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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 September 30, 2022

OR

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

For the transition period from _____ to_____

Commission File Number: 001-39319

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

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

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

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

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of October 31, 2022 there were 59,422,697 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;
- 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 commercial objectives;
- the impact of the COVID-19 pandemic and our response to the pandemic;
- the impact of government laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- developments and expectations regarding developments and projections relating to our competitors and our industry; and
- our ability to maintain and establish collaborations or obtain additional funding.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and stockholders should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report, particularly in the "Risk Factors" section in 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 134,487	$ 375,145
Marketable securities	166,682	—
Tenant receivable	395	—
Prepaid expenses and other current assets	8,994	4,041
Total current assets	310,558	379,186
Property and equipment, net	23,435	25,886
Operating lease right-of-use assets	61,126	65,143
Restricted cash	5,692	5,692
Deferred offering costs	434	461
Other long-term assets	1,554	403
Total assets	$ 402,799	$ 476,771
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,693	$ 2,023
Accrued expenses and other current liabilities	8,995	12,177
Operating lease liability	6,630	4,608
Total current liabilities	17,318	18,808
Operating lease liability, net of current portion	76,732	76,217
Total liabilities	94,050	95,025
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized at September 30, 2022 and December 31, 2021; 59,275,169 and 56,980,701 shares issued at September 30, 2022 and December 31, 2021, respectively; 59,275,169 and 56,969,618 shares outstanding at September 30, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	721,405	689,866
Accumulated other comprehensive income	(302)	—
Accumulated deficit	(412,360)	(308,126)
Total stockholders' equity	308,749	381,746
Total liabilities and stockholders' equity	$ 402,799	$ 476,771

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 21,192	$ 21,991	$ 75,111	$ 63,400
General and administrative	11,477	9,667	31,383	24,755
Total operating expenses	32,669	31,658	106,494	88,155
Loss from operations	(32,669)	(31,658)	(106,494)	(88,155)
Other income:				
Other income (expense) and interest income, net	1,363	(197)	2,260	(53)
Net loss and net loss attributable to common stockholders	$ (31,306)	$ (31,855)	$ (104,234)	$ (88,208)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.53)	$ (0.56)	$ (1.81)	$ (1.57)
Weighted average common shares outstanding, basic and diluted	58,872,334	56,629,193	57,679,635	56,108,492
Comprehensive loss:				
Net loss	$ (31,306)	$ (31,855)	$ (104,234)	$ (88,208)
Other comprehensive loss:				
Unrealized gains (losses) on marketable securities	37	(3)	(302)	(8)
Comprehensive loss	$ (31,269)	$ (31,858)	$ (104,536)	$ (88,216)

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 September 30, 2022					
Balances at June 30, 2022	57,597,141	$ 6	$ 706,261	$ (339)	$ (381,054)	$ 324,874
Issuance of common stock from public ATM offering, net of commissions and offering costs of $315	1,379,887	—	9,617	—	—	9,617
Issuance of common stock upon exercise of stock options	15,026	—	58	—	—	58
Vesting of restricted common stock	280,404	—	(394)	—	—	(394)
Issuance of common stock under other equity plans	2,711	—	15	—	—	15
Stock-based compensation expense	—	—	5,848	—	—	5,848
Unrealized gains on marketable securities	—	—	—	37	—	37
Net loss	—	—	—	—	(31,306)	(31,306)
Balances at September 30, 2022	59,275,169	$ 6	$ 721,405	$ (302)	$ (412,360)	$ 308,749

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Three Months Ended September 30, 2021					
Balances at June 30, 2021	56,431,513	$ 6	$ 678,720	$ 4	$ (245,328)	$ 433,402
Issuance of common stock upon exercise of stock options	145,646	—	697	—	—	697
Vesting of restricted common stock	155,306	—	—	—	—	—
Stock-based compensation expense	—	—	4,970	—	—	4,970
Unrealized losses on marketable securities	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(31,855)	(31,855)
Balances at September 30, 2021	56,732,465	$ 6	$ 684,387	$ —	$ (277,183)	$ 407,210

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				
	Nine Months Ended September 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 $404	1,795,524	—	12,338	—	—	12,338
Issuance of common stock upon exercise of stock options	147,400	—	611	—	—	611
Vesting of restricted common stock	294,767	—	(394)	—	—	(394)
Issuance of common stock under other equity plans	67,860	—	379	—	—	379
Stock-based compensation expense	—	—	18,605	—	—	18,605
Unrealized losses on marketable securities	—	—	—	(302)	—	(302)
Net loss	—	—	—	—	(104,234)	(104,234)
Balances at September 30, 2022	59,275,169	$ 6	$ 721,405	$ (302)	$ (412,360)	$ 308,749

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
	Nine Months Ended September 30, 2021					
Balances at December 31, 2020	46,291,877	$ 5	$ 456,974	$ 9	$ (188,975)	$ 268,013
Issuance of common stock upon initial public offering, net of issuance costs of $590	9,200,000	1	211,285	—	—	211,286
Issuance of common stock upon exercise of stock options	689,166	—	2,947	—	—	2,947
Vesting of restricted common stock	535,911	—	—	—	—	—
Issuance of common stock under other equity plans	15,511	—	355	—	—	355
Stock-based compensation expense	—	—	12,826	—	—	12,826
Unrealized losses on marketable securities	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	(88,208)	(88,208)
Balances at September 30, 2021	56,732,465	$ 6	$ 684,387	$ —	$ (277,183)	$ 407,210

