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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 June 30, 2023

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 July 28, 2023 there were 65,928,503 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, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements;
- the potential achievement of milestones and receipt of payments under our collaboration with ModernaTX, Inc.;
- our ability to enter into additional collaborations with third parties or obtain additional funding;
- our ability to find one or more third parties to assume our lease or sublease the property in Waltham, MA;
- 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, marketing and manufacturing 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 objectives;
- the impact of government laws and regulations;
- our competitive position and our expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available; and
- developments and expectations relating to our competitors and our industry.

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 this Quarterly Report and 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 144,970	$ 93,171
Marketable securities	169,173	185,920
Tenant receivable	340	395
Prepaid expenses and other current assets	6,140	7,530
Total current assets	320,623	287,016
Property and equipment, net	21,968	22,215
Operating lease right-of-use assets	55,834	59,208
Restricted cash	5,692	5,692
Deferred offering costs	433	434
Other long-term assets	333	1,699
Total assets	$ 404,883	$ 376,264
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,328	$ 662
Accrued expenses and other current liabilities	7,751	11,402
Deferred revenue	8,265	—
Operating lease liability	8,135	7,086
Total current liabilities	26,479	19,150
Deferred revenue, net of current portion	51,620	—
Operating lease liability, net of current portion	72,497	74,621
Total liabilities	150,596	93,771
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized at June 30, 2023 and December 31, 2022; 65,784,250 and 59,505,437 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	7	6
Additional paid-in capital	762,228	727,335
Accumulated other comprehensive loss	(23)	(83)
Accumulated deficit	(507,925)	(444,765)
Total stockholders' equity	254,287	282,493
Total liabilities and stockholders' equity	$ 404,883	$ 376,264

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Collaboration revenue	$ 880	$ —	$ 880	$ —
Operating expenses:				
Research and development	21,832	28,365	43,832	53,919
General and administrative	12,967	10,116	25,833	19,906
Total operating expenses	34,799	38,481	69,665	73,825
Loss from operations	(33,919)	(38,481)	(68,785)	(73,825)
Other income:				
Other income and interest income, net	2,853	552	5,625	897
Net loss and net loss attributable to common stockholders	$ (31,066)	$ (37,929)	$ (63,160)	$ (72,928)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.47)	$ (0.66)	$ (1.00)	$ (1.28)
Weighted average common shares outstanding, basic and diluted	65,656,151	57,149,474	62,957,556	57,107,917
Comprehensive loss:				
Net loss	$ (31,066)	$ (37,929)	$ (63,160)	$ (72,928)
Other comprehensive loss:				
Unrealized gains (losses) on marketable securities	(57)	(339)	60	(339)
Comprehensive loss	$ (31,123)	$ (38,268)	$ (63,100)	$ (73,267)

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 (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Three Months Ended June 30, 2023					
Balances at March 31, 2023	65,535,663	$ 7	$ 755,957	$ 34	$ (476,859)	$ 279,139
Vesting of restricted common stock	140,906	—	(119)	—	—	(119)
Issuance of common stock under other equity plans	107,681	—	367	—	—	367
Stock-based compensation expense	—	—	6,023	—	—	6,023
Unrealized gains on marketable securities	—	—	—	(57)	—	(57)
Net loss	—	—	—	—	(31,066)	(31,066)
Balances at June 30, 2023	65,784,250	$ 7	$ 762,228	$ (23)	$ (507,925)	$ 254,287

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Three Months Ended June 30, 2022					
Balances at March 31, 2022	57,004,128	$ 6	$ 696,034	$ —	$ (343,125)	$ 352,915
Issuance of common stock from public ATM offering, net of commissions and offering costs of $89	415,637	—	2,721	—	—	2,721
Issuance of common stock upon exercise of stock options	110,587	—	452	—	—	452
Vesting of restricted common stock	1,640	—	—	—	—	—
Issuance of common stock under other equity plans	65,149		363	—	—	363
Stock-based compensation expense	—	—	6,691	—	—	6,691
Unrealized losses on marketable securities	—	—	—	(339)	—	(339)
Net loss	—	—	—	—	(37,929)	(37,929)
Balances at June 30, 2022	57,597,141	$ 6	$ 706,261	$ (339)	$ (381,054)	$ 324,874

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 (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Six Months Ended June 30, 2023					
Balances at December 31, 2022	59,505,437	$ 6	$ 727,335	$ (83)	$ (444,765)	$ 282,493
Sale of common stock in connection with the Moderna Share Purchase Agreement	5,859,375	1	22,555	—	—	22,556
Vesting of restricted common stock	311,757	—	(318)	—	—	(318)
Issuance of common stock under other equity plans	107,681	—	367	—	—	367
Stock-based compensation expense	—	—	12,289	—	—	12,289
Unrealized gains on marketable securities	—	—	—	60	—	60
Net loss	—	—	—	—	(63,160)	(63,160)
Balances at June 30, 2023	65,784,250	$ 7	$ 762,228	$ (23)	$ (507,925)	$ 254,287

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Six Months Ended June 30, 2022					
Balances at December 31, 2021	56,969,618	$ 6	$ 689,866	$ —	$ (308,126)	$ 381,746
Issuance of common stock from public ATM offering, net of commissions and offering costs of $89	415,637	—	2,721	—	—	2,721
Issuance of common stock upon exercise of stock options	132,374	—	554	—	—	554
Vesting of restricted common stock	14,363	—	—	—	—	—
Issuance of common stock under other equity plans	65,149	—	363	—	—	363
Stock-based compensation expense	—	—	12,757	—	—	12,757
Unrealized losses on marketable securities	—	—	—	(339)	—	(339)
Net loss	—	—	—	—	(72,928)	(72,928)
Balances at June 30, 2022	57,597,141	$ 6	$ 706,261	$ (339)	$ (381,054)	$ 324,874

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)

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (63,160)	$ (72,928)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	12,289	12,757
Depreciation and amortization expense	2,645	2,420
Amortization (accretion) of premium (discount) on marketable securities, net	(4,200)	(240)
Loss on sale of property and equipment	24	28
Loss on impairment of property and equipment	—	5,037
Changes in operating assets and liabilities:		
Tenant receivable	55	(1,778)
Prepaid expenses and other current assets	1,390	(3,097)
Operating lease right-of-use assets	3,375	2,185
Other noncurrent assets	1,366	(3,466)
Accounts payable	1,572	(936)
Accrued expenses and other current liabilities	(3,772)	(2,179)
Deferred revenue	46,620	—
Operating lease liability	(1,075)	3,229
Net cash used in operating activities	(2,871)	(58,968)
Cash flows from investing activities:		
Purchases of property and equipment	(2,207)	(7,468)
Purchases of marketable securities	(166,994)	(154,037)
Maturities of marketable securities	188,000	—
Net cash provided by (used in) investing activities	18,799	(161,505)
Cash flows from financing activities:		
Payment of share issuance costs	(179)	(50)
Proceeds from sale of common stock in connection with the Moderna Share Purchase Agreement	36,000	—
Proceeds from issuance of common stock from public ATM offering, net of commissions and offering costs	—	2,726
Proceeds from exercise of stock options and other types of equity, net	367	917
Tax withholding payments related to net share settlements of restricted stock units	(317)	—
Net cash provided by financing activities	35,871	3,593
Net increase (decrease) in cash, cash equivalents and restricted cash	51,799	(216,880)
Cash, cash equivalents and restricted cash at beginning of period	98,863	380,837
Cash, cash equivalents and restricted cash at end of period	$ 150,662	$ 163,957
Supplemental disclosure of noncash investing and financing information:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 240	$ 544
Unrealized gains (losses) on marketable securities	$ 60	$ (339)

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, 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.

