed. Landlord guarantees, warrants and represents that the individual or individuals signing this Amendment on Landlord's behalf have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

11. Counterparts: Facsimile and PDF Signatures. This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document. A portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the Effective Date first above written.

LANDLORD:

BMR-ROGERS STREET LLC,
a Delaware limited liability company

By: /s/ William F. Kane
Name: William F. Kane
Title: President, East Coast and UK Markets

TENANT:

GENERATION BIO CO.,
a Delaware corporation

By: /s/ Jennifer Elliott
Name: Jennifer Elliott
Title: Chief Legal Officer

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Geoff McDonough, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Generation Bio Co.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2022

/s/ Geoff McDonough

Geoff McDonough, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew Norkunas, hereby certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Generation Bio Co.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2022

/s/ Matthew Norkunas

Matthew Norkunas, M.D., M.B.A.
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Geoff McDonough, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Generation Bio Co. for the quarter ended March 31, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Generation Bio Co.

/s/ Geoff McDonough

Geoff McDonough, M.D.
President and Chief Executive Officer
(Principal Executive Officer)
May 5, 2022

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew Norkunas, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Generation Bio Co. for the quarter ended March 31, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Generation Bio Co.

/s/ Matthew Norkunas

Matthew Norkunas, M.D., M.B.A.
Chief Financial Officer
(Principal Financial and Accounting Officer)
May 5, 2022