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

FORM 10-Q

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

For the quarterly period ended June 30, 2020

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	**81-4301284**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
301 Binney Street Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	**(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

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

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

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

As of July 31, 2020 there were 46,427,673 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, 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 plans to develop and, if approved, subsequently commercialize any product candidates we may develop;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for any product candidates we may develop;
- the potential advantages of our non-viral gene therapy platform;
- 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 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;
- our ability to maintain and establish collaborations or obtain additional funding; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startup Act of 2012.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you 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, 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.

You should read this Quarterly Report and the documents that we file with the Securities and Exchange Commission 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.

Generation Bio Co.

INDEX

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 171,691	$ 15,076
Marketable securities	129,395	—
Tenant receivable	—	448
Prepaid expenses and other current assets	5,091	2,577
Restricted cash	—	55
Total current assets	306,177	18,156
Property and equipment, net	22,822	21,845
Restricted cash, noncurrent	2,052	2,052
Deferred offering costs	—	87
Other long-term assets	151	—
Total assets	$ 331,202	$ 42,140
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,624	$ 2,251
Accrued expenses and other current liabilities	8,912	6,907
Total current liabilities	11,536	9,158
Deferred rent, net of current portion	15,513	15,981
Total liabilities	27,049	25,139
Commitments and contingencies (Note 9)		
Convertible preferred stock (Series A, B and C), $0.0001 par value; no shares and 26,425,664 shares authorized at June 30, 2020 and December 31, 2019, respectively; no shares and 26,425,664 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	115,593
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 5,000,000 and no shares authorized at June 30, 2020 and December 31, 2019, respectively; no shares issued or outstanding	—	—
Common stock, $0.0001 par value; 150,000,000 and 46,750,000 shares authorized at June 30, 2020 and December 31, 2019, respectively; 46,237,096 and 6,976,077 shares issued at June 30, 2020 and December 31, 2019, respectively; 45,028,024 and 5,270,889 shares outstanding at June 30, 2020 and December 31, 2019, respectively	5	1
Additional paid-in capital	448,052	9,859
Accumulated other comprehensive loss	(4)	—
Accumulated deficit	(143,900)	(108,452)
Total stockholders' equity (deficit)	304,153	(98,592)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 331,202	$ 42,140

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 13,456	$ 12,237	$ 26,850	$ 23,956
General and administrative	4,308	3,098	8,950	5,855
Total operating expenses	17,764	15,335	35,800	29,811
Loss from operations	(17,764)	(15,335)	(35,800)	(29,811)
Other income (expense):				
Interest income and other income (expense), net	33	303	352	685
Net loss and net loss attributable to common stockholders	$ (17,731)	$ (15,032)	$ (35,448)	$ (29,126)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.50)	$ (3.30)	$ (4.10)	$ (6.59)
Weighted average common shares outstanding, basic and diluted	11,801,704	4,557,517	8,648,358	4,421,601
Comprehensive loss:				
Net loss	$ (17,731)	$ (15,032)	$ (35,448)	$ (29,126)
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities	(4)	6	(4)	20
Comprehensive loss	$ (17,735)	$ (15,026)	$ (35,452)	$ (29,106)

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

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

	Series A, B and C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
	Three Months Ended June 30, 2020							
Balances at March 31, 2020	46,361,960	$ 224,425	5,570,652	$ 1	$ 11,517	$ —	$ (126,169)	$ (114,651)
Conversion of convertible preferred stock into common stock upon initial public offering	(46,361,960)	(224,425)	27,094,085	3	224,422	—	—	224,425
Issuance of common stock upon initial public offering, net of issuance costs $3,185	—	—	12,105,263	1	210,714	—	—	210,715
Issuance of common stock upon exercise of stock options	—	—	5,434	—	31	—	—	31
Vesting of restricted common stock	—	—	252,590	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,368	—	—	1,368
Unrealized losses on marketable securities	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(17,731)	(17,731)
Balances at June 30, 2020	—	$ —	45,028,024	$ 5	$ 448,052	$ (4)	$ (143,900)	$ 304,153
	Three Months Ended June 30, 2019							
Balances at March 31, 2019	26,425,664	$ 115,593	4,355,671	$ 1	$ 6,554	$ 5	$ (61,229)	$ (54,669)
Vesting of restricted common stock	—	—	259,712	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,049	—	—	1,049
Unrealized gains on marketable securities	—	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	—	(15,032)	(15,032)
Balances at June 30, 2019	26,425,664	$ 115,593	4,615,383	$ 1	$ 7,603	$ 11	$ (76,261)	$ (68,646)

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
	Six Months Ended June 30, 2020							
Balances at December 31, 2019	26,425,664	$ 115,593	5,270,889	$ 1	$ 9,859	$ —	$ (108,452)	$ (98,592)
Issuance of Series C convertible preferred stock, net of issuance costs of $2,640	19,936,296	108,832	—	—	—	—	—	—
Conversion of convertible preferred stock into common stock upon initial public offering	(46,361,960)	(224,425)	27,094,085	3	224,422	—	—	224,425
Issuance of common stock upon initial public offering, net of issuance costs $3,185	—	—	12,105,263	1	210,714	—	—	210,715
Issuance of common stock upon exercise of stock options	—	—	40,263	—	185	—	—	185
Vesting of restricted common stock	—	—	517,524	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,872	—	—	2,872
Unrealized losses on marketable securities	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(35,448)	(35,448)
Balances at June 30, 2020	—	$ —	45,028,024	$ 5	$ 448,052	$ (4)	$ (143,900)	$ 304,153
	Six Months Ended June 30, 2019							
Balances at December 31, 2018	26,425,664	$ 115,593	4,054,475	$ 1	$ 5,552	$ (9)	$ (47,135)	$ (41,591)
Issuance of common stock upon exercise of stock options	—	—	14,861	—	9	—	—	9
Vesting of restricted common stock	—	—	546,047	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,042	—	—	2,042
Unrealized gains on marketable securities	—	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	—	(29,126)	(29,126)
Balances at June 30, 2019	26,425,664	$ 115,593	4,615,383	$ 1	$ 7,603	$ 11	$ (76,261)	$ (68,646)

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

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

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (35,448)	$ (29,126)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,872	2,042
Depreciation and amortization expense	1,502	525
Accretion of discount on marketable securities	—	(281)
Changes in operating assets and liabilities:		
Tenant receivable	448	(2,048)
Prepaid expenses and other current assets	(2,514)	(447)
Other noncurrent assets	(151)	—
Accounts payable	799	953
Accrued expenses and other current liabilities	(304)	1,296
Deferred rent	(468)	10,330
Net cash used in operating activities	(33,264)	(16,756)
Cash flows from investing activities:		
Purchases of property and equipment	(2,223)	(13,203)
Purchases of marketable securities	(129,399)	(20,789)
Sales and maturities of marketable securities	—	73,680
Net cash provided by (used in) investing activities	(131,622)	39,688
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs incurred and paid in current period	108,854	—
Proceeds from initial public offering of common stock, net of commissions and underwriting discounts	213,900	—
Proceeds from exercise of stock options	185	9
Payment of initial public offering costs	(1,493)	—
Net cash provided by financing activities	321,446	9
Net increase in cash, cash equivalents and restricted cash	156,560	22,941
Cash, cash equivalents and restricted cash at beginning of period	17,183	9,466
Cash, cash equivalents and restricted cash at end of period	$ 173,743	$ 32,407
Supplemental disclosure of noncash investing and financing information:		
Conversion of convertible preferred stock to common stock	$ 224,425	$ —
Public offering costs included in accounts payable or accrued expenses	$ 1,692	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ 900	$ 3,579

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

1. Nature of the Business and Basis of Presentation

The Company was incorporated on October 21, 2016 as Torus Therapeutics, Inc. and subsequently changed its name to Generation Bio Co. (the "Company" or "Generation Bio"). The Company is an innovative genetic medicines company creating a new class of gene therapy utilizing its proprietary non-viral gene therapy platform to provide durable, redosable treatments for millions of patients living with rare and prevalent diseases. The Company's non-viral gene therapy platform incorporates its high-capacity DNA construct called closed-ended DNA ("ceDNA"), its cell-targeted lipid nanoparticle delivery system ("ctLNP") and its established, scalable capsid-free manufacturing process. Using its approach, the Company is developing novel gene therapies to provide targeted delivery of genetic payloads that include large and multiple genes to a range of tissues across a broad array of diseases. The Company is also engineering its gene therapies to be redosable, which may enable individualized patient titration to reach the desired therapeutic expression and to maintain efficacy throughout a patient's life. The Company is headquartered in Cambridge, Massachusetts.

The Company is 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, the impact of the COVID-19 pandemic 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 the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On June 16, 2020, the Company completed its initial public offering ("IPO") pursuant to which it issued and sold 12,105,263 shares of its common stock, including 1,578,947 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $19.00 per share, 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 the Company's outstanding convertible preferred stock automatically converted into shares of common stock.

The accompanying 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, the Company has funded its operations with proceeds from the sales of instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the sale of convertible preferred stock, and most recently, with proceeds from the sale of common stock in the IPO completed in June 2020. The Company has incurred recurring losses, including net losses of $35.4 million for the six months ended June 30, 2020 and $61.3 million for the year ended December 31, 2019. As of June 30, 2020, the Company had an accumulated deficit of $143.9 million. The Company expects to continue to generate operating losses in the foreseeable future. As of August 11, 2020, the issuance date of these interim condensed consolidated financial statements, the Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months.

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

The accompanying consolidated financial statements reflect the operations of the Company and the Company's wholly owned subsidiary, Generation Bio Securities Corporation. Intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles ("GAAP") in the United States of America. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("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 revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses and stock-based compensation expense. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes 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 balance sheet at December 31, 2019 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of June 30, 2020 and for the three and six months ended June 30, 2020 and 2019 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (“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 the Company’s audited financial statements included in the Company’s Registration Statement on Form S-1 (File No. 333-238608) on file with SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair presentation of the Company’s financial position as of June 30, 2020, the results of operations for the three and six months ended June 30, 2020 and 2019, and cash flows for the six months ended June 30, 2020 and 2019 have been made. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020 or any other period.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and cash equivalents are held. The Company maintains its cash equivalents in money market funds that invest in U.S. treasury securities. The Company’s cash equivalents and marketable securities as of June 30, 2020 consisted of money market funds, U.S government treasury securities, U.S. government agency bonds, commercial paper and corporate debt securities. The Company has adopted an investment policy that limits the amounts the Company may invest in the securities of single issuer with the exclusion of the U.S. government. The Company has not experienced any credit losses and does not believe that it is subject to significant credit risk.

The Company is dependent on a small number of third-party suppliers for its drug substance and drug product. In particular, the Company relies, and expects to continue to rely, on third-party suppliers for certain materials and components required for the production of any product candidates it may develop for its programs. These programs could be adversely affected by a significant interruption in the supply process.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and financial liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

Recently adopted accounting pronouncements

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Requirements for Fair Value Measurement. The new standard added, modified or removed disclosure requirements under Topic 820 for clarity and consistency. ASU 2018-13 is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company adopted ASU 2018-03 on January 1, 2020 and the adoption did not have a material impact on its consolidated financial statements.

Recently issued accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company can adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. In July 2018, the FASB issued ASU 2018-11, which provides entities with an additional transition method to adopt Topic 842. Under the new transition method, an entity initially applies the new lease requirements at the adoption date, not the earliest period presented, and recognizes a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption. For public entities, the guidance was effective for annual reporting periods beginning after December 15, 2018 and for interim periods within those fiscal years. For nonpublic entities, the guidance was effective for annual reporting periods beginning after December 15, 2019. Early adoption is permitted for all entities. In November 2019, the FASB issued ASU 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. In June 2020, the FASB issued ASU 2020-05, which grants a one-year effective-date delay for nonpublic entities to annual reporting periods beginning after December 15, 2021 and to interim periods within fiscal years beginning after December 15, 2022. Early adoption continues to be allowed. The Company plans to adopt ASU 2016-02 on January 1, 2021 using the modified retrospective approach transition method as of the date of adoption such that prior periods will not be restated. The Company will also elect a package of practical expedients, under which an entity need not reassess whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases, or initial direct costs for any existing leases. The adoption of the new standard is expected to result in the recognition of material liabilities and right-of-use assets, however, the Company has not completed its assessment.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326). The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available-for-sale. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For public entities, the guidance is effective for annual reporting periods beginning after December 15, 2019 and for interim periods within those fiscal years. For nonpublic entities, the guidance was effective for annual reporting periods beginning after December 15, 2020. Early adoption is permitted for all entities. In November 2019, the FASB issued ASU 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. The Company is currently evaluating when to adopt the guidance and the impact the guidance will have on its consolidated financial statements.

3. Fair Value of Financial Assets

As of June 30, 2020, marketable securities by security type consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
U.S. treasury securities	$ 59,943	$ 2	$ (1)	$ 59,944
U.S. government agency bonds	11,990	—	(1)	11,989
Commercial paper	44,862	—	—	44,862
Corporate debt securities	12,604	1	(5)	12,600
Totals	$ 129,399	$ 3	$ (7)	$ 129,395

As of June 30, 2020, marketable securities consisted of investments that mature within one year. The Company did not have marketable securities at December 31, 2019.

The following tables present the Company's assets that are measured at fair value on a recurring basis and indicate the level within the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value, which is described further within Note 2, Summary of Significant Accounting Policies:

	Fair Value Measurements at June 30, 2020 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents:				
Money market funds	$ 169,350	$ —	$ —	$ 169,350
Marketable securities:				
U.S. treasury securities	—	59,944	—	59,944
U.S. government agency bonds	—	11,989	—	11,989
Commercial paper	—	44,862	—	44,862
Corporate debt securities	—	12,600	—	12,600
Totals	$ 169,350	$ 129,395	$ —	$ 298,745

	Fair Value Measurements at December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents:				
Money market funds	$ 15,076	$ —	$ —	$ 15,076
Totals	$ 15,076	$ —	$ —	$ 15,076

Money market funds were valued based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. The Company's marketable securities, which consisted of U.S. treasury securities, U.S. government agency bonds, commercial paper and corporate debt securities were valued using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Accrued employee compensation and benefits	$ 2,852	$ 3,255
Accrued external research and development expenses	1,304	1,344
Accrued professional fees	2,383	619
Deferred rent	1,373	1,370
Accrued property and equipment	786	—
Other	214	319
	$ 8,912	$ 6,907

5. Convertible Preferred Stock

The Company had issued Series A convertible preferred stock (the “Series A”), Series B convertible preferred stock (the “Series B”) and Series C convertible preferred stock (the “Series C”). Collectively the Series A, Series B and Series C are referred to as the Preferred Stock.

On January 9, 2020, the Company issued and sold 19,936,296 shares of Series C at a price of $5.5914 per share for gross proceeds of $111.5 million. The Company incurred issuance costs in connection with this transaction of $2.6 million.

Upon the closing of the IPO in June 2020, the Company’s Preferred Stock automatically converted into 27,094,085 shares of common stock.

6. Equity

As of June 30, 2020, the Company’s amended and restated certificate of incorporation authorizes the Company 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.

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

7. Stock-Based Awards

Stock incentive plans

The Company’s 2017 Stock Incentive Plan (the “2017 Plan”) provided for the Company to grant incentive stock options or nonstatutory stock options, restricted stock, restricted stock units and other equity awards to employees, directors and consultants of the Company. 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 the Company’s board of directors adopted, and in June 2020 the Company’s stockholders approved, the 2020 Stock Incentive Plan (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. Upon effectiveness of the 2020 Plan, the number of shares of common stock that was reserved for issuance under the 2020 Plan was 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 the Company 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. Upon the effectiveness of the 2020 Plan, the Company 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 the Company's IPO, fair value of common stock was determined by the board of directors. Subsequent to the IPO, fair value of common stock will be based on quoted market prices.

As of June 30, 2020, 3,061,794 shares remained available for future issuance under the 2020 Plan. Shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future awards under the 2020 Plan.

Grant of stock options

During the six months ended June 30, 2020, the Company granted service-based options to certain employees, directors and consultants for the purchase of 1,659,661 shares of common stock with a weighted average grant date fair value of $7.07 per share that vest over approximately four years.

During the six months ended June 30, 2020, the Company granted performance-based options to certain employees, directors and consultants for the purchase of 717,154 shares of common stock with a weighted average grant date fair value of $3.26 per share that vest upon the achievement of specified milestones.

Employee stock purchase plan

In May 2020 the Company's board of directors adopted, and in June 2020 the Company's stockholders approved, the 2020 Employee Stock Purchase Plan (the "2020 ESPP"), which became effective June 11, 2020. The 2020 ESPP will be administered by the Company's board of directors or by a committee appointed by the board of directors. The 2020 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 481,231 shares of common stock. The number of shares of common stock reserved for issuance under the 2020 ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year commencing 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. No offering periods have commenced under the 2020 ESPP and 481,231 shares remain available for issuance.

Stock-based compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)			
Research and development expenses	$ 936	$ 675	$ 1,763	$ 1,351
General and administrative expenses	432	374	1,109	691
	$ 1,368	$ 1,049	$ 2,872	$ 2,042

As of June 30, 2020, total unrecognized compensation cost related to unvested stock-based awards was $19.2 million, which is expected to be recognized over a weighted average period of 3.1 years. Additionally, as of June 30, 2020, the Company has unrecognized compensation cost related to unvested stock-based awards with performance-based vesting conditions for which performance has not been deemed probable of $2.3 million.

8. Net Loss per Share

The following potential dilutive securities, presented based on amounts outstanding at each period end, have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive impact:

	June 30,	
	2020	2019
Convertible preferred stock (as converted to common stock)	—	14,961,027
Unvested restricted common stock	1,209,072	2,218,595
Stock options to purchase common stock	5,439,546	2,494,444
	6,648,618	19,674,066

9. Commitments and Contingencies

The Company leases its office and laboratory space under a noncancelable operating lease that was entered into in August 2018, as amended in June 2020, and expires in 2029. The Company has an option to extend for one additional term of five years at the greater of the then-current base rent, or the then-current fair market value. The lease agreement includes provisions for a free-rent period and annual rent increases, which are accrued or deferred as appropriate such that rent expense for the lease is recognized on a straight-line basis over the lease term. The Company is responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises. The lease provides for a tenant improvement allowance, at the cost of the lessor, not to exceed $14.7 million. Costs incurred by the Company for tenant improvements but not yet reimbursed by the landlord are presented on the accompanying consolidated balance sheets as tenant receivable. The Company posted a customary letter of credit in the amount of approximately $2.1 million as a security deposit. The letter of credit is subject to increase if the Company were to sublease any portion of the leased premises.

Rent expense for the three months ended June 30, 2020 and 2019 was $1.9 million and $1.3 million, respectively. Rent expense for the six months ended June 30, 2020 and 2019 was $3.7 million and $3.5 million, respectively.

Future minimum lease payments as of June 30, 2020 are as follows:

Year Ending December 31,	(in thousands)
2020 (remaining 6 months)	$ 3,488
2021	7,053
2022	7,251
2023	7,441
2024	7,679
Thereafter	35,451
	$ 68,363

401(k) Plan

The Company has a defined-contribution plan under Section 401(k) of the Internal Revenue Code of 1986 (the “401(k) Plan”). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. As currently established, the Company is not required to make, and to date has not made, any contributions to the 401(k) Plan.

Indemnification agreements

In the ordinary course of business, the Company 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, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, 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 the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Legal proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the three and six months ended June 30, 2020.

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 should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our final prospectus for our initial public offering, or IPO, filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, 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, 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 an innovative genetic medicines company creating a new class of gene therapy utilizing our proprietary non-viral gene therapy platform to provide durable, redosable treatments for millions of patients living with rare and prevalent diseases. Our non-viral gene therapy platform incorporates our high-capacity DNA construct called closed-ended DNA, or ceDNA; our cell-targeted lipid nanoparticle delivery system, or ctLNP; and our established, scalable capsid-free manufacturing process. Using our approach, we are developing novel gene therapies to provide targeted delivery of genetic payloads that include large and multiple genes to a range of tissues across a broad array of diseases. We are also engineering our gene therapies 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 including rare and prevalent diseases of the liver and retina, as well as in skeletal muscle, oncology and the central nervous system by developing discrete ctLNPs, each engineered to reach a different tissue. In parallel, we are developing the constructs and manufacturing capacity to rapidly advance new disease programs in a tissue or therapeutic area once human proof of concept is established.

Our most advanced programs are in the liver and retina. In the liver, we have programs for phenylketonuria, or PKU, and hemophilia A, which are in preclinical development, during which we conduct *in vivo* studies to identify development candidates and assess these candidates in studies to enable an investigational new drug, or IND, application. In the retina, we have programs for Leber's Congenital Amaurosis 10, or LCA10, and Stargardt disease, which are in lead optimization, during which we seek to identify ceDNA constructs that provide disease relevant expression in an animal model.

We expect to select the final development candidate for each of our PKU and hemophilia A programs and to initiate IND-enabling studies for these programs in 2021, followed by IND applications for these programs in 2022. We anticipate submitting IND applications for additional programs in 2023 and beyond.

Since our inception in October 2016, we have focused substantially all of our resources on building our non-viral gene therapy 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 instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the sales of convertible preferred stock and, most recently, with proceeds from the sale of common stock in our IPO. On June 16, 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.

Since our inception, we have incurred significant operating losses. Our ability to generate any product revenue or product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more product candidates we may develop. For the six months ended June 30, 2020, we reported net losses of $35.4 million, and for the year ended December 31, 2019, we reported net losses of $61.3 million. As of June 30, 2020, we had an accumulated deficit of $143.9 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:

- continue our current research programs and conduct additional research programs;
- advance any product candidates we identify into preclinical and clinical development;
- expand the capabilities of our non-viral gene therapy platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;

- obtain, expand, maintain, enforce and defend our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval; and
- 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.

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 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 2023. We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong. We could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. See "—Liquidity and Capital Resources."

COVID-19

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and to date, the COVID-19 pandemic continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic will 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 are difficult to predict. While we continue to conduct our research and manufacturing activities, the COVID-19 pandemic may cause disruptions that affect our ability to initiate and complete preclinical studies or to procure items that are essential for our research and development activities.

We plan to continue to closely monitor the ongoing impact of the COVID-19 pandemic on our employees and our business operations. In an effort to provide a safe work environment for our employees, we have, among other things, increased the cadence of sanitization of our office and lab facilities, implemented various social distancing measures in our office and labs including replacing all in-person meetings with virtual interactions, and are providing personal protective equipment for our employees present in our office and lab facilities. 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 and contractors and contract research organizations, or CROs;
- the cost of developing and scaling our manufacturing process and manufacturing drug substance and drug product for use in our research and preclinical studies, including under agreements with third parties, such as consultants and contractors and contract development and manufacturing organizations, or CDMOs;
- laboratory supplies and research materials;
- facilities, depreciation and amortization and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third-party licensing agreements.

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

Our external research and development expenses consist of costs that include fees and other costs paid to consultants, contractors, CDMOs and CROs in connection with our 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 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 filing and acceptance of INDs 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 current 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;
- the availability of specialty raw materials for use in production of our product candidates;
- our ability to establish arrangements with third-party manufacturers for clinical supply;
- 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 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 (expense)

Interest income and other income (expense), net

Interest income consists of interest earned on our invested cash balances. We expect our interest income to increase as we invest the cash received from the sale of Series C preferred stock in January 2020 and the net proceeds from our IPO in June 2020.

Other income (expense) consists of miscellaneous income and expense unrelated to our core operations.

Income taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each year, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

As of December 31, 2019, we had federal net operating loss carryforwards of $91.9 million, which may be available to offset future taxable income, of which $8.2 million of the total net operating loss carryforwards begin to expire in 2036, while the remaining $83.7 million do not expire but may be limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2019, we had state net operating loss carryforwards of $90.6 million, which may be available to offset future taxable income and expire at various dates beginning in 2036. As of December 31, 2019, we also had federal and state research and development tax credit carryforwards of $4.0 million and $2.5 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2036 and 2032, respectively. Due to our history of cumulative net losses since inception and uncertainties surrounding our ability to generate future taxable income, we have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of Operations

Comparison of the three months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 13,456	$ 12,237	$ 1,219
General and administrative	4,308	3,098	1,210
Total operating expenses	17,764	15,335	2,429
Loss from operations	(17,764)	(15,335)	(2,429)
Other income (expense):			
Interest income and other income (expense), net	33	303	(270)
Net loss	$ (17,731)	$ (15,032)	$ (2,699)

Research and development expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Personnel related	$ 4,293	$ 3,391	$ 902
Stock-based compensation	936	675	261
Preclinical and manufacturing	3,291	3,440	(149)
Facilities	2,308	1,743	565
Lab supplies	572	936	(364)
Consulting and professional services	1,147	979	168
Other	909	1,073	(164)
Total research and development expenses	$ 13,456	$ 12,237	$ 1,219

Research and development expenses were $13.5 million for the three months ended June 30, 2020 compared to $12.2 million for the three months ended June 30, 2019. The increases in personnel-related costs and stock-based compensation costs of $0.9 million and $0.3 million, respectively, were primarily due to increased headcount in our research and development function. The increase in facility-related expenses of $0.6 million was primarily due to the increased costs of supporting a larger group of research and development personnel and their research efforts and increased amortization of leasehold improvements. The decrease in lab supplies costs of $0.4 million was primarily due to a decrease in activity as a result of the COVID-19 pandemic.

General and administrative expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Personnel related	$ 1,829	$ 1,096	$ 733
Stock-based compensation	432	374	58
Professional and consultant fees	1,528	1,072	456
Facilities	372	198	174
Other	147	358	(211)
Total general and administrative expenses	$ 4,308	$ 3,098	$ 1,210

General and administrative expenses were $4.3 million for the three months ended June 30, 2020 compared to $3.1 million for the three months ended June 30, 2019. The increase in personnel-related costs of $0.7 million was primarily a result of an increase in headcount in our general and administrative function. Professional and consultant fees increased by $0.5 million primarily due to professional fees relating to accounting, audit and legal services as well as costs associated with ongoing business activities and our preparations to operate as a public company.

Other income and expense, net

Other income and expense, net for the three months ended June 30, 2020 was $0.1 million compared to $0.3 million for the three months ended June 30, 2019. Other income consisted primarily of interest earned on invested cash balances.

Comparison of the six months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 26,850	$ 23,956	$ 2,894
General and administrative	8,950	5,855	3,095
Total operating expenses	35,800	29,811	5,989
Loss from operations	(35,800)	(29,811)	(5,989)
Other income (expense):			
Interest income and other income (expense), net	352	685	(333)
Net loss	$ (35,448)	$ (29,126)	$ (6,322)

Research and development expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Personnel related	$ 8,112	$ 6,472	$ 1,640
Stock-based compensation	1,763	1,351	412
Preclinical and manufacturing	6,763	7,115	(352)
Facilities	4,744	3,880	864
Lab supplies	1,850	2,107	(257)
Consulting and professional services	2,138	1,411	727
Other	1,480	1,620	(140)
Total research and development expenses	$ 26,850	$ 23,956	$ 2,894

Research and development expenses were $26.9 million for the six months ended June 30, 2020, compared to $24.0 million for the six months ended June 30, 2019. The increases in personnel-related costs and stock-based compensation costs of $1.6 million and 0.4 million, respectively, were primarily due to increased headcount in our research and development function. The increase in facility-related expenses of $0.9 million was primarily due to the increased costs of supporting a larger group of research and development personnel and their research efforts and increased amortization of leasehold improvements. The decrease in preclinical and manufacturing expense and lab supplies of $0.4 million and $0.3 million, respectively, were primarily due to a decrease in activity as a result of the COVID-19 pandemic. The increase in consulting and professional services of $0.7 million was primarily due to consulting services to develop and scale our manufacturing process.