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), sales of convertible preferred stock (which converted into common stock in 2020), and sales of common stock in underwritten public offerings, "at-the-market" offerings, and in a private placement, as well as payments pursuant to our collaboration with ModernaTX, Inc., or Moderna. We have incurred recurring losses, including net losses of $63.2 million for the six months ended June 30, 2023 and $72.9 million for the six months ended June 30, 2022. As of June 30, 2023, we had an accumulated deficit of $508.0 million. We expect to continue to generate operating losses in the foreseeable future. As of August 2, 2023, the issuance date of these condensed consolidated financial statements, we expect that our cash, cash equivalents and marketable securities 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 additional 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, 2022 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022 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 June 30, 2023, the results of operations for the three and six months ended June 30, 2023 and 2022, and cash flows for the six months ended June 30, 2023 and 2022 have been made. The results of operations for the three and six months ended June 30, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023 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 that was most recently filed with the SEC.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash, cash equivalents, and marketable securities. We believe that we are not exposed to significant credit risk due to the financial strength of the national depository institutions in which our cash, cash equivalents, and marketable securities are held. We maintain our cash equivalents in money market funds that invest in U.S. treasury securities. We have adopted an investment policy that limits the amounts that we may invest in the securities of a single issuer with the exclusion of the U.S. government. We have not experienced any credit losses.

We are dependent on a small number of third-party suppliers for our drug substance and drug product. In particular, we rely, and expect to continue to rely, on third-party suppliers for certain materials and components required for the production of any product candidates we may develop for our programs. These programs could be adversely affected by a significant interruption in the supply process.

Revenue Recognition

We enter into collaboration agreements that are within the scope of ASC Topic 606, “Revenue from Contracts with Customers”, or ASC 606, under which we license rights to certain of our potential product candidates and perform research and development services. The terms of these contracts typically include payment of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, regulatory, and commercial milestone payments; royalties on net sales of licensed products, and a premium or discount on the sale of our common stock.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for contracts determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to the customer.

The promised goods or services in our arrangements typically consist of license rights to our intellectual property and research and development services. We provide options to additional items in the contract, which will be accounted for as separate contracts if and when the other party elects to exercise such options, unless the option provides a material right to such party. We evaluate the other party's options for material rights, or options to acquire additional goods or services for free or at a discount. If the other party's options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the contract. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the other party and are considered distinct when (i) the other party can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of the other party to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

We estimate the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each contract that includes variable consideration, we evaluate the number of potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

Our contracts include development, regulatory, and commercial milestone payments that will be assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within our control or the counterparty's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of such development, regulatory, and commercial milestones and any related constraint, and if necessary, we adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment. To date, we have not recognized any consideration related to the achievement of development, regulatory, or commercial milestone revenue resulting from our collaboration contracts.

For contracts that include sales-based royalties, including milestone payments based on the level of sales, and where the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any consideration related to sales-based royalty revenue resulting from our collaboration contract.

We allocate the transaction price based on the estimated stand-alone selling price of each of the performance obligations. We must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the stand-alone selling price for service obligations, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Additionally, in determining the standalone selling price for material rights, we utilize comparable transactions, clinical trial success probabilities, and estimates of option exercise likelihood. Variable consideration is

allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts we would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations that consist of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due until we perform our obligations. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

3. Marketable Securities and Fair Value Measurements

The following tables present our marketable securities by security type:

	As of June 30, 2023			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 169,196	$ 12	$ (35)	$ 169,173

	As of December 31, 2022			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. treasury securities	$ 186,003	$ 13	$ (96)	$ 185,920

As of June 30, 2023 and December 31, 2022, our marketable securities consisted of investments that mature within one year of their purchase date.

The following tables present our assets that are measured at fair value on a recurring basis and indicate the level within the fair value hierarchy of the valuation techniques that we utilized to determine such fair value:

	Fair Value Measurements at June 30, 2023 Using:			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 49,610	$ —	$ —	$ 49,610
U.S. treasury securities	12,943	—	—	12,943
Marketable securities:				
U.S. treasury securities	—	169,173	—	169,173
Totals	$ 62,553	$ 169,173	$ —	$ 231,726

	Fair Value Measurements at December 31, 2022 Using:			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 77,010	$ —	$ —	$ 77,010
Marketable securities:				
U.S. treasury securities	—	185,920	—	185,920
Totals	$ 77,010	$ 185,920	$ —	$ 262,930

4. Collaboration and License Agreement

Moderna Collaboration and License Agreement

In March 2023, we entered into a Collaboration and License Agreement, or the Collaboration Agreement, with Moderna to collaborate on developing treatments for certain diseases by targeting delivery of nucleic acids to liver cells and certain cells outside of the liver.

Under the Collaboration Agreement, the parties have agreed to collaborate on preclinical research programs relating to lipid nanoparticle, or LNP, delivery systems and nucleic acid payloads, with each party obtaining certain rights to intellectual property used in and arising out of such research programs. Each party will be solely responsible for its own clinical development and commercialization of products under the Collaboration Agreement. Moderna will reimburse us for the internal and external costs incurred by us in conducting the research programs, to the extent consistent with such research plans and budgets.

Moderna has exclusive options, upon payment of option exercise fees, to obtain worldwide, exclusive, sublicensable licenses under specified company intellectual property to develop, manufacture and commercialize (a) products comprising LNP delivery systems and nucleic acid payloads that are directed to (i) up to two liver targets, (ii) up to two non-liver targets and (iii) a third liver or non-liver target and (b) Exclusive Targets, which are Independent Program Products (as defined below) that include messenger RNA, or mRNA, that are directed to gene and protein targets in any of certain agreed-upon immune cell types, referred to as the Cell Target Types. Subject to the our exclusivity obligations described below, each party has granted to the other a worldwide, non-exclusive, sublicensable license under certain LNP-related intellectual property arising out of the non-liver ctLNP program, or the Joint Collaboration ctLNP Intellectual Property, to develop, manufacture and commercialize products comprising LNP delivery systems and nucleic acid payloads directed to gene and protein targets in any of the Cell Target Types, or Independent Program Products.

Each party is obligated to use commercially reasonable efforts to complete the activities assigned to it under the research plans, and Moderna is further obligated to use commercially reasonable efforts to develop, seek regulatory approval for and commercialize at least one product directed to each target for which Moderna exercises its exclusive license option in at least one indication in the United States and in specified European countries.