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)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (104,234)	$ (88,208)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	18,605	12,826
Depreciation and amortization expense	3,784	3,367
Amortization (accretion) of premium (discount) on marketable securities, net	(984)	514
Loss on sale of property and equipment	28	223
Loss on impairment of property and equipment	5,395	—
Changes in operating assets and liabilities:		
Tenant receivable	(395)	—
Prepaid expenses and other current assets	(4,939)	504
Operating lease right-of-use assets	4,017	2,157
Other noncurrent assets	(1,151)	(133)
Accounts payable	(444)	253
Accrued expenses and other current liabilities	(1,663)	523
Operating lease liability	2,536	(3,045)
Net cash used in operating activities	(79,445)	(71,019)
Cash flows from investing activities:		
Purchases of property and equipment	(8,119)	(3,123)
Proceeds from sale of property and equipment	—	105
Purchases of marketable securities	(221,000)	—
Maturities of marketable securities	55,000	188,900
Net cash (used in) provided by investing activities	(174,119)	185,882
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of underwriting discounts and commissions	—	211,876
Payment of offering costs	(50)	(942)
Proceeds from issuance of common stock from public ATM offering, net of commissions and offering costs	12,360	—
Proceeds from exercise of stock options and other types of equity, net	990	3,302
Tax withholding payments related to net share settlements of restricted stock units	(394)	—
Net cash provided by financing activities	12,906	214,236
Net (decrease) increase in cash, cash equivalents and restricted cash	(240,658)	329,099
Cash, cash equivalents and restricted cash at beginning of period	380,837	64,940
Cash, cash equivalents and restricted cash at end of period	$ 140,179	$ 394,039
Supplemental disclosure of noncash investing and financing information:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 165	$ 249
Unrealized losses on marketable securities	$ (302)	$ (8)
Offering costs included in accounts payable and accrued expenses	$ —	$ 80

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.

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

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, we have funded our operations with proceeds from the sale of instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the sales of convertible preferred stock (which converted into common stock in 2020), and most recently, the sales of common stock in underwritten public offerings. We have incurred recurring losses, including net losses of $104.2 million for the nine months ended September 30, 2022 and $88.2 million for the nine months ended September 30, 2021. As of September 30, 2022, we had an accumulated deficit of $412.4 million. We expect to continue to generate operating losses in the foreseeable future. As of November 3, 2022, 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 collaborative or strategic alliances or licensing arrangements. The terms of any financing may adversely affect the holdings or the rights of our stockholders. Arrangements with collaborators or others may require us to relinquish rights to certain of our technologies or programs. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs, pipeline expansion or commercialization efforts, which could adversely affect our business prospects. Although management will continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations when needed or at all.

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

2. Summary of Significant Accounting Policies

Use of estimates

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

Unaudited interim financial information

The condensed consolidated balance sheet as of December 31, 2021 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 have been prepared by us pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These financial statements should be read in conjunction with our audited financial statements included in our Annual Report on Form 10-K that was most recently filed with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair presentation of our financial position as of September 30, 2022, the results of operations for the three and nine months ended September 30, 2022 and 2021, and cash flows for the nine months ended September 30, 2022 and 2021 have been made. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022 or any other period.

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

3. Marketable Securities and Fair Value Measurements

The following tables present our marketable securities by security type:

	As of September 30, 2022			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 9,992	$ —	$ —	$ 9,992
U.S. treasury securities	156,992	8	(310)	156,690
Totals	$ 166,984	$ 8	$ (310)	$ 166,682

As of September 30, 2022, our marketable securities consisted of investments that mature within one year.

We did not have marketable securities as of December 31, 2021.

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 September 30, 2022 Using:			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 1,285	$ —	$ —	$ 1,285
U.S. treasury securities	—	32,841	—	32,841
Marketable securities:				
Commercial paper	—	9,992	—	9,992
U.S. treasury securities	—	156,690	—	156,690
Totals	$ 1,285	$ 199,523	$ —	$ 200,808

	Fair Value Measurements at December 31, 2021 Using:			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 259,609	$ —	$ —	$ 259,609

Money market funds were valued based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. Our marketable securities, which as of September 30, 2022 have consisted of commercial paper and U.S. treasury securities, were valued using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

4. Property and equipment, net

Property and equipment, net consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
Laboratory equipment	$ 13,765	$ 12,826
Computer equipment and software	1,193	1,128
Furniture and fixtures	1,134	826
Leasehold improvements	20,751	17,374
Construction in progress	94	3,748
	36,937	35,902
Less: Accumulated depreciation and amortization	(13,502)	(10,016)
Total	$ 23,435	$ 25,886

Depreciation and amortization expense for the three and nine months ended September 30, 2022 was $1.4 million and $3.8 million, respectively. Depreciation and amortization expense for the three and nine months ended September 30, 2021 was $1.2 million and $3.4 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. Following additional process development of RES, we achieved a significant increase in scale, while maintaining high productivity and ceDNA purity. RES production requires a much smaller manufacturing footprint than previously anticipated, and consequently, we are seeking one or more third parties to assume our lease or sublease the property. As a result, we recognized an impairment of $5.0 million related to the abandonment of leasehold improvements on our condensed consolidated statements of operations and comprehensive loss during the nine months ended September 30, 2022. We have performed an impairment assessment on other assets related to this abandonment of leasehold improvements and concluded that no additional impairment is necessary.

5. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
Accrued employee compensation and benefits	$ 6,405	$ 7,579
Accrued external research and development expenses	1,000	2,091
Accrued professional fees	1,174	962
Property and equipment	46	869
Other	370	676
Total	$ 8,995	$ 12,177

6. Equity

As of September 30, 2022, our amended and restated certificate of incorporation authorizes us to issue 150,000,000 shares of common stock, par value $0.0001 per share, and 5,000,000 shares of preferred stock, par value $0.0001 per share, all of which preferred stock is undesignated.