General and administrative expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Personnel related	$ 3,395	$ 1,978	$ 1,417
Stock-based compensation	1,109	691	418
Professional and consultant fees	3,388	2,102	1,286
Facilities	741	449	292
Other	317	635	(318)
Total general and administrative expenses	$ 8,950	$ 5,855	$ 3,095

General and administrative expenses were $9.0 million for the six months ended June 30, 2020, compared to $5.9 million for the six months ended June 30, 2019. The increases in personnel-related costs and stock-based compensation costs of $1.4 million and $0.4 million, respectively, were primarily a result of an increase in headcount in our general and administrative function. Professional and consultant fees increased by $1.3 million primarily due to professional fees relating to accounting, audit and legal services as well as costs associated with ongoing business activities and our preparations to operate as a public company.

Other income and expense, net

Other income and expense, net for the six months ended June 30, 2020 was $0.4 million compared to $0.7 million for the six months ended June 30, 2019. Other income consisted primarily of interest earned on 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 of our 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 and, most recently, with proceeds from the sale of common stock in our IPO. On June 16, 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. As of June 30, 2020, we had cash, cash equivalents and marketable securities of $301.1 million.

Cash flows

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

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Cash used in operating activities	$ (33,264)	$ (16,756)
Cash provided by (used in) investing activities	(131,622)	39,688
Cash provided by financing activities	321,446	9
Net increase in cash, cash equivalents and restricted cash	$ 156,560	$ 22,941

Operating activities

During the six months ended June 30, 2020, operating activities used $33.3 million of cash, primarily resulting from our net loss of $35.4 million and changes in our operating assets and liabilities of $2.2 million, both partially offset by non-cash charges of $4.4 million. Net cash used by changes in our operating assets and liabilities for the six months ended June 30, 2020 consisted primarily of a $2.5 million increase in prepaid expenses and other current assets and a $0.5 million decrease in deferred rent, partially offset by a decrease of $0.4 million in tenant receivable and an increase of $0.5 million in accounts payable and accrued expenses and other current liabilities.

During the six months ended June 30, 2019, operating activities used $16.8 million of cash, primarily resulting from our net loss of $29.1 million, partially offset by non-cash charges of $2.3 million and cash provided by changes in our operating assets and liabilities of $10.1 million. Net cash provided by changes in our operating assets and liabilities for the six months ended June 30, 2019 consisted primarily of a $10.3 million increase in deferred rent and a $2.2 million increase in accounts payable and accrued expenses and other current liabilities, both partially offset by an increase of $2.0 million in tenant receivable and $0.4 million in prepaid expenses and other current assets.

Changes in accounts payable, accrued expenses and other current liabilities and prepaid expenses in the periods were generally due to growth in our business and the timing of vendor invoicing and payments. Changes in deferred rent and tenant receivable primarily related to a tenant improvement allowance from our landlord.

Investing activities

During the six months ended June 30, 2020, net cash used in investing activities was $131.6 million, due to the purchases of marketable securities and property and equipment during the period. During the six months ended June 30, 2019, net cash provided by investing activities was $39.7 million, due primarily to net sales and maturities of marketable securities of $52.9 million, partially offset by the acquisition of property and equipment during the period of $13.2 million.

Property and equipment purchases during the six months ended June 30, 2020 and 2019 were primarily related to leasehold improvements and lab equipment for our facility in Cambridge, Massachusetts.

Financing activities

During the six months ended June 30, 2020, net cash provided by financing activities was $321.4 million, consisting primarily of proceeds from our IPO of common stock of $213.9 million, net of discounts and commissions, and proceeds from the sale of our Series C preferred stock of $108.9 million, partially offset by the payment of $1.5 million of public offering costs. During the six months ended June 30, 2019, net cash provided by financing activities was less than $0.1 million, consisting of proceeds from the exercise of common stock options.

Funding requirements

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

- the identification of additional research programs and additional 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 completion of 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 gene therapy platform;
- the costs of satisfying any post-marketing requirements;
- the revenue, if any, received from commercial sales of product candidates we may develop for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting applications for patents, obtaining, maintaining, defending and enforcing our intellectual property rights and defending against any intellectual property-related claims, including claims of infringement, misappropriation or other violation of third-party intellectual property;
- the costs of operational, financial and management information systems and associated personnel;
- the associated costs in connection with any acquisition of in-licensed products, intellectual property and technologies; and
- the costs of operating as a public company.

We believe that our existing cash and cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2023. 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 “Risk Factors” for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

During the three months ended June 30, 2020, there were no material changes to our contractual obligations and commitments from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 12, 2020.

Critical Accounting Policies and Significant Judgments and Estimates

We prepare our condensed consolidated financial statements in accordance with GAAP. The preparation of financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management.

There have been no material changes to our critical accounting policies and estimates from those disclosed in our financial statements and the related notes and other financial information included in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 12, 2020.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our condensed consolidated financial statements included in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risks.

As of June 30, 2020, we had cash, cash equivalents, and marketable securities of $301.1 million, which consisted of cash, money market funds, U.S. government securities, commercial paper and corporate securities. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in market interest rates would not have a material effect on the fair market value of our investment portfolio. We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial Officer (our Chief Financial Officer, Treasurer), has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020. 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, our Principal Executive Officer and Principal 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

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Quarterly Report on Form 10-Q, or Quarterly Report, including our consolidated financial statements and the related notes thereto in evaluating our company. The risks described below are not the only risks facing our company. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could cause our business, prospects, operating results and financial condition to suffer materially.

Risks related to our financial position and need for additional capital

We have incurred significant losses since our inception, have no products approved for sale and we expect to incur losses over the next several years.

Since inception, we have incurred significant operating losses. Our net losses were $61.3 million for the year ended December 31, 2019 and $35.4 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $143.9 million. To date, we have funded our operations with the proceeds from instruments convertible into convertible preferred stock (which converted into convertible preferred stock in 2017), the sale of convertible preferred stock and, most recently, from the sale of common stock in our initial public offering, or IPO. We have devoted substantially all of our financial resources and efforts to research and development. We are still in the early stages of development of our product candidates, and we have not commenced or completed clinical development. We expect to continue to incur significant expenses and operating losses over the next several years. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our current research programs and conduct additional research programs;
- advance any product candidates we identify through our research programs into preclinical and clinical development;
- expand the capabilities of our proprietary non-viral gene therapy platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;

- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates we may develop for which we may obtain regulatory approval; and
- 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.

Even if we obtain regulatory approval of and are successful in commercializing one or more of any product candidates we may develop, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We have not initiated clinical development of any product candidate and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must succeed in developing, obtaining the necessary regulatory approvals for and eventually commercializing a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including:

- identifying product candidates and completing preclinical and clinical development of any product candidates we may identify;
- obtaining regulatory approval for any product candidates we may develop;
- manufacturing, marketing and selling any products for which we may obtain regulatory approval;
- achieving market acceptance of any product candidates we may develop for which we obtain regulatory approval as a viable treatment option; and
- satisfying any post-marketing requirements.

We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. We are currently only in the preclinical stage of our research programs. 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 profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate preclinical testing and clinical trials of and potentially seek marketing approval for any product candidates we may develop. In addition, if we obtain marketing approval for any product candidates we may develop, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed, on attractive terms or at all, we may be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of June 30, 2020, we had cash, cash equivalents and marketable securities of $301.1 million. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2023. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our capital resources sooner than we currently expect and could be forced to seek additional funding sooner than planned.

Our future capital requirements will depend on many factors, including:

- the identification of additional research programs and additional 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 completion of 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 gene therapy 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, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including claims of infringement, misappropriation or other violations 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.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, even if we successfully identify and develop product candidates and those are approved, we may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all, and such revenues may not be sufficient to sustain our operations. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize any product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. We could be required to seek collaborators for product candidates we may develop at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates we may develop in markets where we otherwise would seek to pursue development or commercialization ourselves.

If we are unable to obtain funding on a timely basis, 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, as desired, which could materially affect our business, financial condition and results of operations. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2016, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting research activities and filing and prosecuting patent applications. All of our research programs are still in the research or preclinical stage of development, and their risk of failure is high. We have not yet demonstrated our ability to initiate or complete any clinical trials, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions our stockholders make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing genetic medicine products.

Our limited operating history, particularly in light of the rapidly evolving genetic medicine field, may make it difficult to evaluate our technology and industry and predict our future performance. Our limited history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research focus to a company capable of conducting development activities and then to a company supporting commercial activities. We may not be successful in such transitions.

Our ability to utilize our net operating loss carryforwards may be subject to limitations.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our net operating losses, or NOLs, or research and development tax credit carryforwards. As of December 31, 2019, we had federal NOLs of $91.9 million and state NOLs of $90.6 million.

In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership changes in the future through subsequent changes in our stock ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. The Tax Cuts and Jobs Act, or the Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Risks related to discovery and development

We are very early in our development efforts. We have not identified any product candidates for investigational new drug, or IND, -enabling studies or clinical development and as a result it will be years before we commercialize a product candidate, if ever. If we are unable to identify and advance product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have invested our research efforts to date in developing our platform. We have a portfolio of programs that are in early stages of preclinical development and have not identified any product candidates for IND-enabling studies or clinical development. We may never identify any product candidates or advance to clinical-stage development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Commencing clinical trials in the United States is subject to acceptance by the U.S. Food and Drug Administration, or FDA, of an IND application and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our first clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union.

Commercialization of any product candidates we may develop will require preclinical and clinical development; regulatory and marketing approval in multiple jurisdictions, including by the FDA and the European Medicines Agency, or EMA; obtaining manufacturing supply, capacity and expertise; building of a commercial organization; and significant marketing efforts. The success of product candidates we may identify and develop will depend on many factors, including the following:

- timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable;
- effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any product candidates we may develop;
- successful enrollment and completion of clinical trials, including under the FDA's current Good Clinical Practices, or GCPs, current Good Laboratory Practices, or cGLPs, and any additional regulatory requirements from foreign regulatory authorities;
- positive results from our future clinical programs that support a finding of safety and effectiveness and an acceptable risk-benefit profile in the intended populations of any product candidates we may develop;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements through our own facilities or with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities;
- establishment, maintenance, defense and enforcement of patent, trademark, trade secret and other intellectual property protection or regulatory exclusivity for any product candidates we may develop;
- commercial launch of any product candidates we may develop, if approved, whether alone or in collaboration with others;
- acceptance of the benefits and use of our product candidates we may develop, including method of administration, if and when approved, by patients, the medical community and third-party payers;
- effective competition with other therapies;
- maintenance of a continued acceptable safety, tolerability and efficacy profile of any product candidates we may develop following approval; and
- establishment and maintenance of healthcare coverage and adequate reimbursement by payers.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates we may develop, which would materially harm our business. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We may encounter substantial delays in commencement, enrollment or completion of our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing any product candidates we determine to develop on a timely basis, if at all.

The risk of failure for any product candidates we determine to develop is high. It is impossible to predict when or if any product candidate would prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of product candidates in humans. We have not yet begun or completed a clinical trial of any product candidate. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our INDs and other regulatory filings. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of any product candidates. As a result, we cannot be sure that we will be able to submit INDs for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs will result in the FDA allowing clinical trials to begin. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in trial design, dose selection issues, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Identifying and qualifying patients to participate in clinical trials of any product candidates we may develop is critical to our success. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment and trial completion is affected by factors including:

- perceived risks and benefits of novel genetic medicine-based approaches;
- size of the patient population, in particular for rare diseases, and process for identifying patients;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- severity of the disease or disorder under investigation;
- proximity and availability of clinical trial sites for prospective patients;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would harm our business, financial condition, results of operations and prospects.

Other events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CLROs, and clinical trial sites;
- delays in opening clinical trial sites or obtaining required institutional review board, or IRB, or independent ethics committee approval, or the equivalent review groups for sites outside the United States, at each clinical trial site;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or after an inspection of our clinical trial operations or trial sites;
- failure by us, any CLROs we engage or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's GCPs;
- failure by physicians to adhere to delivery protocols leading to variable results;
- delays in the testing, validation, manufacturing and delivery of any product candidates we may develop to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

- occurrence of serious adverse events associated with a product candidate in development by another company, which are viewed to outweigh its potential benefits, and which may negatively impact the perception of our product due to a similarity in technology or approach;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the legal or regulatory regimes domestically or internationally related to patient rights and privacy; or
- lack of adequate funding to continue the clinical trial.

Any inability to successfully complete preclinical studies and clinical trials could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to any product candidates we may develop, we may need to conduct additional studies or trials to bridge our modified product candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any product candidates we may develop or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize any product candidates we may develop and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of future clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with any product candidates we may develop, we may:

- be delayed in obtaining marketing approval for product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Genetic medicine is an emerging area of drug development that poses many scientific and other risks. We have only limited prior experience in genetic medicine research and manufacturing and no prior experience in genetic medicine clinical development. Our lack of experience for our genetic medicine programs may limit our ability to be successful or may delay our development efforts.

Genetic medicine is an emerging field of drug development with only a small number of genetic medicines having received FDA or EMA approval to date. Our genetic medicine research programs are still at an early stage, and there remain several areas of drug development risk, which pose particular uncertainty for our programs given the relatively limited development history of, and our limited prior experience with, genetic medicines. Translational science, manufacturing materials and processes, safety concerns, regulatory pathway and clinical trial design and execution all pose particular risk to our drug development activities. Furthermore, the medical community's understanding of the genetic causes of many diseases continues to evolve and further research may change the medical community's views on what therapies and approaches are most effective for addressing certain diseases.

As an organization, we have not previously conducted any IND-enabling studies or clinical trials, including any later stage or pivotal clinical trials. In pursuing our new technologies, we have begun to establish our own genetic medicine technical capabilities, but we will need to continue to expand those capabilities by either hiring internally or seeking assistance from outside service providers. Genetic medicine is an area of significant investment by biotechnology and pharmaceutical companies and there may be a scarcity of talent available to us in these areas. If we are not able to expand our genetic medicine capabilities, we may not be able to develop in the way we intend or desire any promising product candidates that emerge from our program or our other collaborative genetic medicine sponsored research programs, which would limit our prospects for future growth. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we may develop. Failure to commence or complete, or delays in, our clinical trials, could prevent us from or delay us in commercializing our product candidates.

We will need to build our internal and external capabilities in designing and executing a genetic medicine clinical trial. There are many known and unknown risks involved in translating preclinical development of gene therapies to clinical development, including selecting appropriate endpoints and dosage levels for dosing humans based on preclinical data. Furthermore, our genetic medicine programs are initially targeting rare diseases with relatively small populations, which limits the pool of potential subjects for our genetic medicine clinical trials. If we are unable to initiate and conduct our genetic medicine clinical trials in a manner that satisfies our expectations or regulatory requirements, the value of our genetic medicine programs may be diminished.

Our non-viral gene therapy platform is based on novel technologies that are unproven, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

We have concentrated our research and development efforts on our non-viral gene therapy platform, and our future success depends on the successful development of our platform.

However, the technologies that comprise our platform are new and largely unproven. These technologies have not been clinically tested and the scientific evidence to support the feasibility of developing product candidates based on those technologies is both preliminary and limited. Successful development of product candidates by us will require solving a number of issues, including the expansion of our cell-targeted lipid nanoparticle delivery system, or ctLNP, delivery system to tissues beyond the liver and retina and obtaining expression levels sufficient to address or ameliorate each target disease or indication. There can be no assurance we will be successful in solving any or all of these issues. We have concentrated our research efforts to date on developing the components of our platform, and our future success is highly dependent on the successful development of our ceDNA constructs, our ctLNP delivery system and therapeutic applications of these technologies. We may decide to alter or abandon our initial programs as new data become available and we gain experience in developing our therapeutics. We cannot be sure that our technologies will yield satisfactory products that are safe and effective, scalable or profitable in any indication we pursue.

There can be no assurance that any development problems we experience in the future related to our non-viral gene therapy platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from initiating or conducting clinical trials or commercializing our products on a timely or profitable basis, if at all. In addition, the clinical trial requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Only a small number of non-viral gene therapies have successfully reached the clinical trial phase of development, limiting insight into the regulatory review process for this field of genetic medicine. As a result, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals in either the United States or the European Union for any product candidates we may develop or how long it will take to commercialize any product candidate that receives marketing approval.

If any product candidates we may develop cause undesirable side effects or have other unexpected adverse properties, such side effects or properties could delay or prevent regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

We have not evaluated any product candidates in human clinical trials. Moreover, there have been only a limited number of clinical trials involving the use of non-viral gene therapies and none involving ceDNA constructs or other technology similar to our technology. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. In the genetic medicine field, there have been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia and death. There can be no assurance that our technologies will not cause undesirable side effects.

We use a ctLNP delivery system to deliver our ceDNA constructs. Lipid nanoparticles have been shown to induce necrosis in the liver at certain doses and induce infusion related reactions, as well as to initiate systemic inflammatory responses. While our ctLNPs are a new generation of LNP, there can be no assurance that our ctLNPs will not have undesired effects. Our ctLNPs could contribute, in whole or in part, to immune reactions, infusion reactions, complement reactions or antibody reactions. In addition, certain aspects of our non-viral gene therapies may induce immune reactions from the lipid as well as adverse reactions within liver pathways or degradation of the LNP into its component molecules or metabolites, any of which could lead to significant adverse events in one or more of our future clinical trials. Many of these types of side effects have been seen for LNPs. Once delivered to target cells, DNA-based payloads, such as those carried by our ceDNA constructs, may interact with host proteins or chromosomal DNA in the cell endosome, cytosol or nucleus.

Adeno-associated virus, or AAV, genomes have been shown in some cases to initiate intracellular immune activation, which can lead to transcriptional changes, and local tissue interferon responses, which may lead to immune infiltrates and tissue damage. AAV genetic material may also integrate into the host chromosome, which could contribute to modified cell function transformation. There may be uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in future clinical trials and would result in significant delays in our programs.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects. Many product candidates that initially showed promise in early stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further clinical development of the product candidates.

If in the future we are unable to demonstrate that such side effects were caused by factors others than our product candidates, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates for any or all targeted indications. Even if we are able to demonstrate that any future serious adverse events are not product-related, and regulatory authorities do not order us to cease further development of our product candidates, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

Regulatory approval of and/or demand for our potential products will depend in part on public acceptance of the use of genetic medicine for the prevention or treatment of human diseases. Safety issues that might arise in trials for gene therapies other than our own could adversely impact public attitudes towards our platform and product candidates notwithstanding that the gene therapies we are developing are non-viral.

There are a number of clinical trials of gene therapies ongoing. There is a potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry genetic material. Possible adverse side effects that may occur with treatment with gene therapy products include an immunologic reaction early after administration that could substantially limit the effectiveness of the treatment or represent safety risks for patients.

Any of these events could prevent us from achieving or maintaining market acceptance of any product candidates we may develop and could significantly harm our business, prospects, financial condition and results of operations.

The outcome of preclinical studies and earlier-stage clinical trials may not be predictive of future results or the success of later preclinical studies and clinical trials.

We are in the early stage of research in the development of our platform and have not identified any product candidates or conducted any IND-enabling studies or any clinical trials. As a result, our belief in the capabilities of our platform is based on early research and preclinical studies. However, the results of preclinical studies may not be predictive of the results of preclinical studies or clinical trials, and the results of any early-stage clinical trials may not be predictive of the results of later clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Our future clinical trials may not ultimately be successful or support further clinical development of any product candidates we may develop. There is a high failure rate for product candidates proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any such setbacks in our clinical development could materially harm our business and results of operations.

We may not be successful in our efforts to identify, discover or develop potential product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates based on our non-viral gene therapy platform. All of our product development programs are still in the research or preclinical stage of development. Our research programs may fail to identify potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates, our potential product candidates may be shown to have harmful side effects in preclinical *in vitro* experiments or animal model studies, they may not show promising signals of therapeutic effect in such experiments or studies or they may have other characteristics that may make the product candidates impractical to manufacture, unmarketable or unlikely to receive marketing approval.

In addition, although we believe our platform will position us to rapidly expand our portfolio of programs beyond our current programs, we have not yet successfully developed any product candidate and our ability to expand our portfolio may never materialize. The process by which we identify and disclose product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover product candidates;

- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third parties' patents or other intellectual property rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases or disorders;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is too complex and difficult to navigate successfully or economically.

If we are unable to identify and discover suitable product candidates for clinical development, this would adversely impact our business strategy and our financial position and share price and could potentially cause us to cease operations.

The genetic medicine field is relatively new and evolving rapidly. We are focusing our research and development efforts on our non-viral gene therapy platform, but other gene therapy technologies may be discovered that provide significant advantages over our platform, which could materially harm our business.

To date, we have focused our efforts on the advancement of our non-viral gene therapy platform, which is designed to overcome the limitations of current viral gene therapy approaches. However, while these modalities have demonstrated their limitations, there are many companies that are developing new genetic medicines, including viral gene therapies, gene editing and messenger RNA, or mRNA. There can be no certainty that these companies will not develop genetic medicines that address some of these limitations and will be considered to have advantages over our non-viral gene therapy platform. For example, in December 2019, Dyno Therapeutics announced a new technique for AAV delivery, labeled BRAVE, that allows the researchers to engineer the virus shell to deliver the gene package to the exact cell type in the body they intend to treat. This new method may reduce concerns about off-target AAV delivery and make it a more attractive delivery system.

We may expend our limited resources to pursue a particular program, product candidate or indication and fail to capitalize on programs, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and expect to focus on product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential, or we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

Clinical trial and product liability lawsuits against us could divert our resources, could cause us to incur substantial liabilities and could limit commercialization of any product candidates we may develop.

We will face an inherent risk of clinical trial and product liability exposure related to the testing of any product candidates we may develop in clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have no product candidates in clinical trials or that have been approved for commercial sale, the future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;

- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any product candidates we may develop.

We will need to increase our insurance coverage if we commence clinical trials or if we commence commercialization of any product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks relating to manufacturing

The manufacture of genetic medicine products is complex and difficult and is subject to a number of scientific and technical risks, some of which are common to the manufacture of drugs and biologics and others of which are unique to the manufacture of gene therapies. We could experience manufacturing problems that result in delays in our development or commercialization programs.

Genetic medicine drug products are complex and difficult to manufacture. We have an established current Good Manufacturing Practices, or cGMP, -ready process at the 200-liter scale which we have successfully transferred to external contract development and manufacturing organizations, or CDMOs, to supply our gene therapies for IND-enabling preclinical studies and early clinical trials. We believe that we will be able to enter into arrangements with existing and/or additional CDMOs to provide commercial supply. We may also seek to eventually establish our own manufacturing facility for long-term commercial supply.

A number of factors common to the manufacturing of biologics and drugs could also cause production issues or interruptions for our gene therapies, including raw material or starting material variability in terms of quality, cell line viability, productivity or stability issues, shortages of any kind, shipping, distribution, storage and supply chain failures, growth media contamination, equipment malfunctions, operator errors, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities, or acts of god that are beyond our or our contract manufacturer's control. It is often the case that early stage process development is conducted with materials that are not manufactured using cGMP starting materials, techniques or processes and which are not subject to the same level of analysis that would be required for clinical grade material. We may encounter difficulties in translating the manufacturing processes used to produce research grade materials to cGMP compliant processes, and any changes in the manufacturing process may affect the safety and efficacy profile of our product candidates.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process, such as Sf9 cells, are derived from biologic sources. Such raw materials may be difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of any product candidates we may develop could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations and prospects.

Our non-viral gene therapy platform is novel, and the combination of novel constructs with untested scaling may cause us to experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization programs, limit the supply of any product candidates we may develop or otherwise harm our business.

Our non-viral gene therapy platform is novel and the manufacture of products on the basis of our platform is untested at a large scale. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our preclinical or clinical development of any product candidates we may develop. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. The ability to scale our manufacturing and maintain the manufacturing process at the same levels of quality and efficacy that we are currently manufacturing is yet to be tested. If we or our CDMOs are unable to scale our manufacturing at the same levels of quality and efficiency, we may not be able to supply the required number of doses for clinical trials or commercial supply, and our business could be harmed.

Manufacturing the ctLNP component of a potential product candidate may be complex and difficult, and we could experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization, limit the supply of any product candidates we may develop or otherwise harm our business.

Many product candidates we may develop will require the manufacture of the ctLNP component, which may require processing steps that are more complex than those required for current products that utilize LNPs. In order to manufacture ctLNPs that are specialized for a given platform program, we may need to add biologic ligands to existing LNPs. This process is challenging and may pose a risk to our ability to manufacture on a scale sufficient to meet clinical and commercial needs.

Testing of and changes to methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are tested and then altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives.

An important part of the manufacturing of our potential product candidates is analytical testing. Analytical testing of gene therapies involves tests that are more numerous, more complex in scope and take a longer time to develop and to conduct as compared to traditional dugs. We and our CDMOs may need to expend considerable time and resources to develop assays and other analytical tests for our product candidates, including assays to assess the potency of our product candidates. Some assays may need to be outsourced to specialized testing laboratories. Even when assays are developed, they may need to be further tested, qualified and validated, which may take substantial time and resources. Because of the lagging nature of analytical testing, we may proceed with additional manufacturing and other development activities without having first fully characterized our manufactured materials. If the results of the testing fail to meet our expectations, we may need to delay or repeat certain manufacturing and development activities.

We may make changes to our manufacturing methods as part of our product development activities. Any such changes could cause any product candidates we may develop to perform differently and affect the results of clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

In addition, the FDA, the EMA, and other regulatory authorities may require us to submit samples of any lot of and approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA, or other regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We currently depend on a small number of third-party suppliers for our drug substance and drug product, and we expect to continue to depend on third-party suppliers for materials used in the manufacture of any product candidates we may develop, and the loss of these third-party suppliers or their inability to supply us with adequate materials, particularly those raw materials that are in short supply, could harm our business.

We currently rely on a small number of third-party suppliers for our drug substance and drug product and expect to continue to rely on third-party suppliers for certain materials and components required for the production of any product candidates we may develop. Our dependence on these third-party suppliers and the challenges we may face in obtaining and maintaining adequate supplies of materials involve several risks, including limited control over pricing, availability and quality and delivery schedules. There is substantial demand and limited supply for certain of the raw materials used to manufacture genetic medicine products and these raw materials are usually sole-sourced, as there are a limited number of qualified suppliers. This limited supply, combined with any problems that may arise during the manufacturing process development, may create long lead times to manufacture or procure starting materials. The progress of our non-viral gene therapy platform is highly dependent on these suppliers providing us or our contract manufacturer with the necessary starting materials that meet our requirements in a timely manner. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements.