We have agreed not to, directly or indirectly, alone or with, for or through any third party, develop, manufacture, commercialize or exploit (a) products containing mRNA that are directed to any of the Cell Target Types, during an agreed-upon exclusivity period, which may be extended by payment of extension fees, (b) products directed to any liver target or non-liver target during the option periods for those targets, (c) products directed to any liver target or non-liver target for which Moderna has exercised its exclusive license option or (d) products containing mRNA that are directed to any Exclusive Target for which Moderna has exercised its exclusive license option.

Under the terms of the Collaboration Agreement, in April 2023, Moderna made an upfront payment to us of $40.0 million, and paid us $7.5 million in prepaid research funding. In addition, we are eligible to receive up to $1.8 billion in milestone payments upon the achievement of specified development, regulatory, commercial, and sales milestone events, research term extension fees and exclusivity extension fees. Subject to reductions in specified circumstances, we will also be entitled to receive tiered royalties: (i) ranging from high-single-digits to low-double-digits on sales of licensed products that are directed to any liver target or non-liver target with respect to which Moderna has exercised its exclusive license option, and (ii) in the single digits on sales of Independent Program Products, including the exclusively licensed Independent Program Products directed to the Exclusive Targets. In consideration for the non-exclusive license granted by Moderna to us under the Joint Collaboration ctLNP Intellectual Property, we have agreed to pay Moderna tiered royalties in the single digits on sales of Independent Program Products that include mRNA, subject to reductions in specified circumstances. Royalties will be paid by each party, on a licensed product-by-licensed product and country-by-country basis, until the latest to occur of: (i) expiration of the last-to-expire of specified licensed patent rights; (ii) expiration of regulatory exclusivity; or (iii) ten years after the first commercial sale of the applicable licensed product.

In addition, in connection with the execution of the Collaboration Agreement, we entered into a Share Purchase Agreement, or the Share Purchase Agreement, with Moderna, pursuant to which we issued and sold 5,859,375 shares of our common stock to Moderna, at a price of $6.14 per share, for an aggregate purchase price of $36.0 million, which closed concurrently with the execution of the Collaboration Agreement. Under the Share Purchase Agreement, Moderna has the right, subject to certain terms and conditions, to purchase up to 3.06% of the outstanding shares of our common stock (on a post-closing basis) in connection with a future equity financing of at least $25.0 million by us.

Moderna Agreement Assessment

We assessed the promised goods and services under the Collaboration Agreement, in accordance with ASC Topic 606, "Revenue from Contracts with Customers", or ASC 606. At inception, the Collaboration Agreement included one combined performance obligation, which includes the license to the ctLNP technology to target indications outside of the liver and the related research services to develop such technology, as the two items are not distinct in context of the contract. The Collaboration Agreement also provides Moderna with options to receive additional research services and options to receive exclusive licenses. The options to receive exclusive licenses allow Moderna to develop and commercialize product candidates that utilize our ctLNP and ceDNA technology for targets within the liver, as well as utilizing the ctLNP technology to be developed as part of the Collaboration Agreement and our ceDNA technology for targets outside the liver. These options are considered to be a priced at a discount to its standalone selling price and therefore are considered to be material rights.

The initial transaction price included a $40.0 million upfront fee, premium paid over the fair value of the common stock of $13.3 million in connection with shares issued and sold to Moderna under the Share Purchase Agreement, and estimated revenue associated with the payment for research services, including $7.5 million in prepaid research services. We utilized the expected amount method to determine the amount of reimbursement for these activities. We utilized the most likely amount method to determine the amount of consideration to include in the transaction price related to any variable consideration related to exclusivity fees, and milestones, and the royalty payments are constrained based on the royalty constraint. No amounts are included in the transaction price related to these elements.

We allocated the transaction price to each unit of account as follows:

Performance Obligations (in thousands)	Standalone Selling Price	Transaction Price Allocated
ctLNP technology and research license	$ 52,500	$ 42,576
First liver program commercialization option license	7,000	5,677
Second liver program commercialization option license	7,000	5,677
First non-liver program commercialization option license	11,700	9,488
Second non-liver program commercialization option license	11,700	9,488
Third liver or non-liver program commercialization option license	6,150	4,987
Total	$ 96,050	$ 77,893

The transaction price was allocated to each unit of account based on the relative estimated standalone selling prices, over which management has applied significant judgment, of each element. We developed the estimated standalone selling price for combined performance obligation and each of the options to receive licenses primarily based on the probability-weighted present value of expected future cash flows associated with each license related to each specific program and an estimate of the costs to provide services including a reasonable return. In developing such estimate, we also considered applicable market conditions and relevant entity-specific factors, including those factors contemplated in negotiating the agreement, the probability of success and the time needed to commercialize a product candidate pursuant to the associated license.

We measure proportional performance of the combined performance obligation over time using an input method based on cost incurred relative to the total estimated costs on a quarterly basis by determining the proportion of effort incurred as a percentage of total effort we expect to expend. Any changes to these estimates will be recognized in the period in which they change as a cumulative catch up. All allocated consideration for the material rights is deferred until such time that Moderna exercises its options or the right to exercise the options expires. Upon exercise, we will determine the appropriate revenue recognition methodology and any other implications on the accounting treatment for the arrangement.

The following table provides a summary of the transaction price allocated to each unit of account, in addition to revenue activity during the period:

Performance Obligations	Transaction Price Allocated	Revenue Recognized During	Deferred Revenue
(in thousands)	As of June 30, 2023	Three and Six Months Ended June 30, 2023	As of June 30, 2023
ctLNP technology and research license	$ 42,576	$ 880	$ 32,334
First liver program commercialization option license	5,677	—	4,429
Second liver program commercialization option license	5,677	—	4,429
First non-liver program commercialization option license	9,488	—	7,401
Second non-liver program commercialization option license	9,488	—	7,401
Third liver or non-liver program commercialization option license	4,987	—	3,891
Total	$ 77,893	$ 880	$ 59,885

5. Property and equipment, net

Property and equipment, net consisted of the following:

(in thousands)	June 30, 2023	December 31, 2022
Laboratory equipment	$ 13,938	$ 13,619
Computer equipment and software	1,335	1,189
Furniture and fixtures	1,236	1,146
Leasehold improvements	20,848	20,786
Construction in progress	1,753	13
	39,110	36,753
Less: Accumulated depreciation and amortization	(17,142)	(14,538)
Total	$ 21,968	$ 22,215

Depreciation and amortization expense for the three and six months ended June 30, 2023 was $1.3 million and $2.6 million, respectively. Depreciation and amortization expense for the three and six months ended June 30, 2022 was $1.2 million and $2.4 million, respectively.

In July 2021, we entered into a lease agreement to build out a current Good Manufacturing Practice-, or cGMP-, compliant manufacturing facility in Waltham, Massachusetts in order to scale ceDNA manufacturing utilizing RES for clinical and initial commercial supply. We decided to transition from building out the cGMP compliant manufacturing facility to utilizing an external cleanroom facility after achieving increased scalability of the RES development process in the second half of 2022. Consequently, we are seeking one or more third parties to assume our lease or sublease the property. The balance of construction in progress at June 30, 2023, was comprised primarily of the capitalization of construction costs to renovate the property for alternative use.

6. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	June 30, 2023	December 31, 2022
Accrued employee compensation and benefits	$ 4,343	$ 7,970
Accrued external research and development expenses	2,071	1,959
Accrued professional fees	809	1,047
Property and equipment	122	—
Other	406	426
Total	$ 7,751	$ 11,402

7. Equity

As of June 30, 2023, 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 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 August 2, 2023, the issuance date of these condensed consolidated financial statements, we have issued and sold 1,795,524 shares of our common stock pursuant to this sales agreement resulting in net proceeds of $12.3 million.

In March 2023, in connection with the Share Purchase Agreement with Moderna, we issued and sold 5,859,375 shares of our common stock to Moderna at a price of $6.14 per share for an aggregate purchase price of $36.0 million. For additional information, refer to Note 4, Collaboration and License Agreements.

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.

8. 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 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, 2022 and 2023, 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, from 12,154,517 shares to 14,433,745 shares, and from 14,433,745 shares to 16,813,962 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 June 30, 2023, 883,445 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. In July 2023, an additional 499,952 shares became available for future issuance under the 2020 Plan as a result of the expiration of performance-based stock options granted in March 2020.

Grant of stock options

During the six months ended June 30, 2023, we granted time-based options to certain employees for the purchase of an aggregate of 1,705,581 shares of common stock with a weighted average grant date fair value of $3.66 per share that vest over a weighted average period of approximately four years.

Restricted stock units

During the six months ended June 30, 2023, we issued 828,920 restricted stock units with a fair value of $3.8 million that vest over a weighted average period of approximately four 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 authorized 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 2021, 2022, and 2023, the number of shares of common stock authorized for issuance under the 2020 ESPP was increased from 481,231 shares to 950,931 shares, from 950,931 shares to 1,520,738 shares, and from 1,520,738 shares to 2,115,792 shares, respectively. As of June 30, 2023, 1,826,149 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 June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Research and development expenses	$ 2,879	$ 3,476	$ 5,734	$ 6,628
General and administrative expenses	3,144	3,215	6,555	6,129
Total	$ 6,023	$ 6,691	$ 12,289	$ 12,757

As of June 30, 2023, total unrecognized compensation cost related to unvested time-based stock options and restricted stock units was $38.1 million, with $32.2 million expected to be recognized over a weighted average period of 2.7 years and $5.9 million expected to be recognized over a weighted average period of 2.3 years, respectively. Additionally, as of June 30, 2023, we had unrecognized compensation cost related to unvested stock options with performance-based vesting conditions for which performance has not been deemed probable of $1.7 million.

9. 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 six months ended June 30, 2023.

10. 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:

	June 30,	
	2023	2022
Unvested restricted stock units	1,356,667	1,533,821
Stock options to purchase common stock	10,248,676	8,657,817
Total	11,605,343	10,191,638

11. Related Parties

In March 2023, we entered into the Collaboration Agreement with Moderna. In connection with the Share Purchase Agreement, we issued and sold 5,859,375 shares of our common stock to Moderna, which resulted in Moderna becoming the beneficial owner of 8.9% of our outstanding common stock and a related party.

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 is 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 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 level of therapeutic expression and to maintain efficacy throughout a patient's life.

We are advancing a broad portfolio of programs, including programs for rare and prevalent diseases of the liver. 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 that result from mutations in a single gene, and which can be treated by delivering our ceDNA cargo to cells of the liver, called hepatocytes. We are focusing on indications like hemophilia A, which is our lead program, that have well-established biomarkers and clear clinical and regulatory pathways. We are at the preclinical research stage, and are currently optimizing our ctLNPs to improve hepatocyte delivery to treat hemophilia A and other rare monogenic diseases. The biodistribution of our ctLNPs is driven by biological targeting molecules called ligands, which we believe will enable selective delivery to hepatocytes and ultimately to other cell types and tissues. We plan to expand our portfolio to include programs based on cell-targeted delivery of ceDNA to immune cells, tumors, retina, skeletal muscle, and to the central nervous system by developing discrete ctLNPs specifically engineered to reach each of these cell types or tissues.

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 diseases.

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 ceDNA-based vaccines using our proprietary vaccine-optimized ctLNPs. We believe that, compared to currently approved messenger RNA, or mRNA, vaccines, ceDNA-ctLNP vaccines could enable improved immune responses, more durable protection, 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.

In July 2021, we entered into a lease agreement to build out a current Good Manufacturing Practice-, or cGMP-, compliant manufacturing facility, or the Seyon Facility, in Waltham, Massachusetts in order to scale ceDNA manufacturing utilizing RES for clinical and initial commercial supply. We decided to transition from building out the cGMP compliant manufacturing facility to utilizing an external cleanroom facility after achieving increased scalability of the RES

development process in the second half of 2022. We have entered into an agreement with an external cleanroom facility at which we expect to manufacture cGMP-compliant clinical and initial commercial supply of ceDNA using RES that will allow us to retain control over personnel, quality, infrastructure and process. Additionally, we may enter into agreements with contract manufacturing organizations, or CMOs, to provide further manufacturing capacity.

In March 2023, we entered into a Collaboration and License Agreement, or the Collaboration Agreement, with ModernaTX, Inc., or Moderna, to collaborate on developing treatments for certain diseases by targeting delivery of nucleic acids to liver cells and certain cells outside of the liver. Under the Collaboration Agreement, the parties have agreed to collaborate on preclinical research programs relating to lipid nanoparticle, or LNP, delivery systems and nucleic acid payloads, with each party obtaining certain rights to intellectual property used in and arising out of such research programs.

The research programs will be conducted pursuant to research plans and associated research budgets established by governance committees formed by the parties. Moderna will reimburse us for the internal and external costs we incur in conducting the research programs, to the extent consistent with such research plans and budgets. Each party will be solely responsible for its own clinical development and commercialization of products under the Collaboration Agreement.

In addition, Moderna has exclusive options, upon payment of option exercise fees, to obtain worldwide, exclusive, sublicensable licenses under certain of our specified intellectual property to develop, manufacture and commercialize (a) products comprising LNP delivery systems and nucleic acid payloads that are directed to (i) up to two liver targets, (ii) up to two agreed-upon non-liver targets and (iii) a third liver or non-liver target and (b) Independent Program Products, which are products comprising LNP delivery systems that include mRNA that are directed to gene and protein targets in any of the agreed-upon immune cell types, or Cell Targets Types.

Under the terms of the Collaboration Agreement, in April 2023, Moderna made an upfront payment to us of $40.0 million, and paid us $7.5 million in prepaid research funding. In addition, we are eligible to receive up to $1.8 billion in milestone payments upon the achievement of specified development, regulatory, commercial, and sales milestone events, research term extension fees and exclusivity extension fees. Subject to reduction in specified circumstances, we will also be entitled to receive tiered royalties: (i) ranging from high-single-digits to low-double-digits on sales of licensed products that are directed to the liver targets and non-liver targets with respect to which Moderna has exercised its exclusive license options, and (ii) in the single digits on sales of Independent Program Products, including the exclusively licensed Independent Program Products. In consideration for the non-exclusive license granted by Moderna to us under the LNP-related intellectual property arising out of the research program focused on the discovery and development of ctLNPs directed to agreed-upon immune cell types, we have agreed to pay Moderna tiered royalties ranging from low-single-digits to mid-single-digits on sales of Independent Program Products that include mRNA, subject to reductions in specified circumstances.