In January 2021, we issued and sold 9,200,000 shares of our common stock, including 1,200,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, in a follow-on public offering, resulting in net proceeds of $211.3 million after deducting underwriting discounts and commissions and other offering expenses. In August 2021, we entered into an "at-the-market" sales agreement pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $250.0 million. As of November 3, 2022, 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.

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.

7. Stock-Based Compensation

Stock incentive plans

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

In May 2020, our board of directors adopted, and in June 2020, our stockholders approved, the 2020 Stock Incentive Plan, or the 2020 Plan, and, together with the 2017 Plan, the Plans, which became effective on June 11, 2020. The 2020 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of common stock reserved for issuance under the 2020 Plan is the sum of (1) 2,547,698 shares; plus (2) the number of shares (up to a maximum of 7,173,014 shares) as was equal to the sum of (x) the number of shares of common stock reserved for issuance under the 2017 Plan that remained available for grant under the 2017 Plan on June 11, 2020 and (y) the number of shares of common stock subject to outstanding awards granted under the 2017 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2021 and continuing until, and including, the fiscal year ending December 31, 2030, equal to the lesser of (i) 4% of the number of shares of common stock outstanding on such date, and (ii) an amount determined by the board of directors. In January 2021 and 2022, the number of shares of common stock authorized for issuance under the 2020 Plan was increased from 10,275,717 shares to 12,154,517 shares and from 12,154,517 shares to 14,433,745 shares, respectively. Upon the effectiveness of the 2020 Plan, we ceased granting additional awards under the 2017 Plan.

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

As of September 30, 2022, 675,968 shares remained available for future issuance under the 2020 Plan. Shares subject to outstanding awards granted under the Plans that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right will be available for future awards under the 2020 Plan.

Grant of stock options

During the nine months ended September 30, 2022, we granted service-based options to certain employees and directors for the purchase of 3,368,790 shares of common stock with a weighted average grant date fair value of $4.78 per share that vest over a weighted average period of approximately four years.

Restricted stock units

During the nine months ended September 30, 2022, we issued 1,660,884 restricted stock units with a fair value of $10.9 million that vest over a weighted average period of approximately 2.2 years.

Employee stock purchase plan

In May 2020, our board of directors adopted, and in June 2020, our stockholders approved, the 2020 Employee Stock Purchase Plan, or the 2020 ESPP, which became effective June 11, 2020. The 2020 ESPP is administered by our board of directors or by a committee appointed by the board of directors. The number of shares of common stock reserved for issuance under the 2020 ESPP automatically increases on the first day of each fiscal year, beginning with the fiscal year that commenced on January 1, 2021 and continuing for each fiscal year until, and including the fiscal year commencing on, January 1, 2030, in an amount equal to the lowest of (1) 1,302,157 shares of common stock, (2) 1% of the number of shares of common stock outstanding on such date, and (3) an amount determined by the board of directors. In January 2022, the number of shares of common stock authorized for issuance under the 2020 ESPP was increased from 950,931 shares to 1,520,738 shares. As of September 30, 2022, 1,414,371 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 September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Research and development expenses	$ 3,046	$ 2,498	$ 9,674	$ 6,772
General and administrative expenses	2,802	2,472	8,931	6,054
Total	$ 5,848	$ 4,970	$ 18,605	$ 12,826

As of September 30, 2022, total unrecognized compensation cost related to unvested service-based stock options and restricted common stock was $49.7 million, with $43.0 million expected to be recognized over a weighted average period of 2.6 years and $6.7 million expected to be recognized over a weighted average period of 1.5 years, respectively. Additionally, as of September 30, 2022, we had unrecognized compensation cost related to unvested stock options with performance-based vesting conditions for which performance has not been deemed probable of $1.7 million.

8. 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 nine months ended September 30, 2022.

9. 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:

	September 30,	
	2022	2021
Unvested restricted common stock	—	145,567
Unvested restricted common stock units	1,170,433	14,760
Stock options to purchase common stock	8,786,200	6,071,008
Total	9,956,633	6,231,335

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

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

Overview

We are innovating genetic medicines to provide durable, redosable treatments for potentially hundreds of millions of patients living with rare and prevalent diseases. Our non-viral genetic medicine platform incorporates our high-capacity 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 and expansive portfolio of programs, including programs for rare and prevalent diseases of the liver and retina. We are focused on diseases with significant unmet need for which our non-viral genetic medicine platform may substantially improve clinical efficacy relative to current gene therapy approaches. We are initially prioritizing rare monogenic diseases of the liver and retina, which are diseases that result from mutations in a single gene, that have well-established biomarkers and clear clinical and regulatory pathways. We are currently optimizing our ctLNPs to improve on-target biodistribution, which we believe will enable ligand-directed, selective delivery to hepatocytes and other cell types. We plan to expand our portfolio to include rare and prevalent diseases of the skeletal muscle, the central nervous system and oncology by developing discrete ctLNPs, each engineered to reach a different tissue.

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

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

In July 2021, we entered into a lease agreement, or the Seyon Lease, 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. Following additional process development of RES, we achieved a significant increase in scale, while maintaining high productivity and ceDNA purity. RES production requires a much smaller manufacturing footprint than previously anticipated, and consequently, we are seeking one or more third parties to assume our lease or sublease the property. 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.

Since our inception in October 2016, we have focused substantially all of our resources on building our non-viral genetic medicine platform, establishing and protecting our intellectual property portfolio, conducting research and development activities, developing our manufacturing process, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations with proceeds from the sale of instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the sales of convertible preferred stock (which converted into common stock in 2020) and, most recently, the sales of common stock in public offerings. In June 2020, we completed our initial public offering, or IPO, pursuant to which we issued and sold 12,105,263 shares of our common stock, including 1,578,947 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares. We received net proceeds of $210.7 million, after deducting underwriting discounts and commissions and other offering expenses. In January 2021, we issued and sold 9,200,000 shares of our common stock, including 1,200,000 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares, in a follow-on public offering, resulting in net proceeds of $211.3 million after deducting underwriting discounts and commissions and other offering expenses.

Historically, we have incurred significant operating losses. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more product candidates we may develop. For the nine months ended September 30, 2022 and 2021, we reported net losses of $104.2 million and $88.2 million, respectively. As of September 30, 2022, we had an accumulated deficit of $412.4 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- continue our current research programs and conduct additional research programs;
- expand the capabilities of our proprietary non-viral genetic medicine platform;
- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development, future commercialization efforts and operations as a public company;
- develop our capabilities to manufacture and establish additional commercial manufacturing sources and secure supply chain capacity sufficient to provide necessary quantities of any product candidates we may develop for clinical or commercial use;
- 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. 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.”

COVID-19

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

We continue to closely monitor the ongoing impact and effects of the COVID-19 pandemic on our employees and our other business operations. In an effort to provide a safe work environment for our employees, we have maintained our increased cadence of sanitization of our office and lab facilities and provision of personal protective equipment for our employees present in our office and lab facilities. Moreover, in accordance with updated federal and state guidelines, we have relaxed some of our COVID-19 related restrictions. For example, we are permitting on-site presence in our office and lab facilities. Additionally, we implemented a company policy requiring COVID-19 vaccinations for all employees, with certain limited exceptions.

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

Components of Our Results of Operations

Operating expenses

Research and development expenses

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

- personnel-related costs, including salaries, benefits and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with our research programs, including under agreements with third parties, such as consultants, contractors and CROs, and regulatory agency fees;
- the cost of developing and scaling our manufacturing process and 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 CMOs;
- 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, CMOs 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; and

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

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

General and administrative expenses

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

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

Other income and interest income

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

Results of Operations

Comparison of the three and nine months ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three and nine months ended September 30, 2022 and 2021:

(in thousands)	Three Months Ended September 30, 2022	2021	Change 2022 vs 2021	Nine Months Ended September 30, 2022	2021	Change 2022 vs 2021
Operating expenses:						
Research and development	$ 21,192	$ 21,991	$ (799)	$ 75,111	$ 63,400	$ 11,711
General and administrative	11,477	9,667	1,810	31,383	24,755	6,628
Total operating expenses	32,669	31,658	1,011	106,494	88,155	18,339
Loss from operations	(32,669)	(31,658)	(1,011)	(106,494)	(88,155)	(18,339)
Other income:						
Other income (expense) and interest income, net	1,363	(197)	1,560	2,260	(53)	2,313
Net loss	$ (31,306)	$ (31,855)	$ 549	$ (104,234)	$ (88,208)	$ (16,026)

Research and development expenses

The following table summarizes our research and development expenses for the three and nine months ended September 30, 2022 and 2021:

(in thousands)	Three Months Ended September 30, 2022	2021	Change 2022 vs 2021	Nine Months Ended September 30, 2022	2021	Change 2022 vs 2021
Personnel-related	$ 7,258	$ 6,375	$ 883	$ 22,427	$ 17,530	$ 4,897
Preclinical and manufacturing	3,339	5,946	(2,607)	11,513	19,584	(8,071)
Facilities-related	3,964	2,610	1,354	18,826	7,350	11,476
Stock-based compensation	3,046	2,498	548	9,674	6,772	2,902
Lab supplies	1,180	1,953	(773)	4,111	5,388	(1,277)
Consulting and professional services	562	734	(172)	2,733	1,837	896
Other	1,843	1,875	(32)	5,827	4,939	888
Total research and development expenses	$ 21,192	$ 21,991	$ (799)	$ 75,111	$ 63,400	$ 11,711

Research and development expenses were $21.2 million for the three months ended September 30, 2022, compared to $22.0 million for the three months ended September 30, 2021. The decrease in preclinical and manufacturing costs of $2.6 million was primarily due to a decrease in costs resulting from our transitioning our manufacturing process from the use of Sf9 cells to RES in the second half of 2021. This decrease was partially offset by an increase in facilities-related costs of $1.4 million primarily driven by costs associated with operating our laboratory space, as well as an increase in personnel-related costs of $0.9 million primarily due to increased headcount and overall growth to support our research and development function.

Research and development expenses were $75.1 million for the nine months ended September 30, 2022, compared to $63.4 million for the nine months ended September 30, 2021. The increase in facilities-related costs of $11.5 million was primarily driven by the recognition of a $5.0 million impairment related to the abandonment of leasehold improvements and rent expense related to the Seyon Lease. The increases in personnel-related costs of $4.9 million and stock-based compensation costs of $2.9 million were primarily due to increased headcount in our research and development function. These increases were partially offset by a decrease in preclinical and manufacturing costs of $8.1 million primarily due to a decrease in costs resulting from our transitioning our manufacturing process from the use of Sf9 cells to RES in the second half of 2021.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three and nine months ended September 30, 2022 and 2021:

(in thousands)	Three Months Ended September 30, 2022	2021	Change 2022 vs 2021	Nine Months Ended September 30, 2022	2021	Change 2021 vs 2020
Personnel-related	$ 3,822	$ 3,354	$ 468	$ 11,592	$ 9,646	$ 1,946
Stock-based compensation	2,802	2,472	330	8,931	6,054	2,877
Professional and consultant fees	1,565	2,178	(613)	5,720	5,777	(57)
Facilities-related	2,730	206	2,524	3,528	888	2,640
Other	558	1,457	(899)	1,612	2,390	(778)
Total general and administrative expenses	$ 11,477	$ 9,667	$ 1,810	$ 31,383	$ 24,755	$ 6,628

General and administrative expenses were $11.5 million for the three months ended September 30, 2022, compared to $9.7 million for the three months ended September 30, 2021. The increase in facilities-related costs of $2.5 million was primarily driven by rent expense related to the Seyon Lease.

General and administrative expenses were $31.4 million for the nine months ended September 30, 2022, compared to $24.8 million for the nine months ended September 30, 2021. The increases in stock-based compensation costs and personnel-related costs of $2.9 million and $1.9 million, respectively, were primarily a result of an increase in headcount in our general and administrative function. The increase in facilities-related costs of $2.6 million was primarily driven by rent expense related to the Seyon Lease.

Other income (expense) and interest income, net

Other income and interest income, net for the three and nine months ended September 30, 2022 was $1.4 million and $2.3 million, respectively, as compared to other expense and interest income, net of $0.2 million and $0.1 million for the three and nine months ended September 30, 2021, respectively. The increase in other income (expense) and interest income, net during the three and nine months ended September 30, 2022 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. To date, we have funded our operations with proceeds from instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the sales of convertible preferred stock (which converted into common stock in 2020) and with proceeds from the sales of common stock in public offerings. In June 2020, we completed our IPO, pursuant to which we issued and sold 12,105,263 shares of our common stock, including 1,578,947 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares. We received net proceeds of $210.7 million, after deducting underwriting discounts and commissions and other offering expenses. In January 2021, we issued and sold 9,200,000 shares of our common stock, including 1,200,000 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares, in a follow-on public offering, resulting in net proceeds of $211.3 million, after deducting underwriting discounts and commissions and other offering expenses. In August 2021, we entered into an "at-the-market" sales agreement pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $250.0 million. As of November 3, 2022, 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. As of September 30, 2022, we had cash, cash equivalents and marketable securities of $301.2 million.

Cash flows

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

(in thousands)	Nine Months Ended September 30, 2022	2021
Net cash used in operating activities	$ (79,445)	$ (71,019)
Net cash (used in) provided by investing activities	(174,119)	185,882
Net cash provided by financing activities	12,906	214,236
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (240,658)	$ 329,099

Operating activities

During the nine months ended September 30, 2022, operating activities used $79.4 million of cash, primarily resulting from our net loss of $104.2 million, offset by the net of non-cash charges of $26.8 million and cash used in the changes in our operating assets and liabilities of $2.0 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2022 consisted of a $1.2 million increase of other noncurrent assets, a $2.5 million increase in operating lease liability, a $2.1 million decrease of accrued expense and other current liabilities and accounts payable, a $4.9 million increase in prepaid expenses and other current assets, a $4.0 million decrease in operating lease right-of-use assets and a $0.4 million increase in tenant receivable.

During the nine months ended September 30, 2021, operating activities used $71.0 million of cash, primarily resulting from our net loss of $88.2 million, offset by non-cash charges of $16.9 million and changes in our operating assets and liabilities of $0.3 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2021 consisted primarily of a $3.0 million decrease in operating lease liability, a $2.2 million decrease in operating lease right-of-use assets, a $0.8 million decrease in accrued expense and other current liabilities and accounts payable and a $0.5 million decrease in prepaid expenses and other current assets.

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

Investing activities

During the nine months ended September 30, 2022, net cash used in investing activities was $174.1 million, due to an increase in purchases of marketable securities of $221.0 million and property and equipment of $8.2 million during the period, offset by $55.0 million in maturities of marketable securities. During the nine months ended September 30, 2021, net cash provided by investing activities was $185.9 million, due to the maturities of marketable securities of $188.9 million, partially offset by $3.1 million in purchases of property and equipment during the period.

Property and equipment purchases during the nine months ended September 30, 2022 and 2021 were primarily related to leasehold improvements and lab equipment for our facility in Cambridge, Massachusetts.

Financing activities

During the nine months ended September 30, 2022, net cash provided by financing activities was $12.9 million, consisting primarily of net proceeds from the issuance of common stock pursuant to our “at-the-market” sales agreement of $12.4 million and $1.0 million in proceeds from the exercise of common stock options and other types of equity, net during the period, offset by payments for repurchase of common stock for employee tax withholdings. During the nine months ended September 30, 2021, net cash provided by financing activities was $214.2 million, consisting primarily of proceeds from our follow-on public offering of common stock of $211.9 million, net of underwriting discounts and commissions, and proceeds of $3.3 million from the exercise of common stock options, partially offset by the payment of $0.9 million of public offering costs.

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;
- the costs, timing and outcome of regulatory review of any product candidates we may develop;
- the cost and timing of clinical and commercial-scale manufacturing activities;
- 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. We do not have any committed external source of funds. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter would result in fixed payment obligations and may involve agreements that include grants of security interests on our assets and restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, granting liens over our assets, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. Any debt financing or additional equity that we raise may contain terms that could adversely affect the holdings or the rights of our common stockholders.

If we are unable to raise sufficient capital as and when needed, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate we

may develop, or be unable to expand our operations or otherwise capitalize on our business opportunities. If we raise additional funds through collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Item 3. Quantitative and Qualitative Disclosures about Market Risks.

Interest Rate Market Risk

We are exposed to market risk related to changes in interest rates. We had marketable debt securities of $166.7 million as of September 30, 2022, and we did not record any impairment charges to our marketable debt securities during the nine months ended September 30, 2022. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because a majority of our investments are in short-term securities, including marketable debt securities. Interest rate changes would result in a change in the net fair value of these financial instruments due to the difference between the current market interest rate and the market interest rate at the date of purchase of the financial instrument. We currently do not seek to hedge this exposure to fluctuations in interest rates. We have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

Counterparty Credit Risk

Our investment portfolio is subject 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 September 30, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as

amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no other changes in our internal control over financial reporting (as defined in Rules 13a–15(f) and 15d–15(f) under the Exchange Act) during the three months ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

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.

Risks related to our financial position and need for additional capital

We may continue to incur costs related to the Seyon Lease.

In July 2021, we entered into the Seyon Lease to build out a cGMP-compliant manufacturing facility in Waltham, Massachusetts in order to scale ceDNA manufacturing utilizing RES for clinical and initial commercial supply. Following additional process development of RES, we achieved a significant increase in scale, while maintaining high productivity and ceDNA purity. RES production requires a much smaller manufacturing footprint than previously anticipated, and consequently, we are seeking one or more third parties to assume our lease or sublease the property. We may continue to incur costs relating to this facility as we seek to identify a third party and remain responsible for any payments payable pursuant thereto. Additionally, we may not be able to find one or more third parties to assume or sublease the property within a reasonable period of time, on attractive terms, or at all. Furthermore, even if we are able to sublease the property to a third party, there is no assurance that any third party to which we sublease the property will comply with its obligations under such sublease, and we may remain responsible for payments under the Seyon Lease, which may have a material adverse effect on our business, results of operations or financial condition.

Risks related to manufacturing

We intend to manufacture our drug substance and drug product using external cleanroom facilities and/or CMOs, which will require significant resources. If we fail to successfully execute this strategy, our business may be materially harmed.

We intend to manufacture our drug substance and drug product at external cleanroom facilities and/or by utilizing CMOs for cGMP-compliant clinical and initial commercial supply. We do not yet have sufficient information to reliably estimate the cost of the clinical and commercial manufacturing and processing of any product candidates we may develop, and the actual cost to manufacture and process any product candidates we may develop could materially and adversely affect the commercial viability of such product candidates. In addition, the ultimate dose selected for clinical use and commercial

supply will affect our ability to scale and our costs per dose. As a result, we may never be able to develop a commercially viable product.

We have limited experience in managing the manufacturing process and it may be more difficult or more expensive than expected. Furthermore, we will need to hire additional personnel with such expertise. The manufacture of drugs and biologics is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of drugs and biologics often encounter difficulties in production, particularly in scaling and validating initial production and ensuring the absence of contamination. These difficulties may include those related to production costs and yields, quality control and quality assurance testing, stability of the product, operator error, shortages of qualified personnel, as well as difficulty in compliance with strictly enforced federal, state and foreign regulations. Additionally, we may not be able to achieve clinical or commercial manufacturing on our own to satisfy demands for any of our product candidates, if and when developed.

The application of any new regulatory guidelines or parameters may also adversely affect our ability to manufacture any product candidates we may develop. Furthermore, if contaminants are discovered in our supply of such product candidates or in the manufacturing facility, the facility may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical development of our programs and impair our ability to sell any product candidates we develop commercially. We cannot assure our stockholders that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

In connection with controlling our manufacturing process, we will arrange for storing and shipping of any manufactured materials we may develop, and we may not be successful. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather or global supply chain and shipping challenges, could result in loss of usable materials or prevent or delay the delivery of product candidates to patients. We may also experience manufacturing difficulties due to resource constraints and, as a result, our ability to provide any product candidates we may develop to patients could be jeopardized.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
10.1+*	Offer letter, dated December 8, 2017, by and between the registrant and Phillip Samayoa, as amended.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

\+ Indicates management contract or compensatory plan.

SIGNATURES

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

GENERATION BIO CO.

Date: November 3, 2022

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

Date: November 3, 2022

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

Exhibit 10.1

Generation Bio Co.

December 8, 2017

Phillip Samayoa

Dear Phillip:

On behalf of Generation Bio. Co. (the "Company"), I am pleased to offer you employment with the Company on the following terms and conditions.

1. **Position.** You will be employed by the Company as a Senior Director of Corporate Development and Portfolio Strategy. It is contemplated that you will commence employment on a date to be mutually agreed upon between you and the Company, but which in no event shall be later than December 18, 2017 (the "Start Date"). You shall work out of the Company's office in Cambridge. Massachusetts. You agree to devote your full business time, best efforts, skill, knowledge, attention and energies to the advancement of the Company's business and interests and to the performance of your duties and responsibilities as an employee of the Company, and shall not engage in any other employment, consulting or other business activity without the prior written consent of the Company. However, it is understood that you will be in a transitional period from your start date through January 31, 2018. During this transitional period you may spend 1-2 days per week continuing to work for your previous full-time employer and your semi-monthly based salary noted below will be prorated as appropriate.

2. **Base Salary.** You will receive a base salary at the semi-monthly rate of $9,166.66 which is equivalent to $220,000 on an annualized basis (the "Base Salary"). All payments will be subject to legally required tax withholdings. The Base Salary will be subject to adjustment as determined by the Company in its discretion.

You will also receive a payment of $15,000 which will be made with your first semi-monthly salary payment. All payments will be subject to legally required tax withholdings.

3. **Bonus.** Following the end of each fiscal year during the term of your employment commencing with the year ended December 31. 2018 and provided you remain employed by the Company on the last day of such fiscal year. you will be eligible to receive an annual incentive bonus for such fiscal year with a target of up to twenty percent (20%) of your annual Base Salary. The bonus will be awarded based on criteria established by the Company and shall be determined by the Company in its sole discretion. Any bonus will be paid no later than March 15th of the year following the close of the year to which it relates. Any bonus would be pro-rated for the 2018 fiscal year.

4. **Equity.** Subject to the approval of the Company's Board of Directors (the "Board"), the Company shall grant you an equity award of 175,000 shares of the Company's common stock in the form of either a restricted stock award (the "Restricted Shares") or stock options to purchase the shares (the "Options"). Regardless of the form of equity award, the award will vest as to 25% of the underlying shares on the first anniversary of the Start Date and will vest as to the balance in equal quarterly installments of 6.25% thereafter until the fourth anniversary of the Start Date and will otherwise be subject to the terms and conditions of the stock or option agreement, and/or the Company's stock plan (the "Grant Documents"). The Restricted Shares or Options granted hereunder shall have a purchase price per share or exercise price per share equal to the fair market value of the Company's common stock at the time of grant as determined by the Board.

5. **Benefits.**

a. You may participate in the benefit programs offered by the Company to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion. You will also be entitled to paid vacation each year in accordance with the terms and conditions set forth in the Company's vacation policy as in effect from time to time. You shall also be entitled to receive reimbursement for all reasonable business expenses incurred by you in performing your services to the Company, in accordance with the policies and procedures then in effect and established by the Company.

b. If your employment with the Company is terminated without Cause (as defined below), then the Company shall continue to pay you your Base Salary as in effect on your last day of employment for a period of at least one (1) month. However, you will not be eligible for this benefit unless you: (i) have returned all Company property in your possession on or prior to your last day of employment, and, and (ii) have entered into a separation agreement that has become enforceable and irrevocable and that includes a general release of all employment-related claims that you may have against the Company or persons affiliated with the Company (the "Separation Agreement"). The Separation Agreement must be in substantially the form reasonably prescribed by the Company, and must be executed and must become enforceable and irrevocable on or before the 52nd day following your last day of employment with the Company. If you fail to execute without revocation the Separation Agreement on or before the 52nd day following your last day of employment with the Company, you shall not be entitled to severance payments. The continued salary provided shall be paid in accordance with the Company's normal payroll practices and shall commence on the next payroll date falling after the date the Separation Agreement becomes enforceable and irrevocable. For this section. Cause shall mean (i) your material breach of the Invention Agreement, (ii)

your conviction of, or your plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State, (iii) your gross negligence or willful misconduct in the performance of your duties, (iv) your continuing failure to perform assigned duties after receiving written notification of the failure from your direct supervisor or (v) your failure to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers or employees, if the Company has requested your cooperation.

c. If your employment with the Company is terminated without Cause prior to June 11, 2019, 25% of the unvested portion of the grant of Restricted Shares or Options will fully vest as of the date of termination, provided, however, that: (i) no shares may be transferred and no stock option exercised (in each case with respect to the unvested portion) until the Separation Agreement has become enforceable and irrevocable and (ii) if the Separation Agreement does not become enforceable and irrevocable in accordance with this offer letter, the portions of the Restricted Shares or Options that have vested as a result of this provision shall be cancelled effective as of the date of termination.

6. **Representation Regarding Other Obligations.** Your employment is contingent upon your signing the Company's Invention, Non-Disclosure, Non-Competition and Non-Solicitation Agreement (the "Invention Agreement"). Further, you hereby represent to the Company that you are not a party to any agreement of any type which may impact or limit your ability to become employed by or perform your job at the Company or which is in any way inconsistent with the terms of this offer letter. You will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any current or previous employer or others. Further, you hereby represent that (i) your employment with the Company and this offer letter does not and will not violate or conflict with any obligations you may have to or any agreements you may have with any former employer and (ii) you have provided the Company with all written agreements that describe any continuing post-employment obligations to any former employer.

7. **Proof of Legal Right to Work.** You agree to provide to the Company, within three (3) days of the Start Date, documentation proving your eligibility to work in the United States, as required by the Immigration Reform and Control Act of 1986. You may need a work visa in order to be eligible to work in the United States. If that is the case, your employment with the Company will be conditioned upon your obtaining a work visa in a timely manner as determined by the Company.

8. **Tax Matters.**

a. All forms of compensation referred to in this offer letter are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities and that you will not make any claim against the Company or the Board related to tax liabilities arising from your compensation.

b. All in-kind benefits provided and expenses eligible for reimbursement hereunder shall be provided by the Company or incurred by you during your employment with the Company. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year. Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

9. **Interpretation, Amendment and Enforcement.** This offer letter, along with the Invention Agreement and the Grant Documents, constitute the complete agreement between you and the Company, contain all the terms of your employment, and supersede any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. The terms of this offer letter and the resolution of any disputes as to the meaning, effect, performance or validity of this offer letter or arising out of, related to, or in any way connected with, this offer letter, your employment with the Company or any other relationship between you and the Company (the "Disputes") will be governed by Massachusetts law, excluding laws relating to conflicts or choice of law. You and the Company submit to the exclusive personal jurisdiction of the federal and state courts located in the Commonwealth of Massachusetts in connection with any Dispute or any claim related to any Dispute.

10. **Other Terms.** This letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, which means that you have the right to terminate your employment relationship with the Company at any time for any reason and the Company has the right to terminate its employment relationship with you at any time for any reason, with or without cause or notice. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company.

We are excited about having you join the Company. If this letter correctly sets forth the terms under which you will be employed by the Company, please sign the enclosed duplicate of this letter in the space provided below and return it to me, along with a signed copy of the Invention Agreement. If you do not accept this offer by December 13, 2017, this offer will be deemed revoked.

[Remainder of Page Intentionally Left Blank]

Very truly yours,

Generation Bio. Co.

/s/ Glenn Goddard

Glenn Goddard
Chief Financial Officer

I have read and accept this offer of employment:

/s/ Phillip Samayoa

Name: Phillip Samayoa

Dated: 12.11.2017

generation bio™

Cambridge, MA 02142
generationbio.com

December 3, 2018

Phillip Samayoa

We would like to express our appreciation and commendation for all the passion and commitment you have been exhibiting in your existing role. In recognition of your contribution and leadership, it is my pleasure to inform you that you have been promoted to Vice President, Corporate Development.

In connection with your promotion, we are also pleased to inform you that your base salary will be increased to $245,000.00 (on an annualized basis) effective on December 3, 2018, payable under our standard payroll schedule and subject to applicable deductions and withholdings.

Your target bonus percentage is also being increased. Your new target annual incentive bonus is 30% of your new annual salary (and the new target percentage will be used for your bonus calculation for the period beginning December 3, 2018).

As detailed in your original offer letter, the actual bonus percentage distributed in any year will be determined at the sole discretion of the Board of Directors of Generation Bio. The Board's determination will consider several factors including but not limited to the performance of the company.

On behalf of Generation Bio, the management team, your colleagues and me, thank you for your contributions and we all look forward to continuing to grow Generation Bio together.

Very truly yours, Generation Bio

By: /s/ Geoff McDonough

Name: Geoff McDonough

Title: Chief Executive Officer

I have read and accepted this promotion:

/s/ Phillip Samayoa
Signature

Name: Phillip Samayoa
Dated: 12/13/2018

Cambridge, MA 02142
generationbio.com

April 28, 2021
Phillip
Samayoa

We would like to express our appreciation and commendation for all the passion and commitment you have been exhibiting in your existing role. In recognition of your contribution and leadership, it is my pleasure to inform you that, effective May 1, 2021 (the "Effective Date"), you will be promoted to SVP, Head of Corporate Development.

In connection with your promotion, we are also pleased to inform you that as of the Effective Date your base salary will be increased to $330,000 (on an annualized basis) payable under our standard payroll schedule and subject to applicable deductions and withholdings.

Your target bonus percentage is also being increased as of the Effective Date. Your new target bonus will be 35% of your new annual salary (which will be prorated for the 2021 annual incentive bonus plan).

As detailed in your original offer letter, the actual bonus percentage distributed in any year will be determined at the sole discretion of the Board of Directors of Generation Bio. The Board's determination will consider several factors including but not limited to the performance of the company.

You will also be granted options to purchase an additional 30,000 shares of Generation Bio's common stock (the "Option Grant"), subject to the approval of the Board. The options subject to the Option Grant ("Options") will vest as to 25% of the underlying shares on the first anniversary of the Effective Date and will vest as to the balance in equal quarterly installments of 6.25% thereafter until the fourth anniversary of the Promotion Date. The Option Grant will be subject to the terms and conditions of a written stock option agreement which you will be required to sign, and/or the Company's written stock plan (the "Grant Documents"). The Options shall have an exercise price per share equal to the closing price of Generation Bio's common stock on the Nasdaq Global Select Market on May 3, 2021 (the first trading day after the Effective Date).

In connection with your expanded role, we further extend severance benefits that may apply in the event of an involuntary termination of your employment with the Company other than for cause. The accompanying Severance Plan Benefit Agreement describes this program.

On behalf of Generation Bio, the management team, your colleagues and me, thank you for your contributions and we all look forward to continuing to grow Generation Bio together.

Very truly yours,

Generation Bio

By: /s/ Geoff McDonough
Name: Geoff McDonough, M.D.
Title: Chief Executive Officer

I have read and accepted this promotion,

/s/ Phillip Samayoa
Signature
Name: Phillip Samayoa
Dated: 4/28/2021

Cambridge, MA 02142
generationbio.com

September 16, 2022
Phillip Samayoa

Dear Phillip:

We would like to express our appreciation and commendation for all the passion and commitment you have been exhibiting in your existing role. In recognition of your contribution and leadership, it is my pleasure to inform you that, effective September 16, 2022, you will be promoted to Chief Strategy Officer.

In connection with your promotion, we are also pleased to inform you that your base salary will be increased to $390,000 (on an annualized basis) payable under our standard payroll schedule and subject to applicable deductions and withholdings.

Your target bonus percentage is also being increased. Your new target bonus, effective September 16, 2022, will be 40% of your new annual salary (which will be prorated for the 2022 annual incentive bonus plan).

As detailed in your original offer letter, the actual bonus percentage distributed in any year will be determined at the sole discretion of the Board of Directors of Generation Bio. The Board's determination will consider several factors including but not limited to the performance of the company.

You will also be granted options to purchase an additional 110,000 shares of Generation Bio's common stock (the "Option Grant"), subject to the approval of the Board. The options subject to the Option Grant ("Options") will vest as to 25% of the underlying shares on the first anniversary of your Promotion Date and will vest as to the balance in equal quarterly installments of 6.25% thereafter until the fourth anniversary of the Promotion Date. The Option Grant will be subject to the terms and conditions of a written stock option agreement which you will be required to sign, and/or the Company's written stock plan (the "Grant Documents"). The Options shall have an exercise price per share equal to the fair market value of the Company's common stock at the time of grant, as determined by the Board.

On behalf of Generation Bio, the management team, your colleagues and me, thank you for your contributions and we all look forward to continuing to grow Generation Bio together.

Very truly yours,

Generation Bio
By: /s/ Geoff McDonough
Geoff McDonough, M.D.
Title: Chief Executive Officer

I have read and accepted this promotion,

/s/ Phillip Samayoa
Signature

Phillip Samayoa

Dated: 9/26/2022

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: November 3, 2022

/s/ Geoff McDonough

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

Exhibit 31.2

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

I, Matthew Norkunas, hereby certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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: November 3, 2022

/s/ Matthew Norkunas

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

Exhibit 32.1

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

I, Geoff McDonough, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Generation Bio Co. for the quarter ended September 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Generation Bio Co.

/s/ Geoff McDonough

Geoff McDonough, M.D.
President and Chief Executive Officer
(Principal Executive Officer)
November 3, 2022

Exhibit 32.2

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

I, Matthew Norkunas, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Generation Bio Co. for the quarter ended September 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Generation Bio Co.

/s/ Matthew Norkunas

Matthew Norkunas, M.D., M.B.A.
Chief Financial Officer
(Principal Financial and Accounting Officer)
November 3, 2022