Any supply interruption in limited or sole-sourced raw materials could materially harm our ability to manufacture any product candidates we may develop until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of any product candidates we may develop, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties to conduct some or all aspects of our product manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our product manufacturing, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to many of these items, including CDMOs for the manufacturing of any product candidates we test in preclinical or clinical development, as well as contract research organizations, or CROs for the conduct of our animal testing and research. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third

parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for product candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND-enabling studies and clinical trials are conducted in accordance with the study plan and protocols.

Although we intend to design the clinical trials for any product candidates we may develop, CLROs will conduct some or all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CLROs and other third parties do not perform preclinical studies and future clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of any product candidates we may develop may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CLROs and other third parties, we could be required to repeat, extend the duration of or increase the size of any preclinical studies or clinical trials we conduct and this could significantly delay commercialization and require greater expenditures.

If third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future IND submissions and approval of any product candidates we may develop.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including any contract manufacturers of any product candidates we may develop, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturer must supply all necessary documentation in support of a biologics license application, or BLA, on a timely basis and must adhere to the FDA's cGLP and cGMP regulations enforced through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidates we may develop or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms or at all if they are affiliated with our competitors;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, particularly if they are under contract with our competitors;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in supply. An alternative manufacturer would need to be qualified through a BLA supplement which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

We may from time to time be dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our development candidates and investigational medicines.

We may from time to time depend on single-source suppliers for some of the components and materials used in, and manufacturing processes required to develop, our development candidates and investigational medicines. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of our development candidates or investigational medicines could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our investigational medicines, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our investigational medicines.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from

these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. These current or future laws, regulations and permitting requirements may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We expect to rely on third parties to conduct, supervise and monitor IND-enabling studies and clinical studies, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We expect to rely on CROs and CLROs and research and clinical trial sites to ensure our IND-enabling studies and clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs and CLROs' activities. Nevertheless, we will be responsible for ensuring that each of these studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs and CLROs does not relieve us of our regulatory responsibilities.

We and our CROs and CLROs will be required to comply with the FDA's GCPs for conducting, recording and reporting the results of IND-enabling studies and clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs or CLROs fail to comply with applicable GCPs, the preclinical and clinical data generated in our studies may be deemed unreliable and the FDA may require us to perform additional studies before approving any marketing applications. Upon inspection, the FDA may determine that our studies did not comply with GCPs.

Our CLROs and CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical and nonclinical programs. These CLROs and CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If our CROs or CLROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements, or for any other reasons, our studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidates we may develop. As a result, our financial results and commercial prospects would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

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

We may seek third-party collaborators for the research, development and commercialization of certain of the product candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

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

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

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

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

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic collaborators are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners,

however, may develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop that are the subject of these collaborations with us. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates we may develop.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, fail to devote sufficient resources to the development and commercialization of products, or merge with or be acquired by a third party who may do any of these things. Any of these developments could harm our product development efforts.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of any sales or marketing activities, or increase our own expenditures on the development of the product candidate.

Risks related to commercialization

We face substantial competition, which may result in others discovering, developing or commercializing products before us or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to any product candidates that we may develop from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of many of the disorders for which we are conducting research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are numerous companies that are selling or developing genetic medicines, including in indications for which we may develop our non-viral gene therapies. These companies include viral gene therapy companies such as BioMarin Pharmaceuticals, Inc., Homology Medicines, Inc., Adverum Biotechnologies, Inc. and Hoffmann La Roche Ltd; gene editing companies such as Crispr Therapeutics AG, Intellia Therapeutics, Inc. and Editas Medicine, Inc.; and mRNA companies such as Moderna, Inc.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our product candidates or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if any product candidate that we may develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

If any product candidate we may develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. Sales of medical products depend in part on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost-effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost-effective as compared with competing treatments. Efforts to educate the medical community and third-party payers on the benefits of any product candidates we may develop may require significant resources and may not be successful. If any product candidates we may develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential advantages and limitations compared to alternative treatments;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

The pricing, insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our future product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

The initial target platforms in our pipeline are indications with small patient populations. For product candidates that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such product candidates must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate that accounts for the smaller potential market size. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payers, the adoption of those product candidates and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

We expect that coverage and reimbursement by third-party payers will be essential for most patients to be able to afford these treatments. Accordingly, sales of our future product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payers. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement by government authorities for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, since CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. However, one payer's determination to provide coverage for a product does not assure that other payers will also provide coverage for the drug product. Further, a payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement agencies in the European Union may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as any product candidates we may develop. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the product, possibly for lengthy periods of time. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for product candidates. Accordingly, in markets outside the United States, the reimbursement for any product candidates we may develop may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payers, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for any product candidates we may develop. We expect to experience pricing pressures in connection with the sale of any product candidates we may develop due to the trend toward managed healthcare, the increasing influence of certain third-party payers, such as health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. Recently there have been instances in which third-party payers have refused to reimburse treatments for patients for whom the treatment is indicated in the FDA-approved product label. Even if we are successful in obtaining FDA approvals to commercialize our product candidates, we cannot guarantee that we will be able to secure reimbursement for all patients for whom treatment with our product candidates is indicated.

In addition to CMS and private payers, professional organizations such as the American Medical Association, or the AMA, can influence decisions about reimbursement for new products by determining standards for care. In addition, many private payers contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing any product candidates we may develop if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.

In the future, we may build a sales and marketing infrastructure to market some of the product candidates we may develop if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to educate adequate numbers of physicians on the benefits of any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payers;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute any product candidates we may develop or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates we may develop.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Amendment, or the PPACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our biological products.

There is a risk that any product candidates we may develop that are approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for nonbiological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If the market opportunities for any product candidates we may develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer. Because the target patient populations for many of the initial product candidates we may develop are small, we must be able to successfully identify patients and achieve a significant market share to maintain profitability and growth.

We are focusing our initial research and product development on treatments for rare genetically defined diseases; as a result, the relevant patient population may be small. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product candidates we may develop, or may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Additionally, because of the potential that any product candidates we may develop could cure a target disease, we may not receive recurring revenues from patients and may deplete the patient population prevalence through curative therapy.

Risks related to our intellectual property

Although we own and license a number of pending patent applications which have not yet issued as patents, we do not currently own or exclusively in-license any issued patents relating to any product candidates we may develop or technology, including with respect to our ceDNA constructs, ctLNP delivery system and manufacturing process. If we or our licensors are unable to obtain, maintain and defend patent and other intellectual property protection for our product candidates and technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully develop and commercialize any product candidates we may develop or our technology may be adversely affected due to such competition.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and other jurisdictions with respect to any product candidates we may develop and our technology, including our ceDNA constructs, ctLNP delivery system, manufacturing processes and their respective components, formulations, combination therapies, methods of treatment, processes and development that are important to our business, as well as successfully defending these patents and other intellectual property against third-party challenges. We and our licensors have sought, and will seek, to protect our proprietary position by filing patent applications in the United States and abroad related to certain technologies and our platform that are important to our business. However, our patent portfolio is at an early stage and we currently do not own or exclusively license any issued patents in any jurisdiction. Moreover, there can be no assurance as to whether or when our patent applications will issue as granted patents. Our ability to stop third parties from making, using, selling, marketing, offering to sell, importing and commercializing any product candidates we may develop and our technology is dependent upon the extent to which we have rights under valid and enforceable patents and other intellectual property that cover our platform and technology. If we are unable to secure, maintain, defend and enforce patents and other intellectual property with respect to any product candidates we may develop and technology, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

We own certain patent applications, and exclusively in-license from University of Massachusetts as represented by and solely on behalf of its Medical School, or UMass, and Voyager Therapeutics, Inc. certain other patent applications, which cover our ceDNA platform structure, use and/or function, our ctLNP platform and its use, and ceDNA manufacturing processes, as applicable. Our pending Patent Cooperation Treaty, or PCT, patent applications are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 to 32 months, depending on the jurisdiction, from such application's priority date in the jurisdictions in which we are seeking patent protection. Similarly, our pending provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of such provisional patent application's filing date. If we do not timely file such national stage patent applications or non-provisional patent applications, we may lose our priority date with respect to such PCT or provisional patent applications, respectively, and any patent protection on the inventions disclosed in such PCT or provisional patent applications, respectively. While we and our licensors intend to timely file national stage and non-provisional patent applications relating to our PCT and provisional patent applications, respectively, we cannot predict whether any such patent applications will result in the issuance of patents. If we or our licensors do not successfully obtain issued patents, or, if the scope of any patent protection we or our licensors obtain is not sufficiently broad, we will be unable to prevent others from using any product candidates we may develop or our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. Any failure to obtain or maintain patent protection with respect to our ceDNA constructs, ctLNP delivery system, manufacturing processes or our other product candidates and technology would have a material adverse effect on our business, financial condition, results of operations and prospects.

The patent prosecution process is expensive, time-consuming and complex, and we and our licensors may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We and our licensors may not be able to obtain, maintain or defend patents and patent applications due to the subject matter claimed in such patents and patent applications being in the public domain. For example, in some cases, the work of certain academic researchers in the genetic medicine field has entered or will enter the public domain, which may compromise our and our licensors' ability to obtain patent protection for certain inventions related to or building upon such prior work. It is also possible that we will fail to

identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we would not be able to prevent any third party from using any of our technology that is in the public domain to compete with our product candidates.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not result in patents being issued which protect our technology or product candidates, effectively prevent others from commercializing competitive technologies and product or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all, and even if such patent applications do issue as patents, they may not issue in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent others from competing with us or otherwise provide us with any competitive advantage. In addition, the scope of claims of an issued patent can be reinterpreted after issuance, and changes in either the patent laws or interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patent rights or narrow the scope of our patent protection. Furthermore, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Third parties have developed technologies that may be related or competitive to our own technologies and product candidates and may have filed or may file patent applications, or may have obtained issued patents, claiming inventions that may overlap or conflict with those claimed in our owned or licensed patent applications or issued patents. We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates and technology. Publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know for certain whether the inventors of our owned or licensed patents and patent applications were the first to make the inventions claimed in any owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and other jurisdictions. For example, we may be subject to a third-party submission of prior art to the United States Patent and Trademark Office, or USPTO, challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We may become involved in opposition, derivation, re-examination, *inter partes* review, post-grant review or interference proceedings and similar proceedings in foreign jurisdictions (for example, opposition proceedings) challenging our owned or licensed patent rights. In addition, a third party may claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. An adverse result in any litigation or patent office proceeding could put one or more of our owned or licensed patents at risk of being invalidated, ruled unenforceable or interpreted narrowly and could allow third parties to commercialize products identical or similar to any product candidates we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges and proceedings may result in loss of patent rights, exclusivity, freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and any product candidates we may develop. Such challenges and proceedings may also result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other interim proceedings or developments related to such challenges and proceedings and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Furthermore, patents have a limited lifespan. In the United States, the expiration of a patent is generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority. Patent term adjustments and extensions may be available; however, the overall term of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent and other intellectual property rights may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our technology and any product candidates we may develop. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our rights to develop and commercialize any product candidates are subject, in part, to the terms and conditions of licenses granted to us by third parties. If we fail to comply with our obligations under our current or future intellectual property license agreements or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

We are reliant upon licenses from third parties for certain patent and other intellectual property rights that are important or necessary to the development of our technology and product candidates. For example, we rely on a license from the National Institutes of Health, or NIH, and the Association Institut de Myologie, Universite Pierre et Marie Curie, Centre National de la Recherche Scientifique and Inserm Transfert SA, which we refer to as the French Institutions, pursuant to which we have been granted a non-exclusive, worldwide, royalty-bearing license to certain patent rights related to our ceDNA construct, to make and have made, research and have researched, use and have used, sell and have sold, offer to sell and to import products for the treatment, prevention or palliation of any human disease, disorder or condition. In addition, we rely on a license from UMass pursuant to which we have been granted an exclusive, worldwide, royalty-bearing license to certain patent rights related to our ceDNA construct to research, develop, manufacture, have manufactured, use, offer for sale, sell and import products in the treatment, prevention or palliation of any human disease, disorder or condition. Our existing license agreements, including our license agreements with NIH and UMass, impose, and we expect that future license agreements will impose, specified diligence, milestone payment, royalty, commercialization, development and other obligations on us and require us to meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. We may enter into additional license agreements in the future.

Furthermore, the licensors of our license agreements have the right to terminate the agreement if we materially breach the agreement and fail to cure such breach within a specified period or in the event we undergo certain bankruptcy events. In spite of our best efforts, our current or any future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements. If our license agreements are terminated, we may lose our rights to develop and commercialize any product candidates we may develop and technology, lose patent protection any product candidates we may develop and our technology, experience significant delays in the development and commercialization of our product candidates and technology and incur liability for damages. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our product candidates and technology. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with any product candidates we may develop and our technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensors' ability to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, development, regulatory, commercialization, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If disputes over intellectual property that we have licensed or any other dispute described above related to our license agreements prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technology. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our license agreement with NIH is, and other license agreements we may enter into in the future may be, non-exclusive. Accordingly, third parties may also obtain non-exclusive licenses from such licensors, including NIH, with respect to the intellectual property licensed to us under such license agreements, including our NIH license agreement. Accordingly, our NIH license agreement does not, and other license agreements may not, provide us with exclusive rights to use such licensed patent and other intellectual property rights, or may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and any product candidates we may develop in the future.

Moreover, some of our in-licensed patent and other intellectual property rights are, and may in the future be, subject to third party interests such as co-ownership. If we are unable to obtain an exclusive license to such third-party co-owners' interest, in such patent and other intellectual property rights, such third-party co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. We or our licensors may need the cooperation of any such co-owners of our licensed patent and other intellectual property rights in order to enforce them against third parties, and such cooperation may not be provided to us or our licensors.

Additionally, we do not have complete control over the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. For example, pursuant to each of our intellectual property licenses with NIH and UMass, our licensors retain control of preparation, filing, prosecution and maintenance, and, in certain circumstances, enforcement and defense of their patents and patent applications. It is possible that our licensors' filing, prosecution and maintenance of the licensed patents and patent applications, enforcement of patents against infringers or defense of such patents against challenges of validity or claims of enforceability may be less vigorous than if we had conducted them ourselves, and accordingly, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to file, prosecute, maintain, enforce and defend such patents and patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our technology and any product candidates we may develop that are the subject of such licensed rights could be adversely affected and we may not be able to prevent competitors or other third parties from making, using and selling competing products. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Furthermore, our owned and in-licensed patent rights may be subject to a reservation of rights by one or more third parties. For example, inventions contained within some of our in-licensed patent rights may be made using U.S. government funding. When new technologies are developed with government funding, in order to secure ownership of patent rights related to the technologies, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. We rely on our licensors to ensure compliance with applicable obligations arising from such funding, including such timely disclosure and election of title. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents or patent applications. In addition, the U.S. government has certain rights in such in-licensed patent rights, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. If the U.S. government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. The U.S. government's rights may also permit it to disclose the funded inventions and technology, which may include our confidential information, to third parties and to exercise march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we or our licensors failed to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such in-licensed U.S. government-funded inventions may be subject to certain requirements to manufacture any product candidates we may develop embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, enforcing and defending patents and other intellectual property rights on our technology and any product candidates we may develop in all jurisdictions throughout the world would be prohibitively expensive, and accordingly, our intellectual property rights in some jurisdictions outside the United States could be less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent or other intellectual property protection for certain technology and product candidates outside the United States. In addition, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to obtain

issued patents or other intellectual property rights covering any product candidates we may develop and our technology in all jurisdictions outside the United States and, as a result, may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Third parties may use our technologies in jurisdictions where we and our licensors have not pursued and obtained patent or other intellectual property protection to develop their own products and, further, may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement is not as strong as that in the United States. These products may compete with any product candidates we may develop and our technology and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Additionally, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain jurisdictions, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patent and other intellectual property rights or marketing of competing products in violation of our intellectual property rights generally. For example, an April 2019 report from the Office of the United States Trade Representative identified a number of countries, including China, Russia, Argentina, Chile and India, where challenges to the procurement and enforcement of patent rights have been reported. Proceedings to enforce our or our licensors' patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patent rights. We rely on our outside counsel and other professionals or our licensing partners to pay these fees due to the USPTO and non-U.S. government patent agencies. The USPTO and various non-U.S. government patent agencies also require compliance with several procedural, documentary and other similar provisions during the patent application process. We rely on our outside counsel and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not be successful in obtaining necessary rights to product candidates we may develop through acquisitions and in-licenses.

We currently have rights to certain intellectual property through licenses from third parties. Because our programs may require the use of additional intellectual property rights held by third parties, the growth of our business likely will depend, in part, on our ability to acquire, in-license or use these intellectual property rights. In addition, with respect to any patent or other intellectual property rights that we co-own with third parties, we may require exclusive licenses to such co-owners' interest in such patent or other intellectual property rights. However, we may be unable to secure such licenses or otherwise acquire or in-license any intellectual property rights related to compositions, methods of use, processes or other components from third parties that we identify as necessary for any product candidates we may develop and our technology on commercially reasonable terms, or at all. Even if we are able to in-license any such necessary intellectual property, it could be on non-exclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and the applicable licensors could require us to make substantial licensing and royalty payments. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital

resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We sometimes collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to third parties, potentially blocking our ability to pursue our research program and develop and commercialize our product candidates.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have licensed, we may be required to expend significant time and resources to redesign any product candidates we may develop or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering any product candidates we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our owned and licensed patent rights may be subject to priority, validity, inventorship and enforceability disputes. If we or our licensors are unsuccessful in any of these proceedings, such patent rights may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of one or more of our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If one of our licensing partners, one of our co-owners, we or our licensor's other licensees initiate legal proceedings against a third party to enforce a patent covering any of any product candidates we may develop or our technology, the defendant could counterclaim that the patent covering the product candidate or technology is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, interference proceedings, derivation proceedings, post grant review, *inter partes* review and equivalent proceedings such as opposition, invalidation and revocation proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover any product candidates we may develop or our technology or prevent third parties from competing with any product candidates we may develop or our technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates or technology. Such a loss of patent protection could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, contractors and other parties who have access to such technology and processes. However, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breach or violate the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with any product candidates we may develop and our technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems; however, such systems and security measures may be breached, and we may not have adequate remedies for any breach.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. Competitors or third parties could purchase any product candidates we may develop or our technology and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our intellectual property rights or develop their own competitive technologies that fall outside the scope of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may become party to, or be threatened with, adversarial proceedings or litigation in which third parties may assert infringement, misappropriation or other violation claims against us, alleging that any product candidates we may develop, manufacturing methods, formulations or administration methods are covered by their patents. Given the vast number of patents and other intellectual property in our field of technology, we cannot be certain or guarantee that we do not infringe, misappropriate or otherwise violate patents or other intellectual property. Other companies and institutions have filed, and continue to file, patent applications that may be related to our technology and, more broadly, to gene therapy and related manufacturing methods. Some of these patent applications have already been allowed or issued and others may issue in the future. Since this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. If a patent holder believes the manufacture, use, sale or importation of any product candidates we may develop or our technology infringes its patent, the patent holder may sue us even if we have licensed other patent rights for our technology.

It is also possible that we have failed to identify relevant third-party patents or applications. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, sale or importation of any product candidates we may develop or our technology and we may not be aware of such patents. Furthermore, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States may remain confidential until a patent issues. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to any product candidates we may develop and our technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, any product candidates we may develop or the use of any product candidates we may develop.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could adversely affect our ability to commercialize any product candidates we may develop or any other of our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing any product candidates we may develop and our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other

intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing any product candidates we may develop or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Intellectual property litigation or other proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Competitors may challenge the validity and enforceability of our patent rights or those of our licensing partners, infringe, misappropriate or otherwise violate our or our licensors' patent and other intellectual property rights, or we may be required to defend against claims of infringement, misappropriation or other violation. Litigation and other proceedings in connection with any of the foregoing claims can be unpredictable, expensive and time consuming. Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our scientific, technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors or other third parties may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing any product candidates we may develop or at all. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize any product candidates we may develop and our technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our scientific and management personnel.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. Disputes about the ownership of intellectual property that we own may have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patent rights. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technology and any product candidates we may develop. Such challenges may also result in our inability to develop, manufacture or commercialize our technology and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patent rights are threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology and product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in patent law in the United States or worldwide could diminish the value of patents in general, thereby impairing our ability to protect any product candidates we may develop and our technology.

Changes in either the patent laws or interpretation of patent laws in the United States and worldwide, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of any owned or in-licensed patent applications and the maintenance, enforcement or defense of any current in-licensed issued patents and issued patents we may own or in-license in the future. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our in-licensed issued patents and issued patents we may own or in-license in the future, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. As one example, in the case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable simply because they have been isolated from surrounding material. Moreover, in 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to patent-ineligible subject matter. Accordingly, in view of the guidance memo, there can be no assurance that claims in our patent rights covering any product candidates we may develop or our technology will be held by the USPTO or equivalent foreign patent offices or by courts in the United States or in foreign jurisdictions to cover patentable subject matter. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop and our technology, one or more of our U.S. patents that we license or may own in the future may be eligible for limited patent term extension under Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patent and other intellectual property rights.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patent rights, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or technology. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patent rights, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to any product candidates we may develop or our technology. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We have filed trademark applications with the USPTO for the mark "Generation Bio" and the Generation Bio logo. Our current and future trademark applications in the United States and other foreign jurisdictions may not be allowed or may be subsequently opposed. Once filed and registered, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make gene therapy products that are similar to any product candidates we may develop but that are not covered by the intellectual property, including the claims of the patents, that we own or license currently or in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license currently or in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our or our licensors' current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by third parties;
- third parties might conduct research and development activities in jurisdictions where we do not have patent or other intellectual property rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover our trade secrets or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on certain third parties to manufacture all or part of our drug product and to perform quality testing, and because we collaborate with various organizations and academic institutions for the advancement of our product engine and pipeline, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements and other similar agreements with our collaborators, advisors, employees, consultants and contractors prior to beginning research or disclosing any proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets by third parties. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may harm our business, financial condition, results of operations and prospects.

Risks related to regulatory approval and other legal compliance matters

Regulatory requirements governing genetic medicine products, and in particular any novel gene therapy products we may develop, have changed frequently and may continue to change in the future.

Regulatory requirements governing gene and cell therapy products, and in particular any novel gene therapy products we may develop, have changed frequently and may continue to change in the future. We are aware of a limited number of gene therapy products that have received marketing authorization from the FDA and EMA. Even with respect to more established products in the gene therapy field, the regulatory landscape is still developing. For example, the FDA has established the Office of Tissues and Advanced Therapies (formerly the Office of Cellular, Tissue and Gene Therapies) within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health, or the NIH, also are potentially subject to review by the Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or the RAC; however, the NIH announced that the RAC will soon only publicly review clinical trials if the trials cannot be evaluated by standard oversight bodies and pose unusual risks.

The same applies in the European Union. The EMA's Committee for Advanced Therapies, or CAT, is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the Committee for Medicinal Products for Human Use, or CHMP, before CHMP adopts its final opinion. In the European Union, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any product candidates we may develop, but that remains uncertain at this point.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of any product candidates we may develop or lead to significant post-approval limitations or restrictions. As we advance any product candidates we may develop, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of these product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

Although the FDA decides whether individual genetic medicine protocols may proceed, the RAC public review process, if undertaken, can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Conversely, the FDA can put an IND on a clinical hold even if the RAC has provided a favorable review or an exemption from in-depth, public review. If we were to engage an NIH-funded institution to conduct a clinical trial, that institution's institutional biosafety committee, or IBC, as well as its IRB would need to review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of genetic medicine products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any product candidates we may develop. Similarly, the EMA may issue new guidelines concerning the development and marketing authorization for genetic medicine products and require that we comply with these new guidelines.

As we are initially seeking to identify and develop product candidates to treat diseases using novel technologies, there is heightened risk that the FDA, the EMA or other regulatory authority may not consider the clinical trial endpoints that we propose to provide clinically meaningful results. Even if the endpoints are deemed clinically meaningful, we may not achieve these endpoints to a degree of statistical significance, particularly because many of the diseases we are targeting with our platform have small patient populations, making development of large and rigorous clinical trials more difficult.

Adverse developments in post-marketing experience or in clinical trials conducted by others of gene therapy products or cell therapy products may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for development or approval of any product candidates we may develop or limit the use of products utilizing non-viral gene therapy technologies, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as the product candidates we may develop can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing non-viral gene therapy technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the commercialization of resulting products.

In addition, ethical, social and legal concerns about genetic medicine, genetic testing and genetic research could result in additional regulations or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed their intentions to further regulate biotechnology. More restrictive regulations or claims that any product candidates we may develop are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of any product candidates we may develop under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

As we advance any product candidates we may develop through clinical development, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of any product candidates we may develop or lead to significant post-approval limitations or restrictions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of any product candidates we may develop. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.

Any product candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate we may develop will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CLROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate’s safety, purity and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we may develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Negative public opinion of gene therapy and increased regulatory scrutiny of gene therapy and genetic research may adversely impact public perception of our future product candidates.

Our potential therapeutic products involve introducing genetic material into patients' cells. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene regulation are unsafe, unethical or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. For example, in 2003, trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. Although our delivery system is non-viral, any product candidates we may develop may be associated with such viral delivery systems as a gene therapy platform. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene therapy and we cannot assure that it will not occur in any of our planned or future clinical trials. In addition, there is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. If any such adverse events occur, commercialization of our product candidates or further advancement of our clinical trials could be halted or delayed, which would have a negative impact on our business and operations.

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we may develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any product candidates we may develop in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any jurisdiction, which would materially impair our ability to generate revenue.

Political and socioeconomic factors can adversely affect our business. For example, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the United Kingdom will not accept high regulatory alignment with the European Union.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for any product candidates we may develop, which could significantly and materially harm our business.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of any product candidates we may develop.

If any product candidate we may develop is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. However, a fast track designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while we may seek and receive fast track designation for any product candidates we may develop, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

Breakthrough or RMAT therapy designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of any product candidates we may develop.

If any product candidate we may develop is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development, the sponsor may apply for FDA breakthrough designation or a regenerative medicine advanced therapy, or RMAT, designation. However, neither a breakthrough designation nor an RMAT designation ensures that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while we may seek and receive breakthrough or RMAT designation for any product candidates we may develop, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw breakthrough or RMAT designation if it believes that the designation is no longer supported by data from our clinical development program. Neither breakthrough nor RMAT designation alone guarantees qualification for the FDA's priority review procedures.

Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of any product candidates we may develop.

If the FDA determines that a product candidate we may develop offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for any product candidates we may develop. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate we may develop is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

We may not be able to obtain orphan drug exclusivity for any product candidates we may develop, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA has issued recent draft guidance suggesting that it would not consider two genetic medicine products to be different drugs solely based on minor differences in the transgenes or vectors. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

In 2017, the Congress passed the FDA Reauthorization Act of 2017, or the FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate we may develop or the approval may be for a more narrow indication than we expect.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if any product candidates we may develop demonstrate safety and efficacy in clinical trials, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop. For example, our development of any product candidates for pediatric use is an important part of our current business strategy, and if we are unable to obtain regulatory approval for the desired age ranges, our business may suffer.