In connection with the Collaboration Agreement, we entered into a Share Purchase Agreement with Moderna, pursuant to which we issued and sold 5,859,375 shares of our common stock to Moderna, at a price of $6.14 per share, for an aggregate purchase price of $36.0 million. In addition, under the Share Purchase Agreement, Moderna has the right, subject to certain terms and conditions, to purchase up to 3.06% of the outstanding shares of our common stock (on a post-closing basis) in connection with a future equity financing of at least $25.0 million by us. For additional information on our collaboration with Moderna and the accounting thereunder, refer to Note 4, Collaboration and License Agreements.

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. We expect that any revenue recognized for the next several years will be derived primarily from our current collaboration with Moderna and any additional collaborations that we may enter into in the future. Historically, 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), sales of convertible preferred stock (which converted into common stock in 2020), and sales of common stock in underwritten public offerings, “at-the-market” offerings, and in a private placement, as well as payments pursuant to our collaboration with Moderna. 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. 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 August 2, 2023, we have issued and sold 1,795,524 shares of our common stock pursuant to this sales agreement resulting in net proceeds of $12.3 million. In March 2023, in connection with the Share Purchase Agreement entered into with Moderna, we issued and sold 5,859,375 shares of our common stock to Moderna at a price of $6.14 per share for an aggregate purchase price of $36.0 million.

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 six months ended June 30, 2023 and 2022, we reported net losses of $63.2 million and $72.9 million, respectively. As of June 30, 2023, we had an accumulated deficit of $508.0 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, including pursuant to our collaboration with Moderna;
- 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;
- establish additional manufacturing sources and secure supply chain capacity sufficient to provide necessary quantities of any product candidates we may develop for clinical or commercial use;
- hire additional clinical, regulatory and scientific personnel;
- advance any product candidates we identify into preclinical and clinical development;
- 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, including our collaboration with Moderna. 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, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditures into 2025. 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."

Components of Our Results of Operations

Collaboration revenue

Our revenue consists of collaboration revenue, including amounts recognized for payments for licenses, research funding and milestone payments earned under our collaboration and license agreements.

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 capabilities 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 contract development organizations, or CDOs;
- 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, CDOs 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 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;
- our ability to maintain a continued acceptable safety, tolerability and efficacy profile of our product candidates following approval; and
- the terms and timing of any existing or future collaboration, license or other arrangement, including the terms and timing of any achievement of milestones and the receipt of payments thereunder.

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 substantial 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, net

Other income and interest income, net 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 and six months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three and six months ended June 30, 2023 and 2022:

(in thousands)	Three Months Ended June 30, 2023	2022	Change 2023 vs 2022	Six Months Ended June 30, 2023	2022	Change 2023 vs 2022
Revenue:						
Collaboration revenue	$ 880	$ —	$ 880	$ 880	$ —	$ 880
Operating expenses:						
Research and development	21,832	28,365	(6,533)	43,832	53,919	(10,087)
General and administrative	12,967	10,116	2,851	25,833	19,906	5,927
Total operating expenses	34,799	38,481	(3,682)	69,665	73,825	(4,160)
Loss from operations	(33,919)	(38,481)	4,562	(68,785)	(73,825)	5,040
Other income:						
Other income and interest income, net	2,853	552	2,301	5,625	897	4,728
Net loss	$ (31,066)	$ (37,929)	$ 6,863	$ (63,160)	$ (72,928)	$ 9,768

Collaboration revenue

During the three and six months ended June 30, 2023, we recognized $0.9 million in collaboration revenue under our Collaboration Agreement with Moderna. For additional information on our collaboration with Moderna and the accounting thereunder, refer to Note 4, Collaboration and License Agreements.

Research and development expenses

The following table summarizes our research and development expenses for the three and six months ended June 30, 2023 and 2022:

(in thousands)	Three Months Ended June 30, 2023	2022	Change 2023 vs 2022	Six Months Ended June 30, 2023	2022	Change 2023 vs 2022
Personnel-related	$ 6,815	$ 7,423	$ (608)	$ 14,092	$ 15,169	$ (1,077)
Preclinical and manufacturing	5,405	3,533	1,872	10,206	8,174	2,032
Facilities-related	3,533	9,514	(5,981)	6,892	14,862	(7,970)
Stock-based compensation	2,879	3,476	(597)	5,734	6,628	(894)
Lab supplies	1,031	1,452	(421)	1,855	2,931	(1,076)
Consulting and professional services	415	1,161	(746)	1,018	2,171	(1,153)
Other	1,754	1,806	(52)	4,035	3,984	51
Total research and development expenses	$ 21,832	$ 28,365	$ (6,533)	$ 43,832	$ 53,919	$ (10,087)

Research and development expenses were $21.8 million for the three months ended June 30, 2023, compared to $28.4 million for the three months ended June 30, 2022. The decrease in facilities-related costs of $6.0 million was primarily driven by our decision to transition from building out the Seyon Facility, to utilizing an external cleanroom facility for manufacturing cGMP-compliant clinical and initial commercial supply of ceDNA using RES after achieving increased scalability of the RES development process in the second half of 2022. The decreases in personnel-related and stock-based compensation costs of $0.6 million each, were driven by a slight decrease in headcount. These decreases were offset by an increase in preclinical and manufacturing costs of $1.9 million, driven primarily by increased preclinical activities.

Research and development expenses were $43.8 million for the six months ended June 30, 2023, compared to $53.9 million for the six months ended June 30, 2022. The decrease in facilities-related costs of $8.0 million was primarily driven by our decision to transition from building out the Seyon Facility, to utilizing an external cleanroom facility for

manufacturing cGMP-compliant clinical and initial commercial supply of ceDNA using RES after achieving increased scalability of the RES development process in the second half of 2022. The decreases in personnel-related and stock-based compensation costs of $1.1 million and $0.9 million, respectively, were driven by a slight decrease in headcount. These decreases were offset by an increase in preclinical and manufacturing costs of $2.0 million, driven primarily by increased preclinical activities.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three and six months ended June 30, 2023 and 2022:

(in thousands)	Three Months Ended June 30, 2023	2022	Change 2023 vs 2022	Six Months Ended June 30, 2023	2022	Change 2023 vs 2022
Personnel-related	$ 4,268	$ 3,714	$ 554	$ 8,549	$ 7,770	$ 779
Stock-based compensation	3,144	3,215	(71)	6,555	6,129	426
Professional and consultant fees	2,490	2,123	367	4,615	4,171	444
Facilities-related	2,528	656	1,872	4,948	782	4,166
Other	537	408	129	1,166	1,054	112
Total general and administrative expenses	$ 12,967	$ 10,116	$ 2,851	$ 25,833	$ 19,906	$ 5,927

General and administrative expenses were $13.0 million for the three months ended June 30, 2023, compared to $10.1 million for the three months ended June 30, 2022. The increase in facilities-related costs of $1.9 million was primarily driven by rent expense related to the Seyon Facility after our decision to transition from building out the Seyon Facility to utilizing an external cleanroom facility for manufacturing cGMP-compliant clinical and initial commercial supply of ceDNA using RES in the second half of 2022. The increase in personnel-related costs of $0.6 million was primarily a result of a slight increase in headcount to support our general and administrative function.

General and administrative expenses were $25.8 million for the six months ended June 30, 2023, compared to $19.9 million for the six months ended June 30, 2022. The increase in facilities-related costs of $4.2 million was primarily driven by rent expense related to the Seyon Facility after our decision to transition from building out the Seyon Facility to utilizing an external cleanroom facility for manufacturing cGMP-compliant clinical and initial commercial supply of ceDNA using RES in the second half of 2022. The increases in stock-based compensation costs and personnel-related costs of $0.4 million each, were primarily a result of a slight increase in headcount to support our general and administrative function.

Other income and interest income, net

Other income and interest income, net for the three and six months ended June 30, 2023 was $2.9 million and $5.6 million, as compared to $0.6 million and $0.9 million for the three and six months ended June 30, 2022. The increase in other income and interest income, net during the three and six months ended June 30, 2023 was primarily due to an increase of interest 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. We expect that any revenue recognized for the next several years will be derived primarily from our current collaboration with Moderna and any additional collaborations that we may enter into in the future. Through June 30, 2023, we have recognized $0.9 million in collaboration revenue under the Collaboration Agreement with Moderna. Historically, 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), sales of convertible preferred stock (which converted into common stock in 2020), and sales of common stock in underwritten public offerings,

"at-the-market" offerings, and in a private placement, as well as payments pursuant to our collaboration with Moderna. 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 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 August 2, 2023, the issuance date of the condensed consolidated financial statements, we have issued and sold 1,795,524 shares of our common stock pursuant to this sales agreement resulting in net proceeds of $12.3 million. In March 2023, in connection with the Share Purchase Agreement with Moderna, we issued and sold 5,859,375 shares of our common stock to Moderna at a price of $6.14 per share for an aggregate purchase price of $36.0 million. As of June 30, 2023, we had cash, cash equivalents and marketable securities of $314.1 million.

Cash flows

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

	Six Months Ended June 30,	
(in thousands)	**2023**	**2022**
Net cash used in operating activities	$ (2,871)	$ (58,968)
Net cash provided by (used in) investing activities	18,799	(161,505)
Net cash provided by financing activities	35,871	3,593
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 51,799	$ (216,880)

Operating activities

During the six months ended June 30, 2023, operating activities used $2.9 million of cash, primarily resulting from our net loss of $63.2 million, offset by the net changes in our operating assets and liabilities of $49.5 million and the net of non-cash charges of $10.8 million. Net changes in our operating assets and liabilities for the six months ended June 30, 2023 consisted of a $46.6 million increase of deferred revenue, a $3.4 million decrease in operating lease right-of-use assets, a $1.4 million decrease in prepaid expenses and other current assets, a $1.4 million decrease of other noncurrent assets, a $0.1 million decrease in tenant receivable, offset by a $2.2 million decrease of accrued expense and other current liabilities and accounts payable and a $1.1 million decrease in operating lease liability.

During the six months ended June 30, 2022, operating activities used $59.0 million of cash, primarily resulting from our net loss of $72.9 million, offset by non-cash charges of $20.0 million and changes in our operating assets and liabilities of $6.0 million. Net cash used by changes in our operating assets and liabilities for the six months ended June 30, 2022 consisted of a $3.5 million increase of other noncurrent assets, a $3.2 million increase in operating lease liability, a $3.1 million decrease of accrued expense and other current liabilities and accounts payable, a $3.1 million increase in prepaid expenses and other current assets, a $2.2 million decrease in operating lease right-of-use assets and a $1.8 million increase in tenant receivable.

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 six months ended June 30, 2023, net cash used in investing activities was $19.0 million, primarily due to purchases of marketable securities of $167.0 million and property and equipment of $2.2 million during the period, offset by $188.0 million in maturities of marketable securities. During the six months ended June 30, 2022, net cash used in investing activities was $161.5 million, due to purchases of marketable securities of $154.0 million and property and equipment of $7.5 million during the period. Property and equipment purchases during the six months ended June 30,

2023 and 2022 were primarily related to leasehold improvements and lab equipment for our facility in Cambridge, Massachusetts.

Financing activities

During the six months ended June 30, 2023, net cash provided by financing activities was $35.9 million, consisting primarily of net proceeds from the sale and issuance of our common stock to Moderna. During the six months ended June 30, 2022, net cash provided by financing activities was $3.6 million, consisting primarily of net proceeds from the sale of common stock pursuant to our "at-the-market" sales agreement of $2.7 million and $0.9 million in proceeds from the exercise of common stock options and other types of equity, net during the period.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance 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;
- our research and development costs and the amounts we receive as reimbursement and milestone payments under our collaboration with Moderna;
- the costs, timing and outcome of regulatory review of any product candidates we may develop;
- the cost and timing of completion of commercial-scale manufacturing activities, including the costs and resources required to manufacture our drug substance and drug product using external cleanroom facilities and/or CMOs;
- 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, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditures into 2025. 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. Although we may receive potential future payments under our collaboration with Moderna, 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.

We define our critical accounting policies as those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations as well as the specific manner in which we apply those principles. Management has determined that our most critical accounting policies are those relating to accrued research and development expenses, stock-based compensation, and revenue recognition.

Except for the addition of Revenue Recognition, during six months ended June 30, 2023, 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.

Revenue Recognition

We enter into collaboration agreements that are within the scope of ASC 606, under which we license rights to certain of our potential product candidates and perform research and development services.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for contracts determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination

of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration we are entitled to in exchange for the goods or services we transfer to the customer. For a further discussion, please refer to Note 2 , Revenue Recognition.

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 marketable securities of $169.2 million as of June 30, 2023. During the six months ended June 30, 2023, we recognized $5.7 million in interest earned on our invested cash balances and we did not record any impairment charges to our marketable securities. 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. 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 to 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 June 30, 2023. 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 June 30, 2023, 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 June 30, 2023 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.

The following information updates, and should be read in conjunction with, the risk factors discussed in Part I, Item 1A Risk Factors in our Annual Report, which could materially affect our business, financial condition, or future results.

We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

We hold a portion of cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts. The balance held in these accounts may exceed the Federal Deposit Insurance Corporation, or FDIC, standard deposit insurance limit of $250,000. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

For example, on March 10, 2023, Silicon Valley Bank, or SVB, and Signature Bank were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. While we believe that we are not exposed to significant credit risk due to the financial strength of the national depository institutions in which our cash, cash equivalents, and marketable securities are held, if the financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

We also maintain investment accounts in which we hold our investments and, if access to the funds we use for working capital and operating expenses is impaired, we may not be able to open new operating accounts or to sell investments or transfer funds from our investment accounts to new operating accounts on a timely basis sufficient to meet our operating expense obligations.

We have entered into, and we may continue to enter into, collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

In March 2023, we entered into the Collaboration Agreement with Moderna, to collaborate on developing treatments for certain diseases by targeting delivery of nucleic acids to liver cells and certain cells outside of the liver utilizing our ctLNP proprietary platform. We may seek in the future additional third-party collaborators for the research, development and commercialization of certain of the product candidates we may develop. However, we have agreed to certain exclusivity provisions that limit our ability to develop, manufacture, commercialize or exploit certain products we develop pursuant to the Collaboration Agreement or against certain targets set forth in the Collaboration Agreement and, as a result, could limit our ability to into additional third-party collaborations. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. For example, while Moderna has agreed to use commercially reasonable efforts to complete the activities assigned to it under the research plans set forth in the Collaboration Agreement, we cannot control the amount or timing of resources that they dedicate to these activities. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these

arrangements. We cannot predict the success of our collaboration with Moderna or any other collaboration that we may enter into.

Collaborations involving our research programs or any product candidates we may develop, including our existing collaboration with Moderna, pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay programs, preclinical studies or clinical trials, provide insufficient funding for programs, preclinical studies or clinical trials, stop a preclinical study or clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with any product candidates we may develop if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may be acquired by a third party having competitive products or different priorities;
- collaborators with marketing and distribution rights to one or more medicines may not commit sufficient resources to the marketing and distribution of such medicine or medicines;
- collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our medicines or any product candidates we may develop or that result in costly litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under certain circumstances, including if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates we may develop; and
- collaboration agreements, including the Collaboration Agreement with Moderna, may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development,

regulatory approval and commercialization described in the risk factors discussed in Part I, Item 1A in our Annual Report apply to the activities of our collaborators.

We may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any product candidates we may develop. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement with a future collaborator will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

Our current collaboration with Moderna, future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.

We may acquire additional businesses or drugs, form strategic alliances or collaborations, such as our current collaboration with Moderna, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance, collaboration, including our current collaboration with Moderna, or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure our stockholders that, following any such strategic alliance, acquisition or collaboration, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;
- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the

incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

Item 5. Other Information.

Director and Officer Trading Arrangements

The following table describes, for the period covered by this Quarterly Report, each trading arrangement for the sale or purchase of Company securities adopted or terminated by our directors and officers that is a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) (a "Rule 10b5-1 trading arrangement"). For the period covered by this Quarterly Report, none of our directors or officers adopted or terminated a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K).

Name	Title	Action Taken	Date	Shares to be Sold	Expiration Date
Matthew Stanton	Chief Scientific Officer	Adoption	April 14, 2023	20,000	January 13, 2024
Antoinette Paone	Chief Operating Officer	Adoption	April 24, 2023	155,472*	August 30, 2024
Douglas Kerr	Chief Medical Officer	Adoption	April 24, 2023	24,968	October 24, 2024
Phillip Samayoa	Chief Strategy Officer	Adoption	June 29, 2023	100,947*	May 15, 2024

*In addition to the number of shares acquired through our Employee Stock Purchase Program, which number cannot be determined at this time.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
3.1*	Restated Certificate of Incorporation of the registrant, as amended June 8, 2023
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.

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: August 2, 2023

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

Date: August 2, 2023

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

Exhibit 3.1

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

GENERATION BIO CO.

Generation Bio Co., a corporation organized and existing under the General Corporation Law of the State of Delaware, does hereby certify that the name of the corporation is Generation Bio Co. and the original certificate of incorporation of the corporation was filed with the Secretary of State of the State of Delaware on October 21, 2016 under the name Torus Therapeutics, Inc. This Restated Certificate of Incorporation, having been duly adopted in accordance with Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware, restates, integrates and amends the certificate of incorporation of the Corporation as follows:

FIRST: The name of the Corporation is Generation Bio Co.

SECOND: The address of the Corporation's registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at that address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of all classes of stock that the Corporation shall have authority to issue is 155,000,000 shares, consisting of (i) 150,000,000 shares of Common Stock, $.0001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, $.0001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A COMMON STOCK.

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.

2. Voting. The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation or the General Corporation Law of the State of Delaware. There shall be no cumulative voting.

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

3. Dividends. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor if, as and when determined by the Board of Directors and subject to any preferential dividend or other rights of any then outstanding Preferred Stock.

4. Liquidation. Upon the dissolution, liquidation or winding up of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential or other rights of any then outstanding Preferred Stock.

B PREFERRED STOCK.

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Any shares of Preferred Stock that may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative, participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law. The powers, preferences and relative, participating, optional and other special rights of each series of Preferred Stock, and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Corporation entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

FIFTH: Except as otherwise provided herein, the Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Certificate of Incorporation, and all rights conferred upon stockholders herein are granted subject to this reservation.

SIXTH: In furtherance and not in limitation of the powers conferred upon it by the General Corporation Law of the State of Delaware, and subject to the terms of any series of Preferred Stock, the Board of Directors shall have the power to adopt, amend, alter or repeal the Bylaws of the Corporation by the affirmative vote of a majority of the directors present at any regular or special meeting of the Board of Directors at which a quorum is present. The stockholders may not adopt, amend, alter or repeal the Bylaws of the Corporation, or adopt any provision inconsistent therewith, unless such action is approved, in addition to any other vote required by this Certificate of Incorporation, by the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors. Notwithstanding any other provisions of law, this Certificate of Incorporation or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article SIXTH.

SEVENTH: Except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal. If the General Corporation Law of the State of Delaware is amended to permit further elimination or limitation of the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

EIGHTH: The Corporation shall provide indemnification and advancement of expenses as follows:

1. Actions, Suits and Proceedings Other than by or in the Right of the Corporation. The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter

as an “Indemnitee”), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys’ fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974), and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

2. Actions or Suits by or in the Right of the Corporation. The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys’ fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including attorneys’ fees) which the Court of Chancery of Delaware or such other court shall deem proper.

3. Indemnification for Expenses of Successful Party. Notwithstanding any other provisions of this Article EIGHTH, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 1 and 2 of this Article EIGHTH, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified against all expenses (including attorneys’ fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith. Without limiting the foregoing, if any action, suit or proceeding is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to Indemnitee, (ii) an adjudication that Indemnitee was liable to the Corporation, (iii) a plea of guilty or nolo contendere by Indemnitee, (iv) an adjudication that Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Corporation, and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe his or her conduct was unlawful, Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect thereto.

4. Notification and Defense of Claim. As a condition precedent to an Indemnitee’s right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or

investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (i) the employment of counsel by Indemnitee has been authorized by the Corporation, (ii) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article EIGHTH. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Corporation shall not be required to indemnify Indemnitee under this Article EIGHTH for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

5. Advancement of Expenses. Subject to the provisions of Section 6 of this Article EIGHTH, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article EIGHTH, any expenses (including attorneys' fees) incurred by or on behalf of Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter; provided, however, that the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article EIGHTH; and provided further that no such advancement of expenses shall be made under this Article EIGHTH if it is determined (in the manner described in Section 6) that (i) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (ii) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

6. Procedure for Indemnification and Advancement of Expenses. In order to obtain indemnification or advancement of expenses pursuant to Section 1, 2, 3 or 5 of this Article EIGHTH, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (i) the Corporation has assumed the defense pursuant to Section 4 of this Article EIGHTH (and none of the circumstances described in Section 4 of this Article EIGHTH that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (ii) the Corporation determines within such 60-day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 1, 2 or 5 of this Article EIGHTH, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 1 or 2 of this Article EIGHTH only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 1 or 2 of this Article EIGHTH, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion, or (d) by the stockholders of the Corporation.

7. Remedies. Subject to Article TWELFTH, the right to indemnification or advancement of expenses as granted by this Article EIGHTH shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 6 of this Article EIGHTH that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification or advancement of expenses, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article EIGHTH. Indemnitee's expenses (including attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification or advancement of expenses, in whole or in part, in any such proceeding shall also be indemnified by the Corporation to the fullest extent permitted by applicable law. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification or advancement of expenses hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the General Corporation Law of the State of Delaware.

8. Limitations. Notwithstanding anything to the contrary in this Article EIGHTH, except as set forth in Section 7 of this Article EIGHTH, the Corporation shall not indemnify, or advance expenses to, an Indemnitee pursuant to this Article EIGHTH in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors. Notwithstanding anything to the contrary in this Article EIGHTH, the Corporation shall not indemnify or advance expenses to an Indemnitee to the extent such Indemnitee is reimbursed from the proceeds of insurance, and in the event the Corporation makes any indemnification or advancement payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification or advancement payments to the Corporation to the extent of such insurance reimbursement.

9. Subsequent Amendment. No amendment, termination or repeal of this Article EIGHTH or of the relevant provisions of the General Corporation Law of the State of Delaware or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification or advancement of expenses under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

10. Other Rights. The indemnification and advancement of expenses provided by this Article EIGHTH shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article EIGHTH shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification and expense advancement rights and procedures different from those set forth in this Article EIGHTH. In addition, the Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification and expense advancement rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article EIGHTH.

11. Partial Indemnification. If an Indemnitee is entitled under any provision of this Article EIGHTH to indemnification by the Corporation for some or a portion of the expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement to which Indemnitee is entitled.

12. Insurance. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of the State of Delaware.

13. Savings Clause. If this Article EIGHTH or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article EIGHTH that shall not have been invalidated and to the fullest extent permitted by applicable law.

14. Definitions. Terms used herein and defined in Section 145(h) and Section 145(i) of the General Corporation Law of the State of Delaware shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

NINTH: This Article NINTH is inserted for the management of the business and for the conduct of the affairs of the Corporation.

1. General Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

2. Number of Directors; Election of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Corporation shall be established from time to time by the Board of Directors. Election of directors need not be by written ballot, except as and to the extent provided in the Bylaws of the Corporation.

3. Classes of Directors. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes, designated Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II or Class III at the time such classification becomes effective.

4. Terms of Office. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; provided that each director initially assigned to Class I shall serve for a term expiring at the Corporation's first annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; each director initially assigned to Class II shall serve for a term expiring at the Corporation's second annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; and each director initially assigned to Class III shall serve for a term expiring at the Corporation's third annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; provided further, that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

5. Quorum. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors fixed pursuant to Section 2 of this Article NINTH shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.

6. Action at Meeting. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors unless a greater number is required by law or by this Certificate of Incorporation.

7. Removal. Subject to the rights of holders of any series of Preferred Stock, directors of the Corporation may be removed only for cause and only by the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors.

8. Vacancies. Subject to the rights of holders of any series of Preferred Stock, any vacancies or newly-created directorships on the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy or to fill a position resulting from a newly-created directorship shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor and to such director's earlier death, resignation or removal.

9. Stockholder Nominations and Introduction of Business, Etc. Advance notice of stockholder nominations for election of directors and other business to be brought by stockholders before a meeting of stockholders shall be given in the manner provided by the Bylaws of the Corporation.

10. Amendments to Article. Notwithstanding any other provisions of law, this Certificate of Incorporation or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article NINTH.

TENTH: Stockholders of the Corporation may not take any action by written consent in lieu of a meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article TENTH.

ELEVENTH: Special meetings of stockholders for any purpose or purposes may be called at any time only by the Board of Directors and may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting. Notwithstanding any other provisions of law, this Certificate of Incorporation or the Bylaws of the Corporation, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article ELEVENTH.

TWELFTH: (a) Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, other employee or stockholder of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim arising pursuant to any provision of this Certificate of Incorporation or the Bylaws of the Corporation (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This paragraph (a) of Article TWELFTH does not apply to claims brought to enforce any duty or liability created by the Securities Act of 1933 or the rules and regulations thereunder or the Securities Exchange Act of 1934 or the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction.

(b) Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933.

(c) Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article TWELFTH.

IN WITNESS WHEREOF, this Amended and Restated Certificate of Incorporation, which restates, integrates and amends the certificate of incorporation of the Corporation, and which has been duly adopted in accordance with Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware, has been executed by its duly authorized officer this 16th day of June, 2020.

GENERATION BIO CO.

By: /s/ Geoff McDonough
Name: Geoff McDonough
Title: President and Chief Executive Officer

STATE OF DELAWARE

CERTIFICATE OF AMENDMENT

OF CERTIFICATE OF INCORPORATION

The corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware does hereby certify:

FIRST: That at a meeting of the Board of Directors of Generation Bio Co. resolutions were duly adopted setting forth a proposed amendment of the Certificate of Incorporation of said corporation, declaring said amendment to be advisable and calling a meeting of the stockholders of said corporation for consideration thereof. The resolution setting forth the proposed amendment is as follows:

RESOLVED, that the Certificate of Incorporation of this corporation be amended by changing the Article thereof numbered "SEVENTH" so that, as amended, said Article shall be and read as follows:

To the fullest extent permitted by the General Corporation Law of the State of Delaware, no director or officer of the Corporation shall be personally liable to the Corporation (in the case of directors) or its stockholders (in the case of directors and officers) for monetary damages for any breach of fiduciary duty as a director or officer. No amendment, repeal or elimination of this provision shall apply to or have any effect on its application with respect to any act or omission of a director or officer occurring before such amendment, repeal or elimination. If the General Corporation Law of the State of Delaware is amended to permit further elimination or limitation of the personal liability of directors or officers, then the liability of a director or officer of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

SECOND: That thereafter, pursuant to resolution of its Board of Directors, a meeting of the stockholders of said corporation was duly called and held upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware at which meeting the necessary number of shares as required by statute were voted in favor of the amendment.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, said corporation has cause this certificate to be signed this eighth day of June, 2023

By: /s/ Geoff McDonough
Name: Geoff McDonough
Title: President and Chief Executive 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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: August 2, 2023

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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: August 2, 2023

/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 June 30, 2023 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)
August 2, 2023

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 June 30, 2023 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)
August 2, 2023