Even if we, or any collaborators we may have, obtain marketing approvals for any product candidates we may develop, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The FDA typically advises that patients treated with genetic medicine undergo follow-up observations for potential adverse events for a 15-year period. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more product candidates we may develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition and prospects.

If we fail to comply with applicable regulatory requirements following approval of any product candidates we may develop, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or supplements to a BLA submitted by us;

- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we may develop and generate revenues.

Any product candidate we may develop for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our medicines, when and if any of them are approved.

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our medicines for their approved indications, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Product, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown problems with our medicines, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such medicines, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine;
- requirements to conduct post-marketing clinical trials;
- receipt of warning or untitled letters;
- withdrawal of the medicines from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of medicines;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our medicines;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations and prospects.

Additionally, if any product candidates we may develop receive marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to healthcare practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidate, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

We are affected by the political environment and changes that may be made to regulatory regimes. The efforts of the current presidential administration to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

The current presidential administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. On January 30, 2017, the president issued an executive order, applicable to all executive agencies, including the FDA, that required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for- one" provisions. This executive order includes a budget neutrality provision that required the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management on February 2, 2017, the administration indicated that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Our relationships with healthcare providers, physicians and third-party payers will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers play a primary role in the recommendation and prescription of any product candidates that we develop for which we obtain marketing approval. Our future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other government payers that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $11,181 to $22,363 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, as further amended by the Health Information Technology for Economic and Clinical Health Act, which imposes certain requirements, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services, or HHS, information related to payments and other transfers of value to physicians and teaching hospitals and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the
European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recently enacted and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of any product candidates we may develop, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payers.

The PPACA, which became law in 2010, contains provisions of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any product candidates we may develop and that are approved for sale, the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of federal healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;

- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." The Congress may consider other legislation to replace elements of the PPACA during the next Congressional session.

Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the PPACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the PPACA. The Congress will likely consider other legislation to replace elements of the PPACA, during the next Congressional session. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace PPACA provisions is highly uncertain in many respects, it is also possible that some of the PPACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with PPACA coverage expansion provision.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our potential products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

The current presidential administration has also taken executive actions to undermine or delay implementation of the PPACA. Since January 2017, the president has signed two executive orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. One executive order directs federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. The second executive order terminates the cost-sharing subsidies that reimburse insurers under the PPACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in PPACA risk corridor payments to third-party payers who argued were owed to them. This decision is under review by the U.S. Supreme Court during its current term. The full effects of this gap in reimbursement on third-party payers, the viability of the PPACA marketplace, providers, and potentially our business, are not yet known.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States, and members of Congress and the executive branch have stated that they will address such costs through new legislative and administrative measures. To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the current presidential administration has pressed for drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the current presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. In addition, on December 23, 2019, the Trump Administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, the FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidates we may develop or additional pricing pressures.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants and partners, and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The Securities and Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA and other anti-corruption laws potentially applicable to our business is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, compliance with the FCPA and other anti-corruption laws presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union General Data Protection Regulation (EU) 2016/679, or the GDPR, which took effect across all member states of the European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that such rules should apply to transfers of personal data from clinical trial sites located in the EEA to the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with the GDPR's requirements are rigorous and time intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Similar privacy and data security requirements are either in place or underway in the United States. There are a broad variety of data protection laws that may be applicable to our activities, and a range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act of 2018, or the CCPA, which became effective on January 1, 2020, requires companies that process information on California residents to make new disclosures to consumers about their data collection, use and sharing practices, allow consumers to opt out of certain data sharing with third parties and provide a new cause of action for data breaches. Many other states are considering similar legislation, and a broad range of legislative measures also have been introduced at the federal level.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including certain laws that regulate the use and disclosure of personal health information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. These provisions may be applicable to our business in the future. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have violated these privacy and security laws and/or breached certain contracts with our business partners. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

It is possible that new and existing laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or penalties or orders requiring that we change our practices, which could adversely affect our business. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. We also face a threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business, financial condition, results of operations or prospects.

Risks related to employee matters and managing growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment offer letters with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs and, if any product candidate we may develop receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage the future development and expansion of our company.

Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.

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

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;
- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;

- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

Our internal information technology systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information.

Despite the implementation of security measures, given the size and complexity of our internal information technology systems and those of our current and any future third-party vendors, collaborators and other contractors and consultants, and the increasing amounts of confidential information that they maintain, such information technology systems are vulnerable to damage or interruption from computer viruses, computer hackers, malicious code, employee theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies.

While we seek to protect our information technology systems from system failure, accident and security breach, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary or confidential information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material. In addition, our remediation efforts may not be successful. Moreover, if the information technology systems of our third-party vendors, collaborators and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation based primarily on the laws and regulations discussed above in the privacy discussion, our competitive position and reputation could be harmed and the further development and commercialization of our product candidates could be delayed. Furthermore, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a natural disaster, pandemic or other catastrophic event.

We depend on our employees, consultants, CDMOs, CLROs, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, they might not adequately protect us. Despite any precautions we take for natural disasters or other catastrophic events, these events, including terrorist attack, pandemics, hurricanes, fire, floods and ice and snowstorms, could result in significant disruptions to our research and development, preclinical studies, clinical trials, and, ultimately, commercialization of our products. Long-term disruptions in the infrastructure caused by events, such as natural disasters, the outbreak of war, the escalation of hostilities and acts of terrorism or other ‘‘acts of God,’’ particularly involving cities in which we have offices, manufacturing or clinical trial sites, could adversely affect our businesses. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not respond or be adequate to compensate us for all losses that may occur. Any natural disaster or catastrophic event affecting us, our CDMOs, our CLROs, regulatory agencies or other parties with which we are engaged could have a significant negative impact on our operations and financial performance.

Risks related to ownership of our common stock and our status as a public company

We do not know whether a market will continue to develop or be sustained for our common stock and, as a result, it may be difficult for our stockholders to sell shares of our common stock.

Although our common stock is listed on the Nasdaq Global Select Market, an active trading market for our shares may not continue to develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or at all.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- results of or developments in preclinical studies and clinical trials of any product candidates we may develop or those of our competitors or potential collaborators;
- timing of the results of our preclinical studies and clinical trials or those of our competitors;
- our success in commercializing any product candidates we may develop, if and when approved;
- the success of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any product candidates we may develop;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates, technologies or data referencing rights, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- sales of common stock by us, our executive officers, directors or principal stockholders or others;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, political and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management's attention and resources.

If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provide more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

The COVID-19 pandemic, which began in late 2019 and has spread worldwide, may affect our ability to initiate and complete preclinical studies, delay the initiation of our planned clinical trial or future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, each of which could result in adverse effects on our business, on raising capital and on our operations.

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, is causing many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain. We and our CDMOs, and CROs, have experienced a reduction in the capacity to undertake research-scale production and to execute some preclinical studies, and we may face disruptions that affect our ability to initiate and complete preclinical studies, and disruptions in procuring items that are essential for our research and development activities, such as raw materials used in the manufacture of any product candidates we may develop, laboratory supplies used in our preclinical studies, or animals that are used for preclinical testing for which there are shortages because of ongoing efforts to address the outbreak. We and our CROs and CDMOs may face disruptions related to our future IND-enabling studies and clinical trials arising from delays in preclinical studies, manufacturing disruptions, and the ability to obtain necessary IRB, IBC or other necessary site approvals, as well as other delays at clinical trial sites. The response to the COVID-19 pandemic may redirect resources with respect to regulatory and intellectual property matters in a way that would adversely impact our ability to progress regulatory approvals and protect our intellectual property. In addition, we may face impediments to regulatory meetings and approvals due to measures intended to limit in-person interactions. The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations and prospects.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the 2008 global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the 2008 global financial crisis, could result in a variety of risks to our business, including, weakened demand for any product candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control all matters submitted to stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, own shares representing more than 60% of our common stock as of July 31, 2020. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

We have broad discretion in the use of cash, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the application of cash, cash equivalents and marketable securities and could spend them in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest these funds in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of July 31, 2020, we have 46,427,673 shares of common stock outstanding, which includes the 12,105,263 shares of common stock that we sold in our IPO. The remaining 34,322,410 shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after the expiration of the applicable lock-up period. The representatives of the underwriters may release some or all of the shares of common stock subject to lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market.

Moreover, beginning on December 9, 2020, holders of an aggregate of 31,887,648 shares of our common stock will have rights, along with holders of an additional shares of our common stock issuable upon exercise of outstanding options, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also filed a registration statement on Form S-8 to register shares of common stock that we may issue under our equity compensation plans. Shares registered under this registration statement on Form S-8 can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates, vesting arrangements and exercise of options, and the lock-up agreements entered into in connection with our IPO.

We are an "emerging growth company," and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2025, although if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, if we are a smaller reporting company with less than $100 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either irrevocably elect to "opt out" of such extended transition period or no longer qualify as an EGC. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We have incurred and will continue to incur increased costs as a result of operating as a newly public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an EGC or a smaller reporting company, we will incur significant legal, accounting and other expenses that we did not previously incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements and will make some activities more time-consuming and costly compared to when we were a private company.

We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our filing of an Annual Report on Form 10-K with the SEC for the year ended December 31, 2021. However, while we remain an EGC or a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an EGC under the JOBS Act or a smaller reporting company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the Tax Act, which significantly reformed the Code. The Tax Act, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for NOLs arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the CARES Act was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the Tax Act. It also provides that NOLs arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30 to 50% of adjusted taxable income.

Regulatory guidance under the Tax Act, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the FFCR Act or the CARES Act.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of proceedings:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction. Furthermore, our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from Initial Public Offering

On June 16, 2020, we closed our initial public offering, or IPO, of our common stock 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 at a price to the public of $19.00 per share for aggregate gross proceeds of $230.0 million.

All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-238608), which was declared effective by the SEC on June 11, 2020. J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC acted as joint book-running managers and Wedbush PacGrow acted as lead manager of our IPO.

We received aggregate net proceeds of approximately $210.7 million after deducting underwriting discounts and commissions and other offering expenses payable by us. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

As of June 30, 2020, we have not used any of the net proceeds from the IPO because the IPO closed on June 16, 2020. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 12, 2020.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation of the registrant, effective as of June 16, 2020 (incorporated by reference to Exhibit 3.3 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
3.2	Bylaws of the registrant, effective as of June 16, 2020 (incorporated by reference to Exhibit 3.4 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
10.1†*	Lease, dated August 2, 2018, by and between the registrant and BMR-Rogers Street LLC, as amended June 17, 2020.
10.2+*	Offer letter, dated June 19, 2020, by and between the registrant and Matthew Norkunas, as amended July 6, 2020.
10.3	2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
10.4	Form of Stock Option Agreement under 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
10.5	Form of Restricted Stock Agreement under 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
10.6	Form of Restricted Stock Unit Agreement under 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
10.7	Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
10.8	Form of Indemnification Agreement between the registrant and each of its executive officers and directors (incorporated by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
10.9	Form of Severance Plan Benefit Agreement by and between the registrant and certain of its executive officers (incorporated by reference to Exhibit 10.19 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed May 22, 2020).
10.10	Exclusive License Agreement, dated June 28, 2017, by and between the registrant and the University of Massachusetts, as amended June 5, 2020 (incorporated by reference to Exhibit 10.11 to the registrant's Registration Statement on Form S-1, File No. 333-238608, filed June 8, 2020).

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.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.
** Furnished herewith.
† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
+ 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: August 11, 2020

By: /s/ Geoff McDonough

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

Date: August 11, 2020

By: /s/ Matthew Norkunas

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

Exhibit 10.1

LEASE

by and between

BMR-ROGERS STREET LLC,
a Delaware limited liability company

and

GENERATION BIO CO.,
a Delaware corporation

TABLE OF CONTENTS

LEASE

THIS LEASE (this "Lease") is entered into as of this 2nd day of August, 2018 (the "Execution Date"), by and between BMR-ROGERS STREET LLC, a Delaware limited liability company ("Landlord"), and GENERATION BIO CO., a Delaware corporation ("Tenant").

RECITALS

A. WHEREAS, pursuant to that certain ground lease dated as of March 30, 1999, by and among MBA-Rogers Street, LLC ("Ground Lessor," as successor-in-interest to O&T Realty, LLC, and MBA-Cambridge, LLC (collectively, "Initial Ground Lessor")), as landlord, and Rogers Street, LLC, a Delaware limited liability company ("Initial Ground Lessee"), as tenant; as such ground lease has been amended by that certain letter agreement dated as of July 29, 1999, between Initial Ground Lessor and Initial Ground Lessee, and that certain Agreement Regarding Arbitration and Lease Amendments dated as of December 15, 1999, by and between Initial Ground Lessor and Initial Ground Lessee; and as such ground lease has been assigned pursuant to that certain Assignment and Assumption of Ground Lease dated as of April 4, 2007, by and between Initial Ground Lessee and Landlord (such ground lease, as so amended and assigned, and as the same may be further amended, amended and restated, supplemented or otherwise modified from time to time, the "Ground Lease"), Landlord leases certain real property described on Exhibit A-1 attached hereto (the "Property") and the improvements located thereon, including the buildings at 301 Binney Street (the "Building"), 320 Bent Street and 157 Sixth Street in Cambridge, Massachusetts; and

B. WHEREAS, Landlord wishes to lease to Tenant, and Tenant desires to lease from Landlord, certain premises (the "Premises") located on the first (1st) floor and the fourth (4th) floor of the Building, pursuant to the terms and conditions of this Lease, as detailed below.

AGREEMENT

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

1. Lease of Premises.

1.1 Effective on the Term Commencement Date (as defined below), Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, the Premises, as shown on Exhibit A attached hereto, including exclusive shafts, cable runs, mechanical spaces and rooftop areas, for exclusive use by Tenant (subject to Landlord's rights hereunder) in accordance with the Permitted Use (as defined below) and no other uses. The Property and all landscaping, parking facilities, private drives and other improvements and appurtenances related thereto, including the Building and other buildings located on the Property, are hereinafter collectively referred to as the "Project." All portions of the Building that are for the non-exclusive use of the tenants of the Building only, and not the tenants of the Project generally, such as service corridors, stairways, elevators, public restrooms and public lobbies (all to the extent located in the Building), are hereinafter referred to as "Building Common Area." All portions of the Project that are for the non-exclusive use of tenants of the Project generally, including driveways, sidewalks, parking areas and landscaped areas, are hereinafter referred to as "Project Common Area." The Building Common Area and Project Common Area are collectively referred to herein as "Common Area."

2. Basic Lease Provisions. For convenience of the parties, certain basic provisions of this Lease are set forth herein. The provisions set forth herein are subject to the remaining terms and conditions of this Lease and are to be interpreted in light of such remaining terms and conditions.

2.1 This Lease shall take effect upon the Execution Date and, except as specifically otherwise provided within this Lease, each of the provisions hereof shall be binding upon and inure to the benefit of Landlord and Tenant from the date of execution and delivery hereof by all parties hereto.

2.2 In the definitions below, each current Rentable Area (as defined below) is expressed in rentable square feet. Rentable Area and "Tenant's Pro Rata Share" are subject to adjustment as provided in this Lease.

Definition or Provision	Means the Following (As of the Execution Date)
Approximate Rentable Area of Fourth Floor Premises	52,252 square feet
Approximate Rentable Area of First Floor Premises	19,310 square feet
Approximate Rentable Area of Premises (total)	71,562 square feet
Approximate Rentable Area of Building	417,290 square feet
Tenant's Pro Rata Share of Building	17.15%

2.3 Monthly and annual installments of Base Rent for the Fourth Floor Premises ("Fourth Floor Base Rent") as of the Fourth Floor Rent Commencement Date (as defined below), subject to adjustment under this Lease:

Dates	Square Feet of Rentable Area (Fourth Floor Premises)	Base Rent per Square Foot of Rentable Area	Monthly Base Rent	Annual Base Rent
Fourth Floor Rent Commencement Date—The day immediately prior to the first (1st) annual anniversary of the Fourth Floor Rent Commencement Date	52,252	$86.00 annually	$374,472.67	$4,493,672.00

2.4 Monthly and annual installments of Base Rent for the First Floor Premises ("First Floor Base Rent", together with the Fourth Floor Base Rent, "Base Rent") as of the First Floor Rent Commencement Date (as defined below), subject to adjustment under this Lease:

Dates	Square Feet of Rentable Area (First Floor Premises)	Base Rent per Square Foot of Rentable Area	Monthly Base Rent	Annual Base Rent
First Floor Rent Commencement Date—The day immediately prior to the first (1st) annual anniversary of the First Floor Rent Commencement Date	19,310	$83.00 annually	$133,560.83	$1,602,730

2.5 Estimated Fourth Floor Term Commencement Date: August 3, 2018.

2.6 Estimated First Floor Term Commencement Date: January 18, 2019.

2.7 Estimated Term Expiration Date: April 30, 2029.

2.8 Security Deposit: $2,051,444, subject to increase in accordance with the terms hereof.

2.9 Permitted Use: General office, laboratory and vivarium use in conformity with all federal, state, municipal and local laws, codes, ordinances, rules and regulations of Governmental Authorities (as defined below), committees, associations, or other regulatory committees, agencies or governing bodies having jurisdiction over the Premises, the Building, the Property, the Project, Landlord or Tenant, including both statutory and common law and hazardous waste rules and regulations ("Applicable Laws").

2.10 Address for Rent Payment:

BMR-Rogers Street LLC
Attention Entity 635
P.O. Box 511415
Los Angeles, California 90051-7970

2.11 Address for Notices to Landlord:

BMR-Rogers Street LLC
17190 Bernardo Center Drive
San Diego, California 92128
Attn: Legal Department

2.12 Address for Notices to Tenant:

Prior to the Fourth Floor Term Commencement Date:

Generation Bio Co.
215 First Street, Suite 150
Cambridge, MA 02142
Attention: Chief Financial Officer

After the Fourth Floor Term Commencement Date:

Generation Bio Co.
301 Binney Street
Cambridge, MA 02142
Attention: Chief Financial Officer

2.13 Address for Invoices to Tenant:

Prior to the Fourth Floor Term Commencement Date:

Generation Bio Co.
215 First Street, Suite 150
Cambridge MA 02142
Attention: Chief Financial Officer

After the Fourth Floor Term Commencement Date:

Generation Bio Co.
301 Binney Street
Cambridge, MA 02142
Attention: Chief Financial Officer

2.14 The following Exhibits are attached hereto and incorporated herein by reference:

Exhibit A	Premises
Exhibit A-1	Property
Exhibit A-2	Lab/Office Zone Plan
Exhibit B	Work Letter
Exhibit B-1	Tenant Work Insurance Schedule
Exhibit C	Acknowledgement of Fourth Floor Term Commencement Date and Term Expiration Date

Exhibit D	Acknowledgement of First Floor Commencement Date and Term Expiration Date
Exhibit E	Form of Letter of Credit
Exhibit F	Rules and Regulations
Exhibit G	PTDM
Exhibit H	Tenant's Personal Property
Exhibit I	Form of Estoppel Certificate
Exhibit J	Form of Ground Lease Non-Disturbance and Attornment Agreement

3. Term. The actual term of this Lease (as the same may be extended pursuant to Article 42 hereof, and as the same may be earlier terminated in accordance with this Lease, the "Term") shall commence on the actual Fourth Floor Term Commencement Date (as defined in Article 4) and end on the date (the "Term Expiration Date") that is the last day of the one hundred twenty-eighth (128th) complete calendar month after the Fourth Floor Term Commencement Date, subject to extension as provided herein.

4. Possession and Commencement Date.

4.1 The "Fourth Floor Term Commencement Date" shall be the date that is two (2) days after the Execution Date, and delivery of possession of the Fourth Floor Premises. Tenant shall execute and deliver to Landlord written acknowledgment of the actual Fourth Floor Term Commencement Date and the Term Expiration Date within ten (10) days after Tenant takes occupancy of the Fourth Floor, in the form attached as Exhibit C hereto. Failure to execute and deliver such acknowledgment, however, shall not affect the Fourth Floor Term Commencement Date or Landlord's or Tenant's liability hereunder. Failure by Tenant to obtain validation by any medical review board or other similar governmental licensing of the Fourth Floor required for the Permitted Use by Tenant shall not serve to extend the Fourth Floor Term Commencement Date.

4.2 Tenant shall cause the work described in the Work Letter (the "Fourth Floor Tenant Improvements") to be constructed in the Fourth Floor Premises pursuant to the Work Letter attached hereto as Exhibit B (the "Work Letter") at a cost to Landlord not to exceed (a) Nine Million Four Hundred Five Thousand Three Hundred Sixty and 00/100 Dollars ($9,405,360.00) (based upon One Hundred Eighty Dollars ($180.00) per square foot of Rentable Area (as defined below)) (the "Fourth Floor TI Allowance") plus (b) Seven Hundred Eighty-Three Thousand Seven Hundred Eighty and 00/100 Dollars ($783,780.00) (based upon Fifteen and 00/100 Dollars ($15.00) per square foot of Rentable Area) (the "Fourth Floor Base Building Allowance"). The Fourth Floor TI Allowance may be applied to the costs of (m) construction, (n) actual out-of-pocket costs incurred in connection with project review by Landlord, (o) commissioning of mechanical, electrical/ and plumbing systems by a licensed, qualified commissioning agent hired by Tenant, and review of such party's commissioning report by a licensed, qualified commissioning agent hired by Landlord, (p) space planning, architect, engineering and other related services performed by third parties unaffiliated with Tenant, (q) building permits and other taxes, fees, charges and levies by Governmental Authorities (as defined below) for permits or for inspections of the Tenant Improvements, and (r) costs and expenses for labor, material, equipment and fixtures. The Fourth Floor Base Building Allowance may be applied to the same items as the foregoing sentence, except with respect to base building work, and may also be applied as

reimbursement for the cost of the Fourth Floor Tenant Improvements. In no event shall the Fourth Floor TI Allowance or the Fourth Floor Base Building Allowance be used for (u) the cost of work that is not authorized by the Approved Plans (as defined in the Work Letter) or otherwise approved in writing by Landlord, (v) payments to Tenant or any affiliates of Tenant, (w) the purchase of any furniture, personal property or other non-building system equipment, (x) costs arising from any default by Tenant of its obligations under this Lease (y) costs that are recoverable by Tenant from a third party (e.g., insurers, warrantors, or tortfeasors) or (z) costs related to the First Floor Tenant Improvements. In addition, Landlord shall provide an allowance to Tenant to be used solely for architectural and engineering costs related to the Fourth Floor Premises Tenant Improvements in an amount not to exceed Six Thousand Two Hundred Seventy and 24/100 Dollars ($6,270.24) (based upon 12/100 Dollars ($0.12) per square foot of Rentable Area) (the "Fourth Floor A/E Allowance"; together with the Fourth Floor TI Allowance and the Fourth Floor Base Building Allowance, the "Fourth Floor Allowance").

4.3 Tenant shall have until the date that is eighteen (18) months after the Fourth Floor Term Commencement Date (the "Fourth Floor TI Deadline"), to submit Fund Requests (as defined in the Work Letter) to Landlord for disbursement of the unused portion of the Fourth Floor Allowance, after which date Landlord's obligation to fund any such costs for which Tenant has not submitted a Fund Request to Landlord shall expire.

4.4 The "First Floor Term Commencement Date" shall be the date that Landlord delivers to Tenant vacant possession of the First Floor Premises. Tenant shall be responsible for physically demising the First Floor Premises, demising the mechanical, electrical and plumbing systems and installing submeters as part of the First Floor Tenant Improvements (as defined below). Tenant shall execute and deliver to Landlord written acknowledgment of the actual First Floor Term Commencement Date within ten (10) days after Tenant takes occupancy of the First Floor Premises, in the form attached as Exhibit D hereto. Failure to execute and deliver such acknowledgment, however, shall not affect the First Floor Term Commencement Date or Landlord's or Tenant's liability hereunder. Failure by Tenant to obtain validation by any medical review board or other similar governmental licensing of the First Floor Premises required for the Permitted Use by Tenant shall not serve to extend the First Floor Term Commencement Date. Notwithstanding anything to the contrary set forth herein, in the event the City of Cambridge fails to issue a building permit to Tenant for the First Floor Tenant Improvements due to the insufficient size of the retail space in the adjacent suite in the Building, Landlord agrees to reduce the First Floor Premises by an amount sufficient to satisfy the City of Cambridge's retail requirements for the Building (but in no event shall the First Floor Premises be decreased by more than 5,214 Rentable Square Feet), and the parties shall cooperate to execute a Lease amendment removing such area from the First Floor Premises.

4.5 Tenant shall cause the work described in the Work Letter (the "First Floor Tenant Improvements") to be constructed in the First Floor Premises pursuant to the Work Letter at a cost to Landlord not to exceed One Million Six Hundred Forty One Thousand Three Hundred Fifty Dollars ($1,641,350.00) (based upon Eighty-Five Dollars ($85.00) per square foot of Rentable Area (as defined below)) (the "First Floor TI Allowance"). The First Floor TI Allowance may be applied to the costs of (m) construction, including demising the Premises and submetering, (n) actual out-of-pocket costs incurred in connection with project review by Landlord, (o) commissioning of mechanical, electrical/ and plumbing systems by a licensed, qualified

commissioning agent hired by Tenant, and review of such party's commissioning report by a licensed, qualified commissioning agent hired by Landlord, (p) space planning, architect, engineering and other related services performed by third parties unaffiliated with Tenant, (q) building permits and other taxes, fees, charges and levies by Governmental Authorities (as defined below) for permits or for inspections of the Tenant Improvements, and (r) costs and expenses for labor, material, equipment and fixtures. In no event shall the First Floor TI Allowance or the First Floor Base Building Allowance be used for (v) the cost of work that is not authorized by the Approved Plans (as defined in the Work Letter) or otherwise approved in writing by Landlord, (w) payments to Tenant or any affiliates of Tenant, (x) the purchase of any furniture, personal property or other non-building system equipment, (y) costs arising from any default by Tenant of its obligations under this Lease or (z) costs that are recoverable by Tenant from a third party (e.g., insurers, warrantors, or tortfeasors). Notwithstanding anything to the contrary set forth herein, Tenant may elect to use up to forty percent (40%) of the First Floor TI Allowance to fund the Fourth Floor Tenant Improvements; provided however, that Tenant shall submit separate Fund Requests for costs related to the Fourth Floor Tenant Improvements so that such costs are separately accounted for. In addition, Landlord shall provide an allowance to Tenant to be used solely for architectural and engineering costs related to the Fourth Floor Tenant Improvements in an amount not to exceed Two Thousand Three Hundred Seventeen and 20/100 Dollars ($2,317.20) (based upon 12/100 Dollars ($0.12) per square foot of Rentable Area) (the "First Floor A/E Allowance"; together with the First Floor TI Allowance, the "First Floor Allowance").

4.6 Tenant shall have until the date that is twenty-four (24) months after the First Floor Term Commencement Date (the "First Floor TI Deadline"), to submit Fund Requests to Landlord for disbursement of the unused portion of the First Floor Allowance, after which date Landlord's obligation to fund any such costs for which Tenant has not submitted a Fund Request to Landlord shall expire.

4.7 In no event shall any unused Fourth Floor Allowance or First Floor Allowance entitle Tenant to a credit against Rent payable under this Lease. Tenant shall deliver to Landlord (a) a certificate of occupancy (or its substantial equivalent) for each of the Fourth Floor Premises and First Floor Premises suitable for the Permitted Use and (b) a Certificate of Substantial Completion in the form of the American Institute of Architects document G704, executed by the project architect and the general contractor, upon completion of each of the Fourth Floor Premises and First Floor Premises.

4.8 Prior to entering upon the Premises or any portion thereof, Tenant shall furnish to Landlord evidence satisfactory to Landlord that insurance coverages required of Tenant under the provisions of Article 23 are in effect, and such entry shall be subject to all the terms and conditions of this Lease other than the payment of Base Rent or Tenant's Adjusted Share of Operating Expenses (as defined below).

4.9 Landlord and Tenant shall mutually agree upon the selection of the architect, engineer, general contractor and major subcontractors, and Landlord and Tenant shall each participate in the review of the competitive bid process; provided that Landlord hereby pre- approves of The Richmond Group for the Tenant Improvements and/or Tenant's base building work, and provided further that Landlord's approval of any such party proposed by Tenant shall not be unreasonably withheld, conditioned, or delayed. Landlord may refuse to approve any

architects, consultants, contractors, subcontractors or material suppliers that Landlord reasonably believes could cause labor disharmony or may not have sufficient experience, in Landlord's reasonable opinion, to perform work in an occupied Class "A" laboratory research building and in tenant-occupied lab areas.

4.10 Notwithstanding anything to the contrary in this Lease, Landlord and Tenant agree that all Tenant Improvements shall be programmed generally in accordance with the lab and office zones identified on Exhibit A-2 attached hereto.

5. Condition of Premises. Landlord represents to Tenant that, on the Term Commencement Date, all base building systems within the Premises (or the applicable portion thereof), including the HVAC (as hereinafter defined), electrical, life safety and plumbing systems, shall be in good working order (provided that the sole remedy for any breach of the foregoing representation shall be that Landlord shall promptly repair or remedy the violation of the foregoing representation at its sole cost, provided that Landlord may include the costs thereof in Operating Expenses to the extent that Landlord is permitted to do so under Article 9 below, and Tenant shall not be entitled to any monetary damages for any breach of such representation). Except as set forth in the immediately foregoing sentence, Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the Premises, the Building or the Project, or with respect to the suitability of the Premises, the Building or the Project for the conduct of Tenant's business. Subject to the foregoing, and without in any way derogating from Landlord's ongoing maintenance, repair and restoration obligations set forth elsewhere in this Lease, Tenant acknowledges that (a) it is fully familiar with the condition of the Premises and agrees to take the same in its condition "as is" as of the Execution Date and (b) Landlord shall have no obligation to alter, repair or otherwise prepare the Premises for Tenant's occupancy or to pay for or construct any improvements to the Premises, except with respect to payment of the TI Allowance and the Base Building Allowance. Tenant's taking of possession of the Premises shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the Premises, the Building and the Project were at such time in good, sanitary and satisfactory condition and repair.

6. Rentable Area.

6.1 The term "Rentable Area" shall reflect such areas as reasonably calculated by Landlord's architect in a manner consistent with Landlord's determination of Rentable Area for the remainder of the Building and Project, as the same may be reasonably adjusted from time to time by Landlord in consultation with Landlord's architect only to reflect a physical change to the outer walls, roof or basement of the Building, a physical change to those areas of the Building not utilized as usable area, including that portion of the Building devoted to corridors, equipment rooms, restrooms, elevator lobby, atrium and mailroom, or a physical change to the demising walls of the Premises.

6.2 The Rentable Area of the Building is generally determined by making separate calculations of Rentable Area applicable to each floor within the Building and totaling the Rentable Area of all floors within the Building. The Rentable Area of a floor is computed by measuring to the outside finished surface of the permanent outer Building walls. The full area calculated as previously set forth is included as Rentable Area, without deduction for columns and projections or vertical penetrations, including stairs, elevator shafts, flues, pipe shafts, vertical ducts and the like, as well as such items' enclosing walls.

6.3 The term "Rentable Area," when applied to the Premises, is that area equal to the usable area of the Premises, plus an equitable allocation of Rentable Area within the Building that is not then utilized or expected to be utilized as usable area, including that portion of the Building devoted to corridors, equipment rooms, restrooms, elevator lobby, atrium and mailroom.

7. Rent.

7.1 Tenant shall pay to Landlord as Fourth Floor Base Rent, commencing on the date that is eight (8) months after the Fourth Floor Term Commencement Date (the "Fourth Floor Rent Commencement Date"), the sums set forth in Section 2.3, subject to the rental adjustments provided in Article 8 hereof. Tenant shall pay to Landlord as First Floor Base Rent, commencing on the date that is the earlier of (a) the issuance of a certificate of occupancy (or its equivalent) for the First Floor Premises, or (b) six (6) months after the First Floor Term Commencement Date (the "First Floor Rent Commencement Date"), the sums set forth in Section 2.4, subject to the rental adjustments provided in Article 8 hereof. Base Rent shall be paid in equal monthly installments as set forth in Sections 2.3 and 2.4, subject to the rental adjustments provided in Article 8 hereof, each in advance on the first day of each and every calendar month during the Term.

7.2 In addition to Base Rent, Tenant shall pay to Landlord as additional rent ("Additional Rent") commencing on the Fourth Floor Rent Commencement Date and the First Floor Rent Commencement Date with respect to the Fourth Floor Premises and the First Floor Premises, respectively, (a) Tenant's Adjusted Share (as defined below) of Operating Expenses (as defined below), (b) the Property Management Fee (as defined below), and (c) any other amounts that Tenant assumes or agrees to pay under the provisions of this Lease that are owed to Landlord, including any and all other sums that may become due by reason of any default of Tenant or failure on Tenant's part to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after notice and the lapse of any applicable cure periods.

7.3 Base Rent and Additional Rent shall together be denominated "Rent." Rent shall be paid to Landlord, without abatement, deduction or offset, in lawful money of the United States of America to the address set forth in Section 2.8 or to such other person or at such other place as Landlord may from time designate in writing. In the event the Term commences or ends on a day other than the first day of a calendar month, then the Rent for such fraction of a month shall be prorated for such period on the basis of the number of days in the month and shall be paid at the then-current rate for such fractional month.

7.4 Tenant's obligation to pay Rent shall not be discharged or otherwise affected by (a) any Applicable Laws now or hereafter applicable to the Premises, (b) any other restriction on Tenant's use, (c) except as expressly provided herein, any casualty or taking or (d) any other occurrence; and Tenant waives all rights now or hereafter existing to terminate or cancel this Lease or quit or surrender the Premises or any part thereof, or to assert any defense in the nature of constructive eviction to any action seeking to recover rent. Tenant's obligation to pay Rent with respect to any period or obligations arising, existing or pertaining to the period prior to the date of the expiration or earlier termination of the Term or this Lease shall survive any such expiration or

earlier termination; provided, however, that nothing in this sentence shall in any way affect Tenant's obligations with respect to any other period. Subject to the provisions of this Lease, Tenant shall have the right to injunctive relief or to seek judgements for direct money damages occasioned by Landlord's breach of its Lease covenants beyond notice and applicable cure periods (but may not set-off any such judgement against Rent or other amount owing hereunder). Nothing in this Section 7.4 shall limit the exercise of Tenant's express remedies on the terms and conditions set forth in Section 16.2 below.

8. Rent Adjustments. Each of the Fourth Floor Base Rent and the First Floor Base Rent shall be subject to an annual upward adjustment of three percent (3%) of the then-current applicable Base Rent. The first such adjustment shall become effective commencing on (a) the first (1st) annual anniversary of the Fourth Floor Rent Commencement Date with respect to the Fourth Floor Premises, and (b) the first (1st) anniversary of the First Floor Rent Commencement Date with respect to the First Floor Premises. Subsequent adjustments shall become effective on every successive annual anniversary for each of the Fourth Floor Premises and the First Floor Premises, respectively, for so long as this Lease continues in effect, including during any extension of the Term.

9. Operating Expenses.

9.1 As used herein, the term "Operating Expenses" shall include:

(a) Government impositions, including property tax costs consisting of real and personal property taxes (including amounts due under any improvement bond upon the Building or the Project (including the parcel or parcels of real property upon which the Building, the other buildings in the Project and areas serving the Building and the Project are located)) or assessments in lieu thereof imposed by any federal, state, regional, local or municipal governmental authority, agency or subdivision (each, a "Governmental Authority"); taxes on or measured by gross rentals received from the rental of space in the Project; taxes based on the square footage of the Premises, the Building or the Project, as well as any parking charges, utilities surcharges or any other costs levied, assessed or imposed by, or at the direction of, or arising from Applicable Laws or interpretations thereof, promulgated by any Governmental Authority in connection with the use or occupancy of the Project or the parking facilities serving the Project; taxes on this transaction or any document to which Tenant is a party creating or transferring an interest in the Premises; any fee for a business license to operate an office building; and any expenses, including the reasonable cost of attorneys or experts, reasonably incurred by Landlord in seeking reduction by the taxing authority of the applicable taxes, less tax refunds obtained as a result of an application for review thereof; and

(b) All other costs of any kind paid or incurred by Landlord in connection with the operation or maintenance of the Building and the Project, which shall include costs of repairs and replacements to improvements within the Project as appropriate to maintain the Project as required hereunder; costs of utilities furnished to the Common Area; sewer fees; cable television; trash collection; cleaning, including windows; heating, ventilation and air-conditioning ("HVAC"); maintenance of landscaping and grounds; snow removal; maintenance of drives and parking areas; maintenance of the roof; security services and devices; building supplies; maintenance or replacement of equipment utilized for operation and maintenance of the Project;

license, permit and inspection fees; sales, use and excise taxes on goods and services purchased by Landlord in connection with the operation, maintenance or repair of the Building or Project systems and equipment; telephone, postage, stationery supplies and other expenses incurred in connection with the operation, maintenance or repair of the Project; accounting, legal and other professional fees and expenses incurred in connection with the Project; costs of furniture, draperies, carpeting, landscaping supplies, snow removal and other customary and ordinary items of personal property provided by Landlord for use in the Common Area or the Project office; capital expenditures but only to the extent permitted by Section 9.1(c) below; costs of complying with Applicable Laws (except to the extent such costs are incurred to remedy non-compliance as of the Execution Date with Applicable Laws); costs to keep the Project in compliance with, or costs or fees otherwise required under or incurred pursuant to any Property Operations Documents (as defined below), including condominium fees; insurance premiums, including premiums for commercial general liability, property casualty, earthquake, terrorism and environmental coverages; portions of insured losses paid by Landlord as part of the deductible portion of a loss pursuant to the terms of insurance policies; service contracts; costs of services of independent contractors retained to do work of a nature referenced above; and costs of compensation (including employment taxes and fringe benefits) of all persons who perform regular and recurring duties connected with the day-to-day operation and maintenance of the Project, its equipment, the adjacent walks, landscaped areas, drives and parking areas, including janitors, floor waxers, window washers, watchmen, gardeners, sweepers, plow truck drivers, handymen, and engineering/maintenance/facilities personnel.

(c) Notwithstanding the foregoing, Operating Expenses shall not include any net income, franchise, capital stock, estate or inheritance taxes, or taxes that are the personal obligation of Tenant or of another tenant of the Project; any leasing commissions; expenses (including attorney fees and court costs) incurred in connection with (i) negotiations or disputes with tenants of the Property or other occupants or prospective tenants or other occupants, (ii) the enforcement of any leases or (iii) the defense of Landlord's title to, or interest in, the Building or any part thereof; costs (including permit, license, and inspection fees) incurred in connection with preparing rental space for a tenant, that relate to preparation of rental space for a tenant; expenses of initial development and construction, including grading, paving, landscaping and decorating (as distinguished from maintenance, repair and replacement of the foregoing); Landlord's costs of any services provided to tenants or other occupants for which Landlord is actually reimbursed by such tenants or other occupants (other than reimbursement through Operating Expenses) as an additional charge or rental over and above the basic rent (and escalations thereof) payable under the lease with such tenant or other occupant; costs in connection with services that are provided to another tenant or occupant of the Building, but are not offered to Tenant; capital expenditures, except for those incurred (i) in replacing obsolete equipment, (ii) for the primary purpose of reducing Operating Expenses, or (iii) required to comply with changes in Applicable Laws that take effect after the Execution Date of the Lease, in each case amortized over the useful life thereof (but in no event more than ten (10) years), as reasonably determined by Landlord; costs (i.e., interest and penalties) incurred due to Landlord's default of this Lease or any other lease, mortgage, or other agreement, in each case affecting the Building or Property; payments to subsidiaries or affiliates of Landlord, or to any other party, in each case as a result of a non-arm's length transaction, for management or other services for the Building, or for supplies or other materials for the Building, to the extent that such payments exceed arm's length competitive prices in the Cambridge, Massachusetts market for the services, supplies or materials provided;

Landlord's legal existence and general corporate overhead and general administrative expenses; legal expenses relating to other tenants; costs of repairs to the extent reimbursed by payment of insurance proceeds received by Landlord; advertising and promotional expenditures directly related to Landlord's efforts to lease space in the Building; the cost of repairs of other work occasioned by fire, windstorm or other insured casualty, to the extent Landlord actually receives proceeds of such insurance for such repairs or other work; debt service; interest upon loans to Landlord or secured by mortgage or deed of trust covering the Project or a portion thereof or any other debt of Landlord (provided that interest upon a government assessment or improvement bond payable in installments shall constitute an Operating Expense under Subsection 9.1(a)); rental payments under any ground lease; the cost of correcting defects in the construction of the Building, Building equipment, parking lot or other site improvements, but only to the extent such costs are covered by and actually reimbursed to Landlord under any applicable warranty or service contract held by Landlord; costs incurred directly and solely as a result of Landlord's gross negligence or willful misconduct; salaries of executive officers of Landlord; depreciation claimed by Landlord for tax purposes (provided that this exclusion of depreciation is not intended to delete from Operating Expenses actual costs of repairs and replacements and reasonable reserves in regard thereto that are provided for in Subsection 9.1(b)); taxes that are excluded from Operating Expenses by the last sentence of Subsection 9.1(a); costs or expenses incurred in connection with the financing or sale of the Project or any portion thereof; costs expressly excluded from Operating Expenses elsewhere in this Lease or that are charged to or paid by Tenant under other provisions of this Lease; professional fees and disbursements and other costs and expenses related to the ownership (as opposed to the use, occupancy, operation, maintenance or repair) of the Project; political and charitable contributions; and any item that, if included in Operating Expenses, would involve a double collection for such item by Landlord. To the extent that Tenant uses more than Tenant's Pro Rata Share of any item of Operating Expenses, Tenant shall pay Landlord for such excess in addition to Tenant's obligation to pay Tenant's Pro Rata Share of Operating Expenses (such excess, together with Tenant's Pro Rata Share, "Tenant's Adjusted Share").

9.2 Tenant shall pay to Landlord on the first day of each calendar month of the Term from and after the Fourth Floor Rent Commencement Date and the First Floor Rent Commencement Date (as applicable), as Additional Rent, (a) the Property Management Fee (as defined below) and (b) Landlord's estimate of Tenant's Adjusted Share of Operating Expenses with respect to the Building and the Project, as applicable, for such month.

(x) The "Property Management Fee" shall equal three percent (3%) of the Base Rent due from Tenant. Tenant shall pay the Property Management Fee in accordance with Section 9.2 with respect to the entire Term commencing on the Fourth Floor Rent Commencement Date and the First Floor Rent Commencement Date (as applicable), including any extensions thereof or any holdover periods, regardless of whether Tenant is obligated to pay Base Rent, Operating Expenses or any other Rent with respect to any such period or portion thereof.

(a) Within ninety (90) days after the conclusion of each calendar year (or such longer period as may be reasonably required by Landlord not to exceed one hundred eighty (180) days), Landlord shall furnish to Tenant a statement showing in reasonable detail the actual Operating Expenses, Tenant's Adjusted Share of Operating Expenses, and the cost of providing utilities to the Premises for the previous calendar year ("Landlord's Statement"). Any additional sum due from Tenant to Landlord shall be due and payable within thirty (30) days after receipt of

an invoice therefor. If the amounts paid by Tenant pursuant to this Section exceed Tenant's Adjusted Share of Operating Expenses for the previous calendar year, then Landlord shall credit the difference against the Rent next due and owing from Tenant; provided that, if the Lease term has expired, Landlord shall accompany Landlord's Statement with payment for the amount of such difference.

(b) Any amount due under this Section for any period that is less than a full month shall be prorated for such fractional month on the basis of the number of days in the month.

9.3 Landlord may, from time to time, modify Landlord's calculation and allocation procedures for Operating Expenses, so long as such modifications produce Dollar results substantially consistent with Landlord's then-current practice at the Project. Landlord or an affiliate(s) of Landlord currently own other property(ies) adjacent to the Project or its neighboring properties (collectively, "Neighboring Properties"). In connection with Landlord performing services for the Project pursuant to this Lease, similar services may be performed by the same vendor(s) for Neighboring Properties. In such a case, Landlord shall reasonably allocate to each Building and the Project the costs for such services based upon the ratio that the square footage of the Building or the Project (as applicable) bears to the total square footage of all of the Neighboring Properties or buildings within the Neighboring Properties for which the services are performed, unless the scope of the services performed for any building or property (including the Building and the Project) is disproportionately more or less than for others, in which case Landlord shall equitably allocate the costs based on the scope of the services being performed for each building or property (including the Building and the Project). Since the Project consists of multiple buildings, certain Operating Expenses may pertain to a particular building(s) and other Operating Expenses to the Project as a whole. Landlord reserves the right in its sole discretion to allocate any such costs applicable to any particular building within the Project to such building, and other such costs applicable to the Project to each building in the Project (including the Building), with the tenants in each building being responsible for paying their respective proportionate shares of their buildings to the extent required under their leases. Landlord shall allocate such costs to the buildings (including the Building) in a reasonable, non-discriminatory manner, and such allocation shall be binding on Tenant.

9.4 Landlord's annual statement shall be final and binding upon Tenant unless Tenant, within thirty (30) days after Tenant's receipt thereof, shall contest any item therein by giving written notice to Landlord, specifying each item contested and the reasons therefor; provided that Tenant shall in all events pay the amount specified in Landlord's annual statement, pending the results of the Independent Review and determination of the Accountant(s), as applicable and as each such term is defined below. If, during such thirty (30)-day period, Tenant reasonably and in good faith questions or contests the correctness of Landlord's statement of Tenant's Adjusted Share of Operating Expenses, Landlord shall provide Tenant with reasonable access to Landlord's books and records to the extent relevant to determination of Operating Expenses, and such information as Landlord reasonably determines to be responsive to Tenant's written inquiries. In the event that, after Tenant's review of such information, Landlord and Tenant cannot agree upon the amount of Tenant's Adjusted Share of Operating Expenses, then Tenant shall have the right to have an independent public accounting firm hired by Tenant on an hourly basis and not on a contingent-fee basis (at Tenant's sole cost and expense) and approved by Landlord (which approval Landlord shall not unreasonably withhold or delay) audit and review such of Landlord's

books and records for the year in question as directly relate to the determination of Operating Expenses for such year (the "Independent Review"), but not books and records of entities other than Landlord. Landlord shall make such books and records available at the location where Landlord maintains them in the ordinary course of its business. Landlord need not provide copies of any books or records. Tenant shall commence the Independent Review within thirty (30) days after the date Landlord has given Tenant access to Landlord's books and records for the Independent Review. Tenant shall complete the Independent Review and notify Landlord in writing of Tenant's specific objections to Landlord's calculation of Operating Expenses (including Tenant's accounting firm's written statement of the basis, nature and amount of each proposed adjustment) no later than sixty (60) days after Landlord has first given Tenant access to Landlord's books and records for the Independent Review. Landlord shall review the results of any such Independent Review. The parties shall endeavor to agree promptly and reasonably upon Operating Expenses taking into account the results of such Independent Review. If, as of the date that is sixty (60) days after Tenant has submitted the Independent Review to Landlord, the parties have not agreed on the appropriate adjustments to Operating Expenses, then the parties shall engage a mutually agreeable independent third party accountant with at least ten (10) years' experience in commercial real estate accounting in the Cambridge, Massachusetts area (the "Accountant"). If the parties cannot agree on the Accountant, each shall within ten (10) days after such impasse appoint an Accountant (different from the accountant and accounting firm that conducted the Independent Review) and, within ten (10) days after the appointment of both such Accountants, those two Accountants shall select a third (which cannot be the accountant and accounting firm that conducted the Independent Review). If either party fails to timely appoint an Accountant, then the Accountant the other party appoints shall be the sole Accountant. Within ten (10) days after appointment of the Accountant(s), Landlord and Tenant shall each simultaneously give the Accountants (with a copy to the other party) its determination of Operating Expenses, with such supporting data or information as each submitting party determines appropriate. Within ten (10) days after such submissions, the Accountants shall by majority vote select either Landlord's or Tenant's determination of Operating Expenses. The Accountants may not select or designate any other determination of Operating Expenses. The determination of the Accountant(s) shall bind the parties. If the parties agree or the Accountant(s) determine that the Operating Expenses actually paid by Tenant for the calendar year in question exceeded Tenant's obligations for such calendar year, then Landlord shall, at Tenant's option, either (a) credit the excess to the next succeeding installments of estimated Additional Rent or (b) pay the excess to Tenant within thirty (30) days after delivery of such results. If the parties agree or the Accountant(s) determine that Tenant's payments of Operating Expenses for such calendar year were less than Tenant's obligation for the calendar year, then Tenant shall pay the deficiency to Landlord within thirty (30) days after delivery of such results. If the Independent Review reveals or the Accountant(s) determine that the Operating Expenses billed to Tenant by Landlord and paid by Tenant to Landlord for the applicable calendar year in question exceeded by more than ten percent (10%) what Tenant should have been billed during such calendar year, then Landlord shall pay the reasonable cost of the Independent Review. In all other cases Tenant shall pay the cost of the Independent Review and the Accountant(s).

9.5 Tenant shall not be responsible for Operating Expenses with respect to any time period prior to the date which is eight (8) months after the Term Commencement Date; Tenant's responsibility for Tenant's Adjusted Share of Operating Expenses shall continue to the latest of (a) the date of termination of the Lease, (b) the date Tenant has fully vacated the Premises and (c) if termination of the Lease is due to a default by Tenant, the date of rental commencement of a replacement tenant.

9.6 Operating Expenses for the calendar year in which Tenant's obligation to share therein commences and for the calendar year in which such obligation ceases shall be prorated based on the actual number of days of such calendar year which occur prior to the ceasing of such obligation. Expenses such as taxes, assessments and insurance premiums that are incurred for an extended time period shall be prorated based upon the time periods to which they apply so that the amounts attributed to the Premises relate in a reasonable manner to the time period wherein Tenant has an obligation to share in Operating Expenses.

9.7 Within thirty (30) days after the end of each calendar year quarter (*i.e.* by April 30, July 30, October 30 and January 30) in which Tenant believes it is entitled to reimbursement from Landlord pursuant to the terms of this Lease, Tenant shall submit to Landlord an invoice, or, in the event an invoice is not available, an itemized list, of all costs and expenses that (a) Tenant has incurred (either internally or by employing third parties) during the prior month and (b) for which Tenant reasonably believes it is entitled to reimbursements from Landlord pursuant to the terms of this Lease or the Work Letter. Tenant's failure to send any submittal required by this Section 9.7 shall not be a default of Tenant hereunder nor shall it constitute a waiver of Tenant's right to seek reimbursement from Landlord, however, Tenant shall promptly respond to any written requests from Landlord requesting any such submittal, and to the extent Tenant is seeking any such reimbursement it shall provide the information required under this Section 9.7 in connection with any request for reimbursement.

9.8 In the event that the Building or Project is less than fully occupied during a calendar year, Tenant acknowledges that Landlord may extrapolate Operating Expenses that vary depending on the occupancy of the Building or Project, as applicable, to equal Landlord's reasonable estimate of what such Operating Expenses would have been had the Building or Project, as applicable, been ninety-five percent (95%) occupied during such calendar year; provided, however, that Landlord shall not recover more than one hundred percent (100%) of Operating Expenses.

10. Taxes on Tenant's Property.

10.1 Tenant shall pay prior to delinquency any and all taxes levied against (a) personal property and trade fixtures located at the Premises and (b) any gross or net receipts of or sales by Tenant.

10.2 If any such taxes on Tenant's personal property or trade fixtures are levied against Landlord or Landlord's property or, if the assessed valuation of the Building, the Property or the Project is increased by inclusion therein of a value attributable to Tenant's personal property or trade fixtures, and if Landlord, after written notice to Tenant, pays the taxes based upon any such increase in the assessed value of the Building, the Property or the Project, then Tenant shall, upon demand, repay to Landlord the taxes so paid by Landlord.

10.3 If any improvements in or alterations to the Premises, made or requested by Tenant, whether owned by Landlord or Tenant and whether or not affixed to the real property so as to become a part thereof, are assessed for real property tax purposes at a valuation higher than the valuation at which improvements conforming to Landlord's building standards (the "Building Standard") in other spaces in the Building are assessed, then the real property taxes and assessments levied against Landlord or the Building, the Property or the Project by reason of such excess assessed valuation shall be deemed to be taxes levied against personal property of Tenant and shall be governed by the provisions of Section 10.2. Any such excess assessed valuation due to improvements in or alterations to space in the Project leased by other tenants at the Project shall not be included in Operating Expenses. If the records of the applicable governmental assessor's office are available and sufficiently detailed to serve as a basis for determining whether such Tenant improvements or alterations are assessed at a higher valuation than the Building Standard, then such records shall be binding on both Landlord and Tenant.

11. Security Deposit.

11.1 Tenant shall deposit with Landlord on or before the Execution Date the sum set forth in Section 2.8 (the "Security Deposit"), which sum shall be held by Landlord as security for the faithful performance by Tenant of all of the terms, covenants and conditions of this Lease to be kept and performed by Tenant during the Term and ending upon the expiration or termination of Tenant's obligations under this Lease. If Tenant Defaults (as defined below) with respect to any provision of this Lease, including any provision relating to the payment of Rent, then Landlord may (but shall not be required to) use, apply or retain all or any part of the Security Deposit for the payment of any Rent or any other sum in default, or to compensate Landlord for any other loss or damage that Landlord may suffer by reason of Tenant's default. If any portion of the Security Deposit is so used or applied, then Tenant shall, within ten (10) days following demand therefor, deposit cash with Landlord in an amount sufficient to restore the Security Deposit to its original amount, and Tenant's failure to do so shall be a material breach of this Lease. The provisions of this Article shall survive the expiration or earlier termination of this Lease.

11.2 In the event of bankruptcy or other debtor-creditor proceedings against Tenant, the Security Deposit shall be deemed to be applied first to the payment of Rent and other charges due Landlord for all periods prior to the filing of such proceedings.

11.3 Landlord may deliver to any purchaser of Landlord's interest in the Premises the funds deposited hereunder by Tenant, and thereupon Landlord shall be discharged from any further liability with respect to such deposit. This provision shall also apply to any subsequent transfers.

11.4 If Tenant shall fully and faithfully perform every provision of this Lease to be performed by it, then the Security Deposit, or any balance thereof, shall be returned to Tenant (or, at Landlord's option, to the last assignee of Tenant's interest hereunder) within thirty (30) days after the expiration or earlier termination of this Lease.

11.5 If the Security Deposit shall be in cash, Landlord shall hold the Security Deposit in an account at a banking organization selected by Landlord; provided, however, that Landlord shall not be required to maintain a separate account for the Security Deposit, but may intermingle it with other funds of Landlord. Landlord shall be entitled to all interest and/or dividends, if any, accruing on the Security Deposit. Landlord shall not be required to credit Tenant with any interest for any period during which Landlord does not receive interest on the Security Deposit.

11.6 The Security Deposit may be in the form of cash, a letter of credit or any other security instrument acceptable to Landlord in its sole discretion. Tenant may at any time, except when Tenant is in Default (as defined below), deliver a letter of credit (the "L/C Security") as the entire Security Deposit, as follows:

(a) If Tenant elects to deliver L/C Security, then Tenant shall provide Landlord, and maintain in full force and effect throughout the Term and until the date that is six (6) months after the then-current Term Expiration Date, a letter of credit in the form of Exhibit E issued by an issuer reasonably satisfactory to Landlord, in the amount of the Security Deposit, with an initial term of at least one year. Landlord may require the L/C Security to be re-issued by a different issuer at any time during the Term if Landlord reasonably believes that the issuing bank of the L/C Security is or may soon become insolvent; provided, however, Landlord shall return the existing L/C Security to the existing issuer immediately upon receipt of the substitute L/C Security. If any issuer of the L/C Security shall become insolvent or placed into FDIC receivership, then Tenant shall immediately deliver to Landlord (without the requirement of notice from Landlord) substitute L/C Security issued by an issuer reasonably satisfactory to Landlord, and otherwise conforming to the requirements set forth in this Article. As used herein with respect to the issuer of the L/C Security, "insolvent" shall mean the determination of insolvency as made by such issuer's primary bank regulator (*i.e.*, the state bank supervisor for state chartered banks; the OCC or OTS, respectively, for federally chartered banks or thrifts; or the Federal Reserve for its member banks). If, at the Term Expiration Date, any Rent remains uncalculated or unpaid, then (i) Landlord shall with reasonable diligence complete any necessary calculations, (ii) Tenant shall extend the expiry date of such L/C Security from time to time as Landlord reasonably requires and (iii) in such extended period, Landlord shall not unreasonably refuse to consent to an appropriate reduction of the L/C Security. Tenant shall reimburse Landlord's legal costs (as estimated by Landlord's counsel and not to exceed $3,000) in handling Landlord's acceptance of L/C Security or its replacement or extension.

(b) If Tenant delivers to Landlord satisfactory L/C Security in place of the entire Security Deposit, Landlord shall remit to Tenant any cash Security Deposit Landlord previously held.

(c) Landlord may draw upon the L/C Security, and hold and apply the proceeds in the same manner and for the same purposes as the Security Deposit, if (i) an uncured Default (as defined below) exists, (ii) as of the date that is forty-five (45) days before any L/C Security expires (even if such scheduled expiry date is after the Term Expiration Date) Tenant has not delivered to Landlord an amendment or replacement for such L/C Security, reasonably satisfactory to Landlord, extending the expiry date to the earlier of (1) six (6) months after the then-current Term Expiration Date or (2) the date that is one year after the then-current expiry date of the L/C Security, (iii) the L/C Security provides for automatic renewals, Landlord asks the issuer to confirm the current L/C Security expiry date, and the issuer fails to do so within ten (10) business days, (iv) Tenant fails to pay (when and as Landlord reasonably requires) any bank charges for Landlord's transfer of the L/C Security or (v) the issuer of the L/C Security ceases, or announces that it will cease, to maintain an office in the city where Landlord may present drafts under the L/C Security (and fails to permit drawing upon the L/C Security by overnight courier or facsimile). This Section does not limit any other provisions of this Lease allowing Landlord to draw the L/C Security under specified circumstances.

(d) Tenant shall not seek to enjoin, prevent, or otherwise interfere with Landlord's draw under L/C Security, even if it violates this Lease. Tenant acknowledges that the only effect of a wrongful draw would be to substitute a cash Security Deposit for L/C Security, causing Tenant no legally recognizable damage. Landlord shall hold the proceeds of any draw in the same manner and for the same purposes as a cash Security Deposit. In the event of a wrongful draw, the parties shall cooperate to allow Tenant to post replacement L/C Security simultaneously with the return to Tenant of the wrongfully drawn sums, and Landlord shall upon request confirm in writing to the issuer of the L/C Security that Landlord's draw was erroneous.

(e) If Landlord transfers its interest in the Premises, then Tenant shall at Tenant's expense, within five (5) business days after receiving a request from Landlord, deliver (and, if the issuer requires, Landlord shall consent to) an amendment to the L/C Security naming Landlord's grantee as substitute beneficiary. If the required Security Deposit changes while L/C Security is in force, then Tenant shall deliver (and, if the issuer requires, Landlord shall consent to) a corresponding amendment to the L/C Security.

12. Use.

12.1 Tenant shall use the Premises for the Permitted Use, and shall not use the Premises, or permit or suffer the Premises to be used, for any other purpose without Landlord's prior written consent, which consent Landlord may withhold in its sole and absolute discretion.

12.2 Tenant shall not use or occupy the Premises in violation of Applicable Laws; zoning ordinances; or the certificate of occupancy (or its substantial equivalent) issued for the Building or the Project, and shall, upon five (5) days' written notice from Landlord, discontinue any use of the Premises that is declared or claimed by any Governmental Authority having jurisdiction to be a violation of any of the above, or that in Landlord's reasonable opinion violates any of the above. Tenant shall comply with any direction of any Governmental Authority having jurisdiction that shall, by reason of the nature of Tenant's use or occupancy of the Premises, impose any duty upon Tenant or Landlord with respect to the Premises or with respect to the use or occupation thereof, and shall indemnify, defend (at Landlord's option and with counsel reasonably acceptable to Landlord) and hold harmless (collectively, "Indemnify," "Indemnity" or "Indemnification," as the case may require) Landlord and its affiliates, employees, agents and contractors; and any lender, mortgagee, ground lessor or beneficiary (each, a "Lender" and, collectively with Landlord and its affiliates, employees, agents and contractors, the "Landlord Indemnitees") harmless from and against any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages, suits or judgments, and all reasonable expenses (including reasonable attorneys' fees, charges and disbursements, regardless of whether the applicable demand, claim, action, cause of action or suit is voluntarily withdrawn or dismissed) incurred in investigating or resisting the same (collectively, "Claims") of any kind or nature that arise before, during or after the Term as a result of Tenant's breach of this Section.

12.3 Tenant shall not do or permit to be done anything that will invalidate or increase the cost of any fire, environmental, extended coverage or any other insurance policy covering the Building or the Project, and shall comply with all reasonable rules, orders, regulations and requirements of the insurers of the Building and the Project, and Tenant shall promptly, upon demand, reimburse Landlord for any additional premium charged for such policy by reason of Tenant's failure to comply with the provisions of this Article.

12.4 Tenant shall keep all doors opening onto public corridors closed, except when in use for ingress and egress.

12.5 No additional locks or bolts of any kind shall be placed upon any of the doors or windows by Tenant, nor shall any changes be made to existing locks or the mechanisms thereof without Landlord's prior written consent, which shall not be unreasonably withheld, conditioned, or delayed. Tenant shall, upon termination of this Lease, return to Landlord all keys to offices and restrooms either furnished to or otherwise procured by Tenant. In the event any key so furnished to Tenant is lost, Tenant shall pay to Landlord the cost of replacing the same or of changing the lock or locks opened by such lost key if Landlord shall deem it necessary to make such change.

12.6 No awnings or other projections shall be attached to any outside wall of the Building. No curtains, blinds, shades or screens shall be attached to or hung in, or used in connection with, any window or door of the Premises other than Landlord's standard window coverings. Neither the interior nor exterior of any windows shall be coated or otherwise sunscreened without Landlord's prior written consent, nor shall any bottles, parcels or other articles be placed on the windowsills or items attached to windows that are visible from outside the Premises. No equipment, furniture or other items of personal property shall be placed on any exterior balcony without Landlord's prior written consent.

12.7 No sign, advertisement or notice ("Signage") shall be exhibited, painted or affixed by Tenant on any part of the Premises or the Building without Landlord's prior written consent. Signage shall conform to Landlord's design criteria. For any Signage, Tenant shall, at Tenant's own cost and expense, (a) acquire all permits for such Signage in compliance with Applicable Laws and (b) design, fabricate, install and maintain such Signage in a first-class condition. Tenant shall be responsible for reimbursing Landlord for costs incurred by Landlord in removing any of Tenant's Signage upon the expiration or earlier termination of the Lease. Interior signs in the Building lobby and the directory tablet shall be inscribed, painted or affixed for Tenant by Landlord at Landlord's sole cost and expense, and shall be of a size, color and type and be located in a place acceptable to Landlord. The directory tablet shall be provided exclusively for the display of the name and location of tenants only. Tenant shall not place anything on the exterior of the corridor walls or corridor doors other than Landlord's standard lettering. Tenant, at Tenant's sole cost and expense, shall have Signage rights for the primary entrance to the Premises substantially consistent with the Signage permitted for comparable Tenants in the Project, as Landlord reasonably determines. At Landlord's option, Landlord may install any Tenant Signage, and Tenant shall pay all costs associated with such installation within thirty (30) days after demand therefor.

12.8 Tenant may only place equipment within the Premises with floor loading consistent with the Building's structural design unless Tenant obtains Landlord's prior written approval. Tenant may place such equipment only in a location designed to carry the weight of such equipment.

12.9 Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations therefrom from extending into the Common Area or other offices in the Project.

12.10 Tenant shall not (a) do or permit anything to be done in or about the Premises that shall in any way obstruct or interfere with the rights of other tenants or occupants of the Project, or injure or annoy them, (b) use or allow the Premises to be used for immoral, unlawful or objectionable purposes, (c) cause, maintain or permit any nuisance or waste in, on or about the Project or (d) take any other action that would in Landlord's reasonable determination in any manner adversely affect other tenants' quiet use and enjoyment of their space or adversely impact their ability to conduct business in a professional and suitable work environment. Notwithstanding anything in this Lease to the contrary, Tenant may not install any security systems (including cameras) outside the Premises or that record sounds or images outside the Premises without Landlord's prior written consent, which Landlord may withhold in its sole and absolute discretion.

12.11 Notwithstanding any other provision herein to the contrary, from and after the Term Commencement Date, Tenant shall be responsible for all liabilities, costs and expenses arising from or in connection with the compliance of the Premises with the Americans with Disabilities Act, 42 U.S.C. § 12101, et seq., and any state and local accessibility laws, codes, ordinances and rules (collectively, and together with regulations promulgated pursuant thereto, the "ADA") (except to the extent that any such noncompliance of the Premises with the ADA (as in effect and interpreted as of the Term Commencement Date) existed as of the Term Commencement Date), and Tenant shall Indemnify the Landlord Indemnitees from and against Claims arising out of Tenant's failure to comply with its obligations relating to the ADA under this Section. Landlord shall be responsible for all liabilities, costs and expenses arising out of or in connection with the compliance of the Common Areas with the ADA (which costs may be included in Operating Expenses to the extent permitted in Article 9 except to the extent that any such noncompliance of the Common Areas with the ADA (as in effect and interpreted as of the Term Commencement Date) existed as of the Term Commencement Date). This Section (as well as any other provisions of this Lease dealing with Indemnification of the Landlord Indemnitees by Tenant) shall be deemed to be modified in each case by the insertion in the appropriate place of the following: "except as otherwise provided in Mass. G.L. Ter. Ed., C. 186, Section 15." For the avoidance of doubt, "Lenders" shall also include historic tax credit investors and new market tax credit investors. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

12.12 Tenant shall maintain temperature and humidity in the Premises in accordance with ASHRAE standards at all times.

12.13 Tenant shall establish and maintain a chemical safety program administered by a licensed, qualified individual in accordance with the requirements of the Massachusetts Water Resources Authority ("MWRA") and any other applicable Governmental Authority. Tenant shall be solely responsible for all costs incurred in connection with such chemical safety program, and Tenant shall provide Landlord with such documentation as Landlord may reasonably require evidencing Tenant's compliance with the requirements of (a) the MWRA and any other applicable Governmental Authority with respect to such chemical safety program and (b) this Section. Tenant shall be required to obtain and maintain during the Term (m) any permit required by the MWRA

("MWRA Permit") and (n) a wastewater treatment operator license from the Commonwealth of Massachusetts with respect to Tenant's Acid Neutralization Tank (as defined below) in the Building. Tenant shall not introduce anything into the Acid Neutralization Tank (x) in violation of the terms of the MWRA Permit, (y) in violation of Applicable Laws or (z) that would interfere with the proper functioning of the Acid Neutralization Tank. Landlord agrees to reasonably cooperate with Tenant in order for Tenant to obtain the MWRA Permit and the wastewater treatment operator license, without any obligation for Landlord to incur any costs in connection therewith. Tenant shall reimburse Landlord within ten (10) business days after demand for any costs incurred by Landlord pursuant to this Section.

13. Rules and Regulations, CC&Rs, Parking Facilities and Common Area.

13.1 Tenant shall have the non-exclusive right, in common with others, to use the Common Area in conjunction with Tenant's use of the Premises for the Permitted Use, and such use of the Common Area and Tenant's use of the Premises shall be subject to the rules and regulations adopted by Landlord and attached hereto as Exhibit F, together with such other reasonable and nondiscriminatory rules and regulations as are hereafter reasonably promulgated by Landlord in its sole and absolute discretion (the "Rules and Regulations"). Tenant shall ensure that its contractors, subcontractors, employees, subtenants and invitees faithfully observe and comply with the Rules and Regulations. Landlord shall not be responsible to Tenant for the violation or non-performance by any other tenant or any agent, employee or invitee thereof of any of the Rules and Regulations.

13.2 This Lease is subject to any recorded covenants, conditions or restrictions on the Project or Property (including the Parking and Transportation Demand Management Plan Ordinance- Final Amendment Decision, issued on May 24, 2002, by the City of Cambridge (as the same may be amended from time to time, the "PTDM") , as the same may be amended, amended and restated, supplemented or otherwise modified from time to time (the "CC&Rs") and Tenant shall, at its sole cost and expense, comply with and cause the Project to comply with the CC&Rs and the documents listed on Exhibit G attached hereto (together with the PTDM, the "Property Operations Documents"). Tenant acknowledges that Tenant, at its sole cost and expense, shall comply with the tenant requirements in the PTDM, including the requirements set forth in the "Alternative Work Programs," "Public Transportation Incentives," "Ridesharing Programs" and "Provisions of Bicycle and Pedestrian Amenities" sections thereof. Tenant, at its sole cost and expense, shall also comply with the reporting requirements set forth in the PTDM at Landlord's request. Any costs incurred by Landlord in connection with the PTDM shall constitute an Operating Expense.

13.3 The Charles River Transportation Management Association (of which Landlord or an affiliate of Landlord is currently a member) provides certain programs to help improve transportation in the Cambridge area. Their website is www.charlesrivertma.org.

13.4 Tenant shall have a non-exclusive, irrevocable license to use (a) forty-seven (47) parking spaces with respect to the Fourth Floor Premises, and (b) eighteen (18) parking spaces with respect to the First Floor Premises, in the facilities serving the Building and the Project in common on an unreserved basis with other tenants of the Building and the Project during the Term at a cost of Three Hundred Forty and 00/100 Dollars ($340.00) per parking space per month

(subject to market rate adjustment by Landlord from time to time throughout the Term), which Tenant shall pay commencing on the respective Rent Commencement Date simultaneously with payments of Base Rent as Additional Rent. Tenant, at any time and from time to time during the Term, may elect to waive its right to use some or all or its parking spaces upon written notice to Landlord. If Tenant so elects, then it shall forfeit for the then-remainder of the Term (including any extension thereof) any and all rights to such waived parking spaces, and no amounts shall be due with respect to such waived parking spaces thereafter. Tenant shall have the right to rent additional parking spaces on a monthly basis, subject to availability.

13.5 Tenant agrees not to unreasonably overburden the parking facilities and agrees to cooperate with Landlord and other tenants in the use of the parking facilities, and Landlord hereby agrees that Tenant shall not be deemed to be overburdening the parking facilities if Tenant is using the number of spaces (or fewer) then allocated to Tenant and Tenant is otherwise complying with any rules and regulations concerning the parking facilities. Landlord reserves the right to determine that parking facilities are becoming overcrowded and to limit Tenant's use thereof. Upon such determination, Landlord may reasonably allocate parking spaces among Tenant and other tenants of the Building or the Project; provided, however, that Landlord shall not be permitted to reduce the number of parking spaces to which Tenant is then entitled to use under this Lease. Nothing in this Section, however, is intended to create an affirmative duty on Landlord's part to monitor parking.

13.6 Subject to the terms of this Lease including the Rules and Regulations and the rights of other tenants of the Building, Tenant shall have the non-exclusive right to access the freight loading dock and the freight elevator twenty-four (24) hours per day, seven (7) days per week, at no additional cost. Landlord shall not be responsible for any coordination of the use of the freight elevator or the loading dock by tenants at the Building. Landlord shall provide a dumpster and/or trash compactor at the loading dock for Tenant's use for the disposal of non-Hazardous Materials, and Tenant shall pay Tenant's Adjusted Share of the cost of said dumpster and/or trash compactor. Tenant shall be solely responsible for the disposal of any Hazardous Materials in accordance with Applicable Laws

14. Project Control by Landlord.

14.1 Landlord reserves full control over the Building and the Project to the extent not inconsistent with Tenant's enjoyment of the Premises as provided by this Lease. This reservation includes Landlord's right to subdivide the Project; convert the Building and the other buildings within the Project to condominium units; change the size of the Project by selling all or a portion of the Project or adding real property and any improvements thereon to the Project; grant easements and licenses to third parties; maintain or establish ownership of the Building separate from fee title to the Property; make additions to or reconstruct portions of the Building and the Project; install, use, maintain, repair, replace and relocate for service to the Premises and other parts of the Building or the Project pipes, ducts, conduits, wires and appurtenant fixtures, wherever located in the Premises, the Building or elsewhere at the Project; and alter or relocate any other Common Area or facility, including private drives, lobbies, entrances and landscaping; provided, however, that such rights shall be exercised in a way that does not materially adversely affect Tenant's beneficial use and occupancy of the Premises, including the Permitted Use and Tenant's access to the Premises. Tenant acknowledges that Landlord specifically reserves the right to allow

the exclusive use of corridors and restroom facilities located on specific floors to one or more tenants occupying such floors; provided, however, that Tenant shall not be deprived of the use of the corridors reasonably required to serve the Premises or of restroom facilities serving the floor upon which the Premises are located.

14.2 Possession of areas of the Premises necessary for utilities, services, safety and operation of the Building is reserved to Landlord.

14.3 Tenant shall, at Landlord's request, promptly execute such further documents as may be reasonably appropriate to assist Landlord in the performance of its obligations hereunder; provided that Tenant need not execute any document that creates additional liability for Tenant or that deprives Tenant of the quiet enjoyment and use of the Premises as provided for in this Lease.

14.4 Landlord may, at any and all reasonable times during non-business hours (or during business hours, if (a) with respect to Subsections 14.4(u) through 14.4(y), Tenant so requests, and (b) with respect to Subsection 14.4(z), if Landlord so requests), and upon twenty-four (24) hours' prior notice (which may be oral or by email to the office manager or other Tenant-designated individual at the Premises; but provided that no time restrictions shall apply or advance notice be required if an emergency necessitates immediate entry), enter the Premises to (u) inspect the same and to determine whether Tenant is in compliance with its obligations hereunder, (v) supply any service Landlord is required to provide hereunder, (w) alter, improve or repair any portion of the Building other than the Premises for which access to the Premises is reasonably necessary, (x) post notices of nonresponsibility, (y) access the telephone equipment, electrical substation and fire risers and (z) show the Premises to prospective tenants during the final year of the Term and current and prospective purchasers and lenders at any time. In connection with any such alteration, improvement or repair as described in Subsection 14.4(w), Landlord may erect in the Premises or elsewhere in the Project scaffolding and other structures reasonably required for the alteration, improvement or repair work to be performed. In no event shall Tenant's Rent abate as a result of Landlord's activities pursuant to this Section; provided, however, that all such activities shall be conducted in such a manner so as to cause as little interference to Tenant as is reasonably possible. Landlord shall at all times retain a key with which to unlock all of the doors in the Premises. If an emergency necessitates immediate access to the Premises, Landlord may use whatever force is necessary to enter the Premises, and any such entry to the Premises shall not constitute a forcible or unlawful entry to the Premises, a detainer of the Premises, or an eviction of Tenant from the Premises or any portion thereof.

15. Quiet Enjoyment. Landlord covenants that Tenant, so long as no Default (as hereinafter defined) has occurred and is continuing under this Lease, may peacefully and quietly have, hold and enjoy the Premises, free from any claim by Landlord or persons claiming under Landlord, but subject to all of the terms and provisions hereof, provisions of Applicable Laws and rights of record to which this Lease is or may become subordinate. This covenant is in lieu of any other quiet enjoyment covenant, either express or implied.

16. Utilities and Services.

16.1 Tenant shall pay for all water (including the cost to service, repair and replace reverse osmosis, de-ionized and other treated water), gas, heat, light, power, telephone, internet service, cable television, other telecommunications and other utilities supplied to the Premises, together with any fees, surcharges and taxes thereon commencing on the applicable Term Commencement Date. If any such utility is not separately metered or sub-metered to Tenant, Tenant shall pay Tenant's Adjusted Share of all charges of such utility jointly metered with other premises as part of Tenant's Adjusted Share of Operating Expenses or, in the alternative, Landlord may, at its option, monitor the usage of such utilities by Tenant and charge Tenant with the cost of purchasing, installing and monitoring such metering equipment, which cost shall be paid by Tenant as Additional Rent. Landlord may base its bills for utilities on reasonable estimates; provided that Landlord adjusts such billings promptly thereafter or as part of the next Landlord's Statement to reflect the actual cost of providing utilities to the Premises. To the extent that Tenant uses more than Tenant's Pro Rata Share of any utilities, then Tenant shall pay Landlord for Tenant's Adjusted Share of such utilities to reflect such excess. In the event that the Building or Project is less than fully occupied during a calendar year, Tenant acknowledges that Landlord may extrapolate utility usage that varies depending on the occupancy of the Building or Project (as applicable) to equal Landlord's reasonable estimate of what such utility usage would have been had the Building or Project, as applicable, been ninety-five percent (95%) occupied during such calendar year; provided, however, that Landlord shall not recover more than one hundred percent (100%) of the cost of such utilities. Tenant shall not be liable for the cost of utilities supplied to the Premises attributable to the time period prior to the Term Commencement Date; provided, however, that, if Landlord shall permit Tenant possession of the Premises prior to the Term Commencement Date and Tenant uses the Premises for any purpose other than placement of personal property as set forth in Section 4.3, then Tenant shall be responsible for the cost of utilities supplied to the Premises from such earlier date of possession.

16.2 Landlord shall not be liable for, nor shall any eviction of Tenant result from, the failure to furnish any utility or service, whether or not such failure is caused by accidents; breakage; casualties (to the extent not caused by the party claiming Force Majeure); Severe Weather Conditions (as defined below); physical natural disasters (but excluding weather conditions that are not Severe Weather Conditions); strikes, lockouts or other labor disturbances or labor disputes (other than labor disturbances and labor disputes resulting solely from the acts or omissions of the party claiming Force Majeure); acts of terrorism; riots or civil disturbances; wars or insurrections; shortages of materials (which shortages are not unique to the party claiming Force Majeure); government regulations, moratoria or other governmental actions, inactions or delays; failures to grant consent or delays in granting consent by any Lender whose consent is required under any applicable Loan Document failures by third parties to deliver gas, oil or another suitable fuel supply, or inability of the party claiming Force Majeure, by exercise of reasonable diligence, to obtain gas, oil or another suitable fuel; or other causes beyond the reasonable control of the party claiming that Force Majeure has occurred (collectively, "Force Majeure"); or, to the extent permitted by Applicable Laws, Landlord's negligence. In the event of such failure, Tenant shall not be entitled to termination of this Lease or any abatement or reduction of Rent, nor shall Tenant be relieved from the operation of any covenant or agreement of this Lease. "Severe Weather Conditions" means weather conditions that are materially worse than those that reasonably would be anticipated for the Property at the applicable time based on historic meteorological records. Notwithstanding anything to the contrary in this Lease, if, for more than five (5) consecutive business days following written notice to Landlord and as a direct result of Landlord's gross negligence or willful misconduct (and except to the extent that such failure is caused in whole or in part by the action or inaction of a Tenant Party (as defined below)), the provision of HVAC or

other utilities to all or a material portion of the Premises that Landlord must provide pursuant to this Lease is interrupted (a "Material Services Failure"), then Tenant's Base Rent and Tenant's Adjusted Share of Operating Expenses (or, to the extent that less than all of the Premises are affected, a proportionate amount (based on the Rentable Area of the Premises that is rendered unusable) of Base Rent and Tenant's Adjusted Share of Operating Expenses) shall thereafter be abated until the Premises are again usable by Tenant for the Permitted Use; provided, however, that, if Landlord is diligently pursuing the restoration of such HVAC and other utilities and Landlord provides substitute HVAC and other utilities reasonably suitable for Tenant's continued use and occupancy of the Premises for the Permitted Use (e.g., supplying potable water or portable air conditioning equipment), then neither Base Rent nor Operating Expenses shall be abated. During any Material Services Failure, Tenant will cooperate with Landlord to arrange for the provision of any interrupted utility services on an interim basis via temporary measures until final corrective measures can be accomplished, and Tenant will permit Landlord the necessary access to the Premises to remedy such Material Service Failure. In the event of any interruption of HVAC or other utilities that Landlord must provide pursuant to this Lease, regardless of the cause, Landlord shall diligently pursue the restoration of such HVAC and other utilities. Notwithstanding anything in this Lease to the contrary, but subject to Article 24 (which shall govern in the event of a casualty), the provisions of this Section shall be Tenant's sole recourse and remedy in the event of an interruption of HVAC or other utilities to the Premises, including related to Section 16.8.

16.3 Tenant shall pay for, prior to delinquency of payment therefor, any utilities and services that may be furnished to the Premises during or, if Tenant occupies the Premises after the expiration or earlier termination of the Term, after the Term, beyond those utilities provided by Landlord, including telephone, internet service, cable television and other telecommunications, together with any fees, surcharges and taxes thereon. Upon Landlord's demand, utilities and services provided to the Premises that are separately metered shall be paid by Tenant directly to the supplier of such utilities or services.

16.4 Tenant shall not, without Landlord's prior written consent, use any device in the Premises (including data processing machines) that will in any way (a) increase the amount of ventilation, air exchange, gas, steam, electricity or water required or consumed in the Premises based upon Tenant's Pro Rata Share of the Building or Project (as applicable) beyond the existing capacity of the Building or the Project usually furnished or supplied for the Permitted Use or (b) exceed Tenant's Pro Rata Share of the Building's or Project's (as applicable) capacity to provide such utilities or services. Notwithstanding anything to the contrary set forth herein, Tenant shall have the right to use Air Handling Unit 4-1, Air Handling Unit 4-2, and Air Handling Unit 4-5, each exclusively serving the Premises, and Tenant shall not exceed the capacity of the aforementioned air handling units.

16.5 If Tenant shall require utilities or services in excess of those usually furnished or supplied for tenants in similar spaces in the Building or the Project by reason of Tenant's equipment or extended hours of business operations, then Tenant shall first procure Landlord's consent for the use thereof, which consent Landlord may condition upon the availability of such excess utilities or services, and Tenant shall pay as Additional Rent an amount equal to the cost of providing such excess utilities and services.

16.6 Landlord shall provide water in the Common Area for lavatory and landscaping purposes only, which water shall be from the local municipal or similar source; provided, however, that if Landlord determines that Tenant requires, uses or consumes water provided to the Common Area for any purpose other than ordinary lavatory purposes, Landlord may install a water meter ("Tenant Water Meter") and thereby measure Tenant's water consumption for all purposes. Tenant shall pay Landlord for the costs of any Tenant Water Meter and the installation and maintenance thereof during the Term. If Landlord installs a Tenant Water Meter, Tenant shall pay for water consumed by Tenant, as shown on such meter, as and when bills are rendered. If Tenant fails to timely make such payments, Landlord may pay such charges and collect the same from Tenant. Any such costs or expenses incurred or payments made by Landlord for any of the reasons or purposes stated in this Section shall be deemed to be Additional Rent payable by Tenant and collectible by Landlord as such.

16.7 Landlord reserves the right to stop service of the elevator, plumbing, ventilation, air conditioning and utility systems, when Landlord reasonably deems necessary or desirable, due to accident, emergency or the need to make repairs, alterations or improvements, until such repairs, alterations or improvements shall have been completed, and, except as provided in Section 16.2, Landlord shall further have no responsibility or liability for failure to supply elevator facilities, plumbing, ventilation, air conditioning or utility service when prevented from doing so by Force Majeure or, to the extent permitted by Applicable Laws, Landlord's negligence. Without limiting the foregoing, it is expressly understood and agreed that any covenants on Landlord's part to furnish any service pursuant to any of the terms, covenants, conditions, provisions or agreements of this Lease, or to perform any act or thing for the benefit of Tenant, shall not be deemed breached if Landlord is unable to furnish or perform the same by virtue of Force Majeure or, to the extent permitted by Applicable Laws, Landlord's negligence.

16.8 For the Premises, Landlord shall (a) maintain and operate the HVAC systems (not including supplemental units installed by Tenant) used for the Permitted Use only ("Base HVAC") and (b) furnish HVAC as reasonably required (except as this Lease otherwise provides or as to any special requirements that arise from Tenant's particular use of the Premises) for reasonably comfortable occupancy of the Premises twenty-four (24) hours a day, every day during the Term, subject to casualty, eminent domain or as otherwise specified in this Article. Notwithstanding anything to the contrary in this Section, Landlord shall have no liability, and Tenant shall have no right or remedy, on account of any interruption or impairment in HVAC services except as provided in Section 16.2.

16.9 For any utilities serving the Premises for which Tenant is billed directly by such utility provider, Tenant agrees to furnish to Landlord (a) any invoices or statements for such utilities within thirty (30) days after Tenant's receipt thereof, (b) within thirty (30) days after Landlord's request, any other utility usage information reasonably requested by Landlord, and (c) within thirty (30) days after each calendar year during the Term, authorization to allow Landlord to access Tenant's usage information necessary for Landlord to complete an ENERGY STAR® Statement of Performance (or similar comprehensive utility usage report (e.g., related to Labs 21), if requested by Landlord) and any other information in Tenant's possession reasonably requested by Landlord for the immediately preceding year; and Tenant shall comply with any other energy usage or consumption requirements required by Applicable Laws. Tenant shall retain records of utility usage at the Premises, including invoices and statements from the utility provider, for at

least sixty (60) months, or such other period of time as may be requested by Landlord. Tenant acknowledges that any utility information for the Premises, the Building and the Project may be shared with third parties, including Landlord's consultants and Governmental Authorities. In the event that Tenant fails to comply with this Section, Tenant hereby authorizes Landlord to collect utility usage information directly from the applicable utility providers, and Tenant shall pay Landlord a fee of Five Hundred Dollars ($500) per month to collect such utility usage information. In addition to the foregoing, Tenant shall comply with all Applicable Laws related to the disclosure and tracking of energy consumption at the Premises. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

16.10 Tenant, at its sole cost and expense, and subject to the terms and provisions of Article 17 of this Lease, may install a separate acid neutralization tank (the "Acid Neutralization Tank") in the portion of the Premises located on the first floor of the Building, as shown on Exhibit A. In connection with the installation of the Acid Neutralization Tank, Tenant may connect to the Building's common laboratory waste sanitary sewer connection and to the municipal sewer line in the street adjacent to the Building. Tenant, at its sole cost and expense, shall be responsible for obtaining, and complying with at all times, the MWRA Permit and any other permits and approvals from Governmental Authorities necessary to install, use or operate the Acid Neutralization Tank, and Tenant may not operate the Acid Neutralization Tank without first having provided to Landlord, for Landlord's approval, copies of all such permits and approvals. Tenant shall be responsible for all costs, charges and expenses in connection with or arising out of the operation, use, maintenance, repair or refurbishment of the Acid Neutralization Tank, including all clean-up costs relating to the Acid Neutralization Tank. Tenant shall Indemnify the Landlord Indemnitees from and against any and all Claims, including (a) diminution in value of the Project or any portion thereof, (b) damages for the loss or restriction on use of rentable or usable space or of any amenity of the Project, (c) damages arising from any adverse impact on marketing of space in the Project or any portion thereof and (d) sums paid in settlement of Claims that arise during or after the Term as a result of Tenant's improper use of the Acid Neutralization Tank. This Indemnification by Tenant includes costs incurred in connection with any investigation of site conditions or any clean-up, remediation, removal or restoration required by any Governmental Authority arising from Tenant's use of the Acid Neutralization Tank.

16.11 Subject to each and every term and provision of this Lease (including reasonable closures for repairs or maintenance pursuant to the terms of this Lease), and subject to reasonable closures as the result of casualty, condemnation, emergencies or other circumstances beyond Landlord's control, Tenant shall have the right to access the Premises twenty-four (24) hours per day, seven (7) days per week.

17. Alterations.

17.1 Tenant shall make no alterations, additions or improvements in or to the Premises or engage in any construction, demolition, reconstruction, renovation or other work (whether major or minor) of any kind in, at or serving the Premises ("Alterations") without Landlord's prior written approval, which approval may be subject to the consent of one or more Lenders, if required under any applicable Loan Document, but which approval Landlord shall not otherwise unreasonably withhold; provided, however, that, in the event any proposed Alteration affects (a) any structural portions of the Building, including exterior walls, the roof, the foundation or slab, foundation or

slab systems (including barriers and subslab systems) or the core of the Building, (b) the exterior of the Building or (c) any Building systems, including elevator, plumbing, HVAC, electrical, security, life safety and power, then Landlord may withhold its approval in its sole and absolute discretion. Tenant shall, in making any Alterations, use only those architects, contractors, suppliers and mechanics of which Landlord has given prior written approval, which approval shall be in Landlord's reasonable discretion. In seeking Landlord's approval, Tenant shall provide Landlord, at least thirty (30) days in advance of the proposed construction, with plans, specifications, bid proposals, certified stamped engineering drawings and calculations by Tenant's engineer of record or architect of record (including connections to the Building's structural system, modifications to the Building's envelope, non-structural penetrations in slabs or walls, and modifications or tie-ins to life safety systems), work contracts, requests for laydown areas and such other information concerning the nature and cost of the Alterations as Landlord may reasonably request, provided that Tenant shall not commence any such Alterations that require Landlord's consent unless and until Tenant has received the written approval of Landlord and any and all Lenders whose consent is required under any applicable Loan Document. In no event shall Tenant use or Landlord be required to approve any architects, consultants, contractors, subcontractors or material suppliers that Landlord reasonably believes could cause labor disharmony or may not have sufficient experience, in Landlord's reasonable opinion, to perform work in an occupied Class "A" laboratory research building and in tenant-occupied lab areas. Notwithstanding the foregoing, Tenant may make strictly cosmetic changes to the Premises that do not require any permits or more than three (3) total contractors and subcontractors ("Cosmetic Alterations") without Landlord's consent; provided that (y) the cost of any Cosmetic Alterations does not exceed Eighty-Five Thousand Dollars ($85,000.00) in any one instance or Three Hundred Fifty Thousand Dollars ($350,000.00) annually, (z) such Cosmetic Alterations do not (i) require any structural or other substantial modifications to the Premises, (ii) require any changes to or adversely affect the Building systems, (iii) affect the exterior of the Building, or (iv) trigger any requirement under Applicable Laws that would require Landlord to make any alteration or improvement to the Premises, the Building or the Project. Tenant shall give Landlord at least fifteen (15) days' prior written notice of any Cosmetic Alterations. Notwithstanding anything in this Article 17 to the contrary, the installation of the Acid Neutralization Tank shall not be deemed a Cosmetic Alteration, irrespective of cost.

17.2 Tenant shall not construct or permit to be constructed partitions or other obstructions that might interfere with free access to mechanical installation or service facilities of the Building or with other tenants' components located within the Building, or interfere with the moving of Landlord's equipment to or from the enclosures containing such installations or facilities.

17.3 Tenant shall accomplish any work performed on the Premises or the Building in such a manner as to permit any life safety systems to remain fully operable at all times.

17.4 Any work performed on the Premises, the Building or the Project by Tenant or Tenant's contractors shall be done at such times and in such manner as Landlord may from time to time designate. Tenant covenants and agrees that all work done by Tenant or Tenant's contractors shall be performed in full compliance with Applicable Laws. Within thirty (30) days after completion of any Alterations (other than Cosmetic Alterations, unless requested in advance by Landlord), Tenant shall provide Landlord with complete "as built" drawing print sets and

electronic CADD files on disc (or files in such other current format in common use as Landlord reasonably approves or requires) showing any changes in the Premises, as well as a commissioning report prepared by a licensed, qualified commissioning agent hired by Tenant and reasonably approved by Landlord for all new or affected mechanical, electrical and plumbing systems. Any such "as built" plans shall show the applicable Alterations as an overlay on the Building as-built plans; provided that Landlord provides the Building "as built" plans to Tenant.

17.5 Before commencing any Alteration, Tenant shall (a) give Landlord at least thirty (30) days' prior written notice of the proposed commencement of such work and the names and addresses of the persons supply labor or materials therefor so that Landlord may enter the Premises to post and keep posted thereon and therein notices or to take any further action that Landlord may reasonably deem proper for the protection of Landlord's interest in the Project and (b) shall, if required by Landlord, secure, at Tenant's own cost and expense, a completion and lien indemnity bond satisfactory to Landlord for such work.

17.6 Tenant shall repair any damage to the Premises arising from Tenant's removal of any property from the Premises. During any such restoration period, Tenant shall pay Rent to Landlord as provided herein as if such space were otherwise occupied by Tenant. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

17.7 The Premises plus any Alterations; Signage; Tenant Improvements; attached equipment, decorations, fixtures and trade fixtures; movable laboratory casework and related appliances; and other additions and improvements attached to or built into the Premises made by either of the parties (including all floor and wall coverings; paneling; sinks and related plumbing fixtures; laboratory benches; exterior venting fume hoods; walk-in freezers and refrigerators; ductwork; conduits; electrical panels and circuits; attached machinery and equipment; and built-in furniture and cabinets, in each case, together with all additions and accessories thereto), shall (unless, prior to such construction or installation, or in connection with Landlord's consent thereto, Landlord elects otherwise in writing) at all times remain the property of Landlord, shall remain in the Premises and shall (unless, prior to construction or installation thereof, Landlord elects otherwise in writing) be surrendered to Landlord upon the expiration or earlier termination of this Lease. For the avoidance of doubt, the items listed on Exhibit H attached hereto (which Exhibit H may be updated by Tenant from and after the Term Commencement Date, subject to Landlord's reasonable written consent) constitute Tenant's property and shall be removed by Tenant upon the expiration or earlier termination of the Lease.

17.8 Notwithstanding any other provision of this Article to the contrary, in no event shall Tenant remove any improvement from the Premises in which any Lender has a security interest or as to which Landlord contributed payment, including the Tenant Improvements, without Landlord's prior written consent, which consent Landlord may withhold in its sole and absolute discretion.

17.9 If Tenant shall fail to remove any of its property from the Premises prior to the expiration or earlier termination of this Lease, then Landlord may, at its option, remove the same in any manner that Landlord shall choose and store such effects without liability to Tenant for loss thereof or damage thereto, and Tenant shall pay Landlord, upon demand, any costs and expenses incurred due to such removal and storage or Landlord may, at its sole option and without notice to

Tenant, sell such property or any portion thereof at private sale and without legal process for such price as Landlord may obtain and apply the proceeds of such sale against any (a) amounts due by Tenant to Landlord under this Lease and (b) any actual and reasonable expenses incident to the removal, storage and sale of such personal property.

17.10 Except with respect to Cosmetic Alterations, Tenant shall pay to Landlord (upon demand) any out-of-pocket third party costs incurred by Landlord for professional review of any plans or specifications for Alterations that require Landlord's consent. Tenant shall reimburse Landlord for any extra expenses incurred by Landlord by reason of faulty work done by Tenant or its contractors, or by reason of delays arising from such work (other than delays to the extent such delays were caused by Landlord), or by reason of inadequate clean-up.

17.11 Within sixty (60) days after final completion of any Alterations performed by Tenant with respect to the Premises, Tenant shall submit to Landlord documentation showing the amounts expended by Tenant with respect to such Alterations, together with supporting documentation reasonably acceptable to Landlord.

17.12 Tenant shall take, and shall cause its contractors to take, commercially reasonable steps to protect the Premises during the performance of any Alterations, including covering or temporarily removing any window coverings so as to guard against dust, debris or damage.

17.13 Tenant shall require its contractors and subcontractors performing work on the Premises to name Landlord and its affiliates and Lenders as additional insureds on their respective insurance policies.

17.14 Notwithstanding anything to the contrary in this Lease, Landlord and Tenant agree that Landlord shall be permitted to withhold its approval (in its sole and absolute discretion) of any Alteration that converts (office to lab or lab to office, as applicable) the office and lab zones identified on Exhibit A-2 attached hereto.

17.15 With respect to any Alterations related to building management systems ("BMS"), including without limitation, the Tenant Improvements, Tenant shall integrate tenant BMS for the Premises into the base building management system and utilize the same system for all of Tenant's HVAC control requirements. The base building management system is currently operated by Johnson Controls. No alternatives or BACnet protocol will be allowed. Tenant's BMS controls contractor shall be subject to Landlord's approval.

18. Repairs and Maintenance.

18.1 Landlord shall repair and maintain the structural and exterior portions and Common Area of the Building and the Project, including roofing and covering materials; foundations (excluding any architectural slabs, but including any structural slabs); exterior walls; plumbing; fire sprinkler systems (if any); base Building HVAC systems; the HVAC system located within the Premises up to the first damper or isolation valve that serves the Premises (for purposes of clarity, the portion of the HVAC system that includes such first damper or isolation valve and extends into and through the Premises, including any distribution systems and any supplemental HVAC serving the Premises shall not be part of the base building HVAC and shall be Tenant's obligation to maintain and repair pursuant to Section 18.2 hereof); elevators; and base Building electrical systems installed or furnished by Landlord. Notwithstanding the foregoing, Landlord has elected to repair and maintain Air Handling Unit 4-5, which is located outside the Premises but exclusively serves the Premises (the "Landlord AHU").

18.2 Except for services of Landlord, if any, required by Section 18.1, Tenant shall at Tenant's sole cost and expense maintain and keep the Premises (including but not limited to any systems or equipment exclusively serving the Premises other than the Landlord AHU, but excluding the base Building HVAC systems up to the first damper or isolation valve that extends into and serves the Premises) and every part thereof in good condition and repair, damage thereto from ordinary wear and tear excepted, and shall, within ten (10) days after receipt of written notice from Landlord, provide to Landlord any maintenance records that Landlord reasonably requests. Tenant shall, upon the expiration or sooner termination of the Term, surrender the Premises to Landlord in as good a condition as existed when received, ordinary wear and tear excepted (except that, with respect to Alterations, in substantially the same condition as existed on the date such Alterations are substantially completed by Tenant). Upon Landlord's written request, Tenant shall remove all telephone and data systems, writing and equipment from the Premises and repair any damage to the Premises caused thereby. Landlord shall have no obligation to alter, remodel, improve, repair, decorate or paint the Premises or any part thereof.

18.3 Throughout the Term of the Lease, Tenant shall, at Tenant's sole cost and expense, maintain copies of all service contracts, service, repair and maintenance records, and inspection reports on all equipment installed by or maintained by Tenant. Tenant shall, within ten (10) days after receipt of written notice from Landlord, provide to Landlord any maintenance records, service or inspection reports that Landlord reasonably requests.

18.4 Landlord shall not be liable for any failure to make any repairs or to perform any maintenance that is Landlord's obligation pursuant to this Lease unless such failure shall persist for an unreasonable time after Tenant provides Landlord with written notice of the need of such repairs or maintenance. Except as otherwise set forth in Section 31.12 of this Lease, Tenant waives its rights under Applicable Laws now or hereafter in effect to make repairs at Landlord's expense.

18.5 If any excavation shall be made upon land adjacent to or under the Building, or shall be authorized to be made, Tenant shall afford to the person causing or authorized to cause such excavation, license to enter the Premises for the purpose of performing such work as such person shall deem necessary or desirable to preserve and protect the Building from injury or damage and to support the same by proper foundations, without any claim for damages or liability against Landlord and without reducing or otherwise affecting Tenant's obligations under this Lease.

18.6 This Article relates to repairs and maintenance arising in the ordinary course of operation of the Building and the Project. In the event of a casualty described in Article 24, Article 24 shall apply in lieu of this Article. In the event of eminent domain, Article 25 shall apply in lieu of this Article.

18.7 Costs incurred by Landlord pursuant to this Article shall constitute Operating Expenses, subject to the limitations on inclusion of certain costs associated with capital expenditures, as set forth in Section 9.1(c).

19. Liens.

19.1 Subject to the immediately succeeding sentence, Tenant shall keep the Premises, the Building and the Project free from any liens arising out of work or services performed, materials furnished to or obligations incurred by Tenant. Tenant further covenants and agrees that any mechanic's or materialman's lien filed against the Premises, the Building or the Project for work or services claimed to have been done for, or materials claimed to have been furnished to, or obligations incurred by Tenant shall be discharged or bonded by Tenant within ten (10) days after the filing thereof, at Tenant's sole cost and expense.

19.2 Should Tenant fail to discharge or bond against any lien of the nature described in Section 19.1, Landlord may, at Landlord's election, pay such claim or post a statutory lien bond or otherwise provide security to eliminate the lien as a claim against title, and Tenant shall immediately reimburse Landlord for the actual costs thereof as Additional Rent. Tenant shall Indemnify the Landlord Indemnitees from and against any Claims arising from any such liens, including any administrative, court or other legal proceedings related to such liens.

19.3 In the event that Tenant leases or finances the acquisition of office equipment, furnishings or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code financing statement shall, upon its face or by exhibit thereto, indicate that such financing statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Premises, the Building or the Project be furnished on a financing statement without qualifying language as to applicability of the lien only to removable personal property located in an identified suite leased by Tenant. Should any holder of a financing statement record or place of record a financing statement that appears to constitute a lien against any interest of Landlord or against equipment that may be located other than within an identified suite leased by Tenant, Tenant shall, within ten (10) days after filing such financing statement, cause (a) a copy of the lender security agreement or other documents to which the financing statement pertains to be furnished to Landlord to facilitate Landlord's ability to demonstrate that the lien of such financing statement is not applicable to Landlord's interest and (b) Tenant's lender to amend such financing statement and any other documents of record to clarify that any liens imposed thereby are not applicable to any interest of Landlord in the Premises, the Building or the Project. If requested by Tenant or its lender, Landlord will agree to deliver a written statement to such lender providing that this Lease does not grant to Landlord a security interest in Tenant's personal property.

20. Estoppel Certificate. Tenant shall, within ten (10) business days after receipt of written notice from Landlord, execute, acknowledge and deliver a statement in writing substantially in the form attached to this Lease as Exhibit I, or on any other form reasonably requested by a current or proposed Lender or encumbrancer or proposed purchaser, (a) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which rental and other charges are paid in advance, if any, (b) acknowledging that there are not, to Tenant's knowledge, any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (c) setting forth such further information with respect to this Lease or the Premises as may be reasonably requested thereon. Any such statements may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the Property. Tenant's failure

to deliver any such statement within the prescribed time shall, at Landlord's option, constitute a Default (as defined below) under this Lease, and, in any event, shall be binding upon Tenant that the Lease is in full force and effect and without modification except as may be represented by Landlord in any certificate prepared by Landlord and delivered to Tenant for execution.

21. Hazardous Materials.

21.1 Tenant shall not cause or permit any Hazardous Materials (as defined below) to be brought upon, kept or used in or about the Premises, the Building or the Project in violation of Applicable Laws by Tenant or any of its employees, agents, contractors or invitees (collectively with Tenant, each a "Tenant Party"). If (a) Tenant breaches such obligation, (b) the presence of Hazardous Materials as a result of such a breach results in contamination of the Project, any portion thereof, or any adjacent property, (c) contamination of the Premises otherwise occurs during the Term or any extension or renewal hereof or holding over hereunder (other than if such contamination results from (i) migration of Hazardous Materials from outside the Premises arising from the acts or omissions of a Tenant Party or coming from property owned or leased by a Tenant Party, or (ii) to the extent such contamination is caused by Landlord's gross negligence or willful misconduct) or (d) contamination of the Project occurs as a result of Hazardous Materials that are placed on or under or are released into the Project by a Tenant Party, then Tenant shall Indemnify the Landlord Indemnitees from and against any and all Claims of any kind or nature, including (w) diminution in value of the Project or any portion thereof, (x) damages for the loss or restriction on use of rentable or usable space or of any amenity of the Project, (y) damages arising from any adverse impact on marketing of space in the Project or any portion thereof and (z) sums paid in settlement of Claims that arise before, during or after the Term as a result of such breach or contamination. This Indemnification by Tenant includes costs incurred in connection with any investigation of site conditions or any clean-up, remedial, removal or restoration work required by any Governmental Authority because of Hazardous Materials present in the air, soil or groundwater above, on, under or about the Project. Without limiting the foregoing, if the presence of any Hazardous Materials in, on, under or about the Project, any portion thereof or any adjacent property caused or permitted by any Tenant Party results in any contamination of the Project, any portion thereof or any adjacent property, then Tenant shall promptly take all actions at its sole cost and expense as are necessary to return the Project, any portion thereof or any adjacent property to its respective condition existing prior to the time of such contamination; provided that Landlord's written approval of such action shall first be obtained, which approval Landlord shall not unreasonably withhold or delay; and provided, further, that it shall be reasonable for Landlord to withhold its consent if such actions could have a material adverse long-term or short-term effect on the Project, any portion thereof or any adjacent property. Tenant's obligations under this Section shall not be affected, reduced or limited by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant under workers' compensation acts, disability benefit acts, employee benefit acts or similar legislation.

21.2 Landlord acknowledges that it is not the intent of this Article to prohibit Tenant from operating its business for the Permitted Use. Tenant may operate its business according to the custom of Tenant's industry so long as the use or presence of Hazardous Materials is strictly and properly monitored in accordance with Applicable Laws. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord (a) a list identifying each type of Hazardous Material to be present

at the Premises that is subject to regulation under any environmental Applicable Laws in the form of a Tier II form pursuant to Section 312 of the Emergency Planning and Community Right-to-Know Act of 1986 (or any successor statute) or any other form reasonably requested by Landlord, (b) a list of any and all approvals or permits from Governmental Authorities required in connection with the presence of such Hazardous Material at the Premises and (c) correct and complete copies of (i) notices of violations of Applicable Laws related to Hazardous Materials and (ii) plans relating to the installation of any storage tanks to be installed in, on, under or about the Project (provided that installation of storage tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent Landlord may withhold in its sole and absolute discretion) and closure plans or any other documents required by any and all Governmental Authorities for any storage tanks installed in, on, under or about the Project for the closure of any such storage tanks (collectively, "Hazardous Materials Documents"). Tenant shall deliver to Landlord updated Hazardous Materials Documents, within fourteen (14) days after receipt of a written request therefor from Landlord, not more often than once per year, unless (m) there are any changes to the Hazardous Materials Documents or (n) Tenant initiates any Alterations or changes its business, in either case in a way that involves any material increase in the types or amounts of Hazardous Materials, in which case Tenant shall deliver updated Hazardous Materials documents (without Landlord having to request them) before or, if not practicable to do so before, as soon as reasonably practicable after the occurrence of the events in Subsection 21.2(m) or (n). For each type of Hazardous Material listed, the Hazardous Materials Documents shall include (t) the chemical name, (u) the material state (e.g., solid, liquid, gas or cryogen), (v) the concentration, (w) the storage amount and storage condition (e.g., in cabinets or not in cabinets), (x) the use amount and use condition (e.g., open use or closed use), (y) the location (e.g., room number or other identification) and (z) if known, the chemical abstract service number. Notwithstanding anything in this Section to the contrary, Tenant shall not be required to provide Landlord with any documents containing information of a proprietary nature, unless such documents contain a reference to Hazardous Materials or activities related to Hazardous Materials. Landlord may, at Landlord's expense, cause the Hazardous Materials Documents to be reviewed by a person or firm qualified to analyze Hazardous Materials to confirm compliance with the provisions of this Lease and with Applicable Laws. In the event that a review of the Hazardous Materials Documents indicates non-compliance with this Lease or Applicable Laws, Tenant shall, at its expense, diligently take steps to bring its storage and use of Hazardous Materials into compliance. Notwithstanding anything in this Lease to the contrary or Landlord's review into Tenant's Hazardous Materials Documents or use or disposal of hazardous materials, however, Landlord shall not have and expressly disclaims any liability related to Tenant's or other tenants' use or disposal of Hazardous Materials, it being acknowledged by Tenant that Tenant is best suited to evaluate the safety and efficacy of its Hazardous Materials usage and procedures.

21.3 Tenant represents and warrants to Landlord that is not nor has it been, in connection with the use, disposal or storage of Hazardous Materials, (a) subject to a material enforcement order issued by any Governmental Authority or (b) required to take any remedial action.

21.4 At any time, and from time to time, prior to the expiration of the Term, Landlord shall have the right to conduct appropriate tests of the Project or any portion thereof to demonstrate that Hazardous Materials are present or that contamination has occurred due to the acts or omissions of a Tenant Party. Tenant shall pay all reasonable costs of such tests if such tests reveal that Hazardous Materials exist at the Project in violation of this Lease.

21.5 If underground or other storage tanks storing Hazardous Materials installed or utilized by Tenant are located on the Premises, or are hereafter placed on the Premises by Tenant (or by any other party, if such storage tanks are utilized by Tenant), then Tenant shall monitor the storage tanks, maintain appropriate records, implement reporting procedures, properly close any underground storage tanks, and take or cause to be taken all other steps necessary or required under the Applicable Laws. Tenant shall have no responsibility or liability for underground or other storage tanks installed by anyone other than Tenant unless Tenant utilizes such tanks, in which case Tenant's responsibility for such tanks shall be as set forth in this Section.

21.6 Tenant shall promptly report to Landlord any actual or suspected presence of mold or water intrusion at the Premises.

21.7 Tenant's obligations under this Article shall survive the expiration or earlier termination of the Lease. During any period of time needed by Tenant or Landlord after the termination of this Lease to complete the removal from the Premises of any such Hazardous Materials for which Tenant is responsible under this Lease, Tenant shall be deemed a holdover tenant and subject to the provisions of Article 27.

21.8 As used herein, the term "Hazardous Material" means any toxic, explosive, corrosive, flammable, infectious, radioactive, carcinogenic, mutagenic or otherwise hazardous substance, material or waste that is or becomes regulated by Applicable Laws or any Governmental Authority.

21.9 Notwithstanding anything to the contrary in this Lease, Landlord shall have sole control over the allocation of fire control areas (as defined in the Uniform Building Code as adopted by the city or municipality(ies) in which the Project is located (the "UBC")) within the Project for the storage of Hazardous Materials. Tenant shall be allocated (a) one (1) control area within the Fourth Floor Premises, and (b) one (1) control area within the First Floor Premises, and the boundaries of each control area shall be at Tenant's discretion. Notwithstanding anything to the contrary in this Lease, the quantity of Hazardous Materials allowed by this Section is specific to Tenant and shall not run with the Lease in the event of a Transfer (as defined in Article 29). In the event of a Transfer, if the use of Hazardous Materials by such new tenant ("New Tenant") is such that New Tenant utilizes fire control areas in the Project in excess of the area allocated by Landlord, then New Tenant shall, at its sole cost and expense and upon Landlord's written request, establish and maintain a separate area of the Premises classified by the UBC as an "H" occupancy area for the use and storage of Hazardous Materials, or take such other action as is necessary to ensure that its share of the fire control areas of the Building and the Project is not greater than the area allocated by Landlord. Notwithstanding anything in this Lease to the contrary, Landlord shall not have and expressly disclaims any liability related to Tenant's or other tenants' use or disposal of fire control areas, it being acknowledged by Tenant that Tenant and other tenants are best suited to evaluate the safety and efficacy of its Hazardous Materials usage and procedures.

22. Odors and Exhaust. Tenant acknowledges that Landlord would not enter into this Lease with Tenant unless Tenant assured Landlord that under no circumstances will any other occupants of the Building or the Project (including persons legally present in any outdoor areas of the Project) be subjected to odors or fumes (whether or not noxious), and that the Building and the Project will not be damaged by any exhaust, in each case from Tenant's operations. Landlord and Tenant therefore agree as follows:

22.1 Tenant shall not cause or permit (or conduct any activities that would cause) any release of any odors or fumes of any kind from the Premises.

22.2 If the Building has a ventilation system that, in Landlord's judgment, is adequate, suitable, and appropriate to vent the Premises in a manner that does not release odors affecting any indoor or outdoor part of the Project, Tenant shall vent the Premises through such system. If Landlord at any time determines that any existing ventilation system is inadequate, or if no ventilation system exists, Tenant shall in compliance with Applicable Laws vent all fumes and odors from the Premises (and remove odors from Tenant's exhaust stream) as Landlord requires. The placement and configuration of all ventilation exhaust pipes, louvers and other equipment shall be subject to Landlord's approval. Tenant acknowledges Landlord's legitimate desire to maintain the Project (indoor and outdoor areas) in an odor-free manner, and Landlord may require Tenant, consistent with Landlord's non-discriminatory requirements for the Building, to abate and remove all odors in a manner that goes beyond the requirements of Applicable Laws.

22.3 Tenant shall, at Tenant's sole cost and expense, provide odor eliminators and other devices (such as filters, air cleaners, scrubbers and whatever other equipment may in Landlord's judgment be necessary or appropriate from time to time) to completely remove, eliminate and abate any odors, fumes or other substances in Tenant's exhaust stream that, in Landlord's judgment, emanate from Tenant's Premises. Any work Tenant performs under this Section shall constitute Alterations.

22.4 Tenant's responsibility to remove, eliminate and abate odors, fumes and exhaust shall continue throughout the Term. Landlord's approval of the Tenant Improvements shall not preclude Landlord from requiring additional measures to eliminate odors, fumes and other adverse impacts of Tenant's exhaust stream (as Landlord may reasonably designate in Landlord's discretion). Tenant shall install additional equipment as Landlord reasonably requires from time to time under the preceding sentence. Such installations shall constitute Alterations. Tenant shall have no obligation or liabilities for odors, fumes or exhaust arising or emanating from portions of the Project that are not the Premises unless arising from the actions or omissions of Tenant or another Tenant Party.

22.5 If Tenant fails to install satisfactory odor control equipment within ten (10) business days after Landlord's demand made at any time, then Landlord may, without limiting Landlord's other rights and remedies, require Tenant to cease and suspend any operations in the Premises that, in Landlord's reasonable determination, cause odors, fumes or exhaust. For the purpose of the immediately foregoing sentence, Landlord's determination shall be "reasonable" if Landlord has received a complaint regarding such odors, fumes or exhaust. For example, if Landlord determines that Tenant's production of a certain type of product causes odors, fumes or exhaust, and Tenant does not install satisfactory odor control equipment within ten (10) business days after Landlord's request, then Landlord may require Tenant to stop producing such type of product in the Premises unless and until Tenant has installed odor control equipment satisfactory to Landlord.

23. Insurance.

23.1 Landlord shall maintain insurance for the Building and the Project in amounts equal to full replacement cost (exclusive of the costs of excavation, foundations and footings, engineering costs or such other costs to the extent the same are not incurred in the event of a rebuild and without reference to depreciation taken by Landlord upon its books or tax returns) or such lesser coverage as Landlord may elect, provided that such coverage shall not be less than the amount of such insurance Landlord's Lender, if any, requires Landlord to maintain, providing protection against any peril generally included within the classification "Fire and Extended Coverage," together with insurance against sprinkler damage (if applicable), vandalism and malicious mischief. Landlord, subject to availability thereof, shall further insure, if Landlord deems it appropriate, coverage against flood, environmental hazard, earthquake, loss or failure of building equipment, rental loss during the period of repairs or rebuilding, Workers' Compensation insurance and fidelity bonds for employees employed to perform services. Notwithstanding the foregoing, Landlord may, but shall not be deemed required to, provide insurance for any improvements installed by Tenant or that are in addition to the standard improvements customarily furnished by Landlord, without regard to whether or not such are made a part of or are affixed to the Building.

23.2 In addition, Landlord shall carry Commercial General Liability insurance with combined single limits of not less than One Million Dollars ($1,000,000) per occurrence/general aggregate and an umbrella policy of not less than Five Million Dollars ($5,000,000) for bodily injury (including death), or property damage with respect to the Project, written on an occurrence basis; provided that such coverage is at least as broad as the primary coverages required herein.

23.3 Tenant shall, at its own cost and expense, procure and maintain during the Term the following insurance for the benefit of Tenant and Landlord (as their interests may appear) with insurers financially acceptable and lawfully authorized to do business in the state where the Premises are located:

(a) Commercial General Liability insurance on a broad-based occurrence coverage form, with coverages including but not limited to bodily injury (including death), property damage (including loss of use resulting therefrom), premises/operations, personal & advertising injury, and contractual liability with limits of liability of not less than $2,000,000 for bodily injury and property damage per occurrence, $2,000,000 general aggregate, which limits may be met by use of excess and/or umbrella liability insurance provided that such coverage is at least as broad as the primary coverages required herein.

(b) Commercial Automobile Liability insurance covering liability arising from the use or operation of any auto on behalf of Tenant or invited by Tenant (including those owned, hired, rented, leased, borrowed, scheduled or non-owned). Coverage shall be on a broad-based occurrence form in an amount not less than $2,000,000 combined single limit per accident for bodily injury and property damage. Such coverage shall apply to all vehicles and persons, whether accessing the property with active or passive consent.

(c) Commercial Property insurance covering property damage to the full replacement cost value and business interruption. Covered property shall include all tenant improvements in the Premises (to the extent not insured by Landlord pursuant to Section 23.1) and Tenant's Property including personal property, furniture, fixtures, machinery, equipment, stock, inventory and improvements and betterments, which may be owned by Tenant or Landlord and required to be insured hereunder, or which may be leased, rented, borrowed or in the care custody or control of Tenant, or Tenant's agents, employees or subcontractors. Such insurance, with respect only to all Tenant Improvements, Alterations or other work performed on the Premises by Tenant (collectively, "Tenant Work"), shall name Landlord and Landlord's current and future mortgagees as loss payees as their interests may appear. Such insurance shall be written on an "all risk" of physical loss or damage basis including the perils of fire, extended coverage, electrical injury, mechanical breakdown, windstorm, vandalism, malicious mischief, sprinkler leakage, back-up of sewers or drains, terrorism and such other risks Landlord may from time to time designate, for the full replacement cost value of the covered items with an agreed amount endorsement with no co-insurance. Business interruption coverage shall have limits sufficient to cover Tenant's necessary continuing expenses, including rents due Landlord under the Lease. The minimum period of indemnity for business interruption coverage shall be twelve (12) months, plus twelve (12) months' extended period of indemnity.

(d) Workers' Compensation insurance as is required by statute or law, or as may be available on a voluntary basis and Employers' Liability insurance with limits of not less than the following: each accident, Five Hundred Thousand Dollars ($500,000); disease ($500,000); disease (each employee), Five Hundred Thousand Dollars ($500,000).

(e) Medical malpractice insurance at limits of not less than $1,000,000 each claim during such periods, if any, that Tenant engages in the practice of medicine at the Premises or conducts clinical trials on human subjects at the Premises.

(f) During all construction by Tenant at the Premises, with respect to tenant improvements being constructed (including the Tenant Improvements and any Alterations, insurance required in Exhibit B-1 must be in place.

23.4 The insurance required of Tenant by this Article shall be with companies at all times having a current rating of not less than A- and financial category rating of at least Class VII in "A.M. Best's Insurance Guide" current edition. Tenant shall obtain for Landlord from the insurance companies/broker or cause the insurance companies/broker to furnish certificates of insurance evidencing all coverages required herein to Landlord. Landlord reserves the right to require complete, certified copies of all required insurance policies including any endorsements. No such policy shall be cancelable or subject to reduction of coverage or other modification or cancellation except after thirty (30) days' prior written notice to Landlord from Tenant or its insurers (except in the event of non-payment of premium, in which case ten (10) days' written notice shall be given). All such policies shall be written as primary policies, not contributing with and not in excess of the coverage that Landlord may carry. Tenant's required policies shall contain severability of interests clauses stating that, except with respect to limits of insurance, coverage shall apply separately to each insured or additional insured. Tenant shall, on the date of expiration of such policies, furnish Landlord with renewal certificates of insurance or binders. Tenant agrees that if Tenant does not take out and maintain such insurance and such failure continues for five (5) business days after written notice to Tenant, Landlord may (but shall not be required to) procure such insurance on Tenant's behalf and at its cost to be paid by Tenant as Additional Rent.

Commercial General Liability, Commercial Automobile Liability, Umbrella Liability and Pollution Legal Liability insurance as required above shall name Landlord, BioMed Realty LLC, BioMed Realty, L.P., BRE Edison L.P., BRE Edison LLC, BRE Edison Holdings L.P., BRE Edison Holdings LLC, and BRE Edison Parent L.P. and their respective officers, employees, agents, general partners, members, subsidiaries, affiliates and Lenders ("Landlord Parties") as additional insureds as respects liability arising from work or operations performed by or on behalf of Tenant, Tenant's use or occupancy of Premises, and ownership, maintenance or use of vehicles by or on behalf of Tenant.

23.5 In each instance where insurance is to name Landlord Parties as additional insureds, Tenant shall, upon Landlord's written request, also designate and furnish certificates evidencing such Landlord Parties as additional insureds to (a) any Lender of Landlord holding a security interest in the Building or the Project, (b) the landlord under any lease whereunder Landlord is a tenant of the real property upon which the Building is located if the interest of Landlord is or shall become that of a tenant under a ground lease rather than that of a fee owner and (c) any management company retained by Landlord to manage the Project.

23.6 Subject to Section 23.7 below, Tenant assumes the risk of damage to any fixtures, goods, inventory, merchandise, equipment and leasehold improvements, and Landlord shall not be liable for injury to Tenant's business or any loss of income therefrom, relative to such damage, all as more particularly set forth within this Lease. Tenant shall, at Tenant's sole cost and expense, carry such insurance as Tenant desires for Tenant's protection with respect to personal property of Tenant or business interruption.

23.7 Tenant, on behalf of itself and its insurers, hereby waives any and all rights of recovery against the Landlord Parties with respect to any loss, damage, claims, suits or demands, howsoever caused, that are covered, or should have been covered, by valid and collectible workers' compensation, employer's liability insurance and other liability insurance required to obtained and carried by Tenant pursuant to this Article, including any deductibles or self-insurance maintained thereunder. Tenant agrees to endorse the required workers' compensation, employer's liability and other liability insurance policies to permit waivers of subrogation as required hereunder and hold harmless and indemnify the Landlord Parties for any loss or expense incurred as a result of a failure to obtain such waivers of subrogation from insurers. Such waivers shall continue so long as Tenant's insurers so permit. Any termination of such a waiver shall be by written notice to Landlord, containing a description of the circumstances hereinafter set forth in this Section. Tenant, upon obtaining the policies of workers' compensation, employer's liability and other liability insurance required or permitted under this Lease, shall give notice to its insurance carriers that the foregoing waiver of subrogation is contained in this Lease. If such policies shall not be obtainable with such waiver or shall be so obtainable only at a premium over that chargeable without such waiver, then Tenant shall notify Landlord of such conditions. In addition, each of Landlord and Tenant, on behalf of itself and its insurers, hereby waives all rights of subrogation against the other party or such other party's insurers with respect to any Claims covered by any other insurance policies required to be obtained and maintained by the non-waiving party pursuant to this Lease, or that would have been covered had the non-waiving party obtained and maintained such policies, except to the extent of the non-waiving party's willful misconduct.

23.8 Landlord may require insurance policy limits required under this Lease to be raised to conform with requirements of Landlord's Lender or to bring coverage limits to levels then being required of new tenants within the Project.

23.9 Any costs incurred by Landlord pursuant to this Article shall constitute a portion of Operating Expenses.

23.10 The provisions of this Article 23 shall survive the expiration or earlier termination of this Lease.

24. Damage or Destruction.

24.1 In the event of a partial destruction of (a) the Premises or (b) the Common Area of the Building or the Project ((a) and (b) together, the "Affected Areas") by fire or other perils covered by extended coverage insurance not exceeding twenty-five percent (25%) of the full insurable value thereof, and provided that (w) the damage thereto is such that the Affected Areas may be repaired, reconstructed or restored within a period of twelve (12 months from the date of the happening of such casualty, (x) Landlord shall receive insurance proceeds from its insurer or Lender sufficient to cover the cost of such repairs, reconstruction and restoration (except for any deductible amount provided by Landlord's policy, which deductible amount, if paid by Landlord, shall constitute an Operating Expense), (y) the repair, reconstruction or restoration of the Affected Areas is permitted by all applicable Loan Documents or otherwise consented to by any and all Lenders whose consent is required thereunder, and (z) such casualty was not intentionally caused by a Tenant Party, then Landlord shall commence and proceed diligently with the work of repair, reconstruction and restoration of the Affected Areas (including all Tenant Improvements) and this Lease shall continue in full force and effect.

24.2 In the event of any damage to or destruction of the Building or the Project other than as described in Section 24.1, Landlord may elect to repair, reconstruct and restore the Building or the Project, as applicable, in which case this Lease shall continue in full force and effect. If Landlord elects not to repair, reconstruct and restore the Building or the Project, as applicable, then this Lease shall terminate as of the date of such damage or destruction. In the event of any damage or destruction (regardless of whether such damage is governed by Section 24.1 or this Section), if (a) in Landlord's determination as set forth in the Damage Repair Estimate (as defined below), the Affected Areas cannot be repaired, reconstructed or restored within twelve (12) months after the date of the Damage Repair Estimate, (b) subject to Section 24.6, the Affected Areas are not actually repaired, reconstructed and restored within eighteen (18) months after the date of the Damage Repair Estimate, or (c) the damage and destruction occurs within the last twelve (12) months of the then-current Term, then Tenant shall have the right to terminate this Lease, effective as of the date of such damage or destruction, by delivering to Landlord its written notice of termination (a "Termination Notice") (y) with respect to Subsections 24.2(a) and (c), no later than fifteen (15) days after Landlord delivers to Tenant Landlord's Damage Repair Estimate and (z) with respect to Subsection 24.2(b), no later than fifteen (15) days after such twelve (12) month period (as the same may be extended pursuant to Section 24.6) expires. If Tenant provides Landlord with a Termination Notice pursuant to Subsection 24.2(z), Landlord shall have an additional thirty (30) days after receipt of such Termination Notice to complete the repair, reconstruction and restoration. If Landlord does not complete such repair, reconstruction and

restoration within such thirty (30) day period, then Tenant may terminate this Lease by giving Landlord written notice within two (2) business days after the expiration of such thirty (30) day period. If Landlord does complete such repair, reconstruction and restoration within such thirty (30) day period, then this Lease shall continue in full force and effect.

24.3 As soon as reasonably practicable, but in any event within sixty (60) days following the date of damage or destruction, Landlord shall notify Tenant of Landlord's good faith estimate of the period of time in which the repairs, reconstruction and restoration will be completed (the "Damage Repair Estimate"), which estimate shall be based upon the opinion of a contractor reasonably selected by Landlord and experienced in comparable repair, reconstruction and restoration of similar buildings. Additionally, Landlord shall give written notice to Tenant within sixty (60) days following the date of damage or destruction of its election not to repair, reconstruct or restore the Building or the Project, as applicable.

24.4 Upon any termination of this Lease under any of the provisions of this Article, the parties shall be released thereby without further obligation to the other from the date possession of the Premises is surrendered to Landlord, except with regard to (a) items occurring prior to the damage or destruction and (b) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof.

24.5 In the event of repair, reconstruction and restoration as provided in this Article, all Rent to be paid by Tenant under this Lease shall be abated proportionately based on the extent to which Tenant's use of the Premises is impaired during the period of such repair, reconstruction or restoration, unless Landlord provides Tenant with other space during the period of repair, reconstruction and restoration that, in Tenant's reasonable opinion, is suitable for the temporary conduct of Tenant's business; provided, however, that the amount of such abatement shall be reduced by the amount of Rent that is received by Tenant as part of the business interruption or loss of rental income with respect to the Premises from the proceeds of business interruption or loss of rental income insurance.

24.6 Notwithstanding anything to the contrary contained in this Article, (a) Landlord shall not be required to repair, reconstruct or restore any damage or destruction to the extent that Landlord is prohibited from doing so by any applicable Loan Document or any Lender whose consent is required thereunder withholds its consent, and (b) should Landlord be delayed or prevented from completing the repair, reconstruction or restoration of the damage or destruction to the Premises after the occurrence of such damage or destruction by Force Majeure or delays caused by a Lender or Tenant Party, then the time for Landlord to commence or complete repairs, reconstruction and restoration shall be extended on a day-for-day basis; provided, however, that, at Landlord's election, Landlord shall be relieved of its obligation to make such repairs, reconstruction and restoration.

24.7 If Landlord is obligated to or elects to repair, reconstruct or restore as herein provided, then Landlord shall be obligated to make such repairs, reconstruction or restoration only with regard to (a) those portions of the Premises that were originally provided at Landlord's expense and (b) the Common Area portion of the Affected Areas. The repairs, reconstruction or restoration of improvements not originally provided by Landlord or at Landlord's expense shall be the obligation of Tenant. In the event Tenant has elected to upgrade certain improvements from

Landlord's building standards (the "Building Standard"), Landlord shall, upon the need for replacement due to an insured loss, provide only the Building Standard, unless Tenant again elects to upgrade such improvements and pay any incremental costs related thereto, except to the extent that excess insurance proceeds, if received, are adequate to provide such upgrades, in addition to providing for basic repairs, reconstruction and restoration of the Premises, the Building and the Project.

24.8 Notwithstanding anything to the contrary contained in this Article, Landlord shall not have any obligation whatsoever to repair, reconstruct or restore the Premises if the damage resulting from any casualty covered under this Article occurs (a) during the thirteenth (13th) through the twenty-fourth (24th) months prior to the expiration of the Term and the Damage Repair Estimate indicates that more than six (6) months will be required for such repair, reconstruction or restoration, (b) during the seventh (7th) through twelfth (12th) months prior to the expiration of the Term and the Damage Repair Estimate indicates that more than thirty (30) days will be required for such repair, reconstruction or restoration, (c) during the last six (6) months of the Term or (d) to the extent that insurance proceeds are not available therefor.

24.9 Landlord's obligation, should it elect or be obligated to repair, reconstruct or restore, shall be limited to the Affected Areas, and shall be conditioned upon Landlord receiving any permits or authorizations required by Applicable Laws. Tenant shall, at its expense, replace or fully repair all of Tenant's personal property and any Alterations installed by Tenant existing at the time of such damage or destruction. If Affected Areas are to be repaired, reconstructed or restored in accordance with the foregoing, Landlord shall make available to Tenant any portion of insurance proceeds it receives that are allocable to the Alterations constructed by Tenant pursuant to this Lease; provided that Landlord shall not be required to do so while Tenant is in default under this Lease, and subject to the requirements of any Lender of Landlord.

24.10 This Article sets forth the terms and conditions upon which this Lease may terminate in the event of any damage or destruction. Accordingly, the parties hereby waive the provisions of any Applicable Laws (and any successor statutes) permitting the parties to terminate this Lease as a result of any damage or destruction.

25. Eminent Domain.

25.1 In the event (a) the whole of all Affected Areas or (b) such part thereof as shall substantially interfere with Tenant's use and occupancy of the Premises for the Permitted Use shall be taken for any public or quasi-public purpose by any lawful power or authority by exercise of the right of appropriation, condemnation or eminent domain, or sold to prevent such taking, Tenant or Landlord may terminate this Lease effective as of the date possession is required to be surrendered to such authority, except with regard to (y) items occurring prior to the taking and (z) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof.

25.2 In the event of a partial taking of (a) the Building or the Project or (b) drives, walkways or parking areas serving the Building or the Project for any public or quasi-public purpose by any lawful power or authority by exercise of right of appropriation, condemnation, or eminent domain, or sold to prevent such taking, then, without regard to whether any portion of the

Premises occupied by Tenant was so taken, Landlord may elect to terminate this Lease (except with regard to (y) items occurring prior to the taking and (z) provisions of this Lease that, by their express terms, survive the expiration or earlier termination hereof) as of such taking if such taking is, in Landlord's sole opinion, of a material nature such as to make it uneconomical to continue use of the unappropriated portion for purposes of renting office or laboratory space.

25.3 To the extent permitted under all applicable Loan Documents or otherwise consented to by any and all Lenders whose consent is required thereunder, Tenant shall be entitled to any award that is specifically awarded as compensation for (a) the taking of Tenant's personal property that was installed at Tenant's expense and (b) the costs of Tenant moving to a new location. Except as set forth in the previous sentence, any award for such taking shall be the property of Landlord.

25.4 If, upon any taking of the nature described in this Article, this Lease continues in effect, then Landlord shall promptly proceed to restore the Affected Areas to substantially their same condition prior to such partial taking. To the extent such restoration is infeasible, as determined by Landlord in its sole and absolute discretion, the Rent shall be decreased proportionately to reflect the loss of any portion of the Premises no longer available to Tenant. Notwithstanding anything to the contrary contained in this Article, Landlord shall not be required to restore the Affected Areas to the extent that Landlord is prohibited from doing so by any applicable Loan Document or any Lender whose consent is required thereunder withholds its consent.

25.5 This Article sets forth the terms and conditions upon which this Lease may terminate in the event of any damage or destruction. Accordingly, the parties hereby waive the provisions of any Applicable Laws (and any successor statutes) permitting the parties to terminate this Lease as a result of any damage or destruction.

26. Surrender.

26.1 At least thirty (30) days prior to Tenant's surrender of possession of any part of the Premises, Tenant shall provide Landlord with a facility decommissioning and Hazardous Materials closure plan for the Premises ("Exit Survey") prepared by an independent third party state-certified professional with appropriate expertise, which Exit Survey must be reasonably acceptable to Landlord. The Exit Survey shall comply with the American National Standards Institute's Laboratory Decommissioning guidelines (ANSI/AIHA Z9.11-2008) or any successor standards published by ANSI or any successor organization (or, if ANSI and its successors no longer exist, a similar entity publishing similar standards). In addition, at least ten (10) days prior to Tenant's surrender of possession of any part of the Premises, Tenant shall (a) provide Landlord with written evidence of all appropriate governmental releases obtained by Tenant in accordance with Applicable Laws, including laws pertaining to the surrender of the Premises, (b) place Laboratory Equipment Decontamination Forms on all decommissioned equipment to assure safe occupancy by future users and (c) conduct a site inspection with Landlord. In addition, Tenant agrees to remain responsible after the surrender of the Premises for the remediation of any recognized environmental conditions set forth in the Exit Survey and comply with any recommendations set forth in the Exit Survey. Tenant's obligations under this Section shall survive the expiration or earlier termination of the Lease.

26.2 No surrender of possession of any part of the Premises shall release Tenant from any of its obligations hereunder, unless such surrender is accepted in writing by Landlord.

26.3 The voluntary or other surrender of this Lease by Tenant shall not effect a merger with Landlord's fee title or leasehold interest in the Premises, the Building, the Property or the Project, unless Landlord consents in writing, and shall, at Landlord's option, operate as an assignment to Landlord of any or all subleases.

26.4 The voluntary or other surrender of any ground or other underlying lease that now exists or may hereafter be executed affecting the Building or the Project, or a mutual cancellation thereof or of Landlord's interest therein by Landlord and its lessor shall not effect a merger with Landlord's fee title or leasehold interest in the Premises, the Building or the Property and shall, at the option of the successor to Landlord's interest in the Building or the Project, as applicable, operate as an assignment of this Lease.

27. Holding Over.

27.1 If, with Landlord's prior written consent, Tenant holds possession of all or any part of the Premises after the Term, Tenant shall become a tenant from month to month after the expiration or earlier termination of the Term, and in such case Tenant shall continue to pay (a) Base Rent in accordance with Article 7, as adjusted in accordance with Article 8, and (b) any amounts for which Tenant would otherwise be liable under this Lease if the Lease were still in effect, including payments for Tenant's Adjusted Share of Operating Expenses. Any such month-to-month tenancy shall be subject to every other term, covenant and agreement contained herein.

27.2 Notwithstanding the foregoing, if Tenant remains in possession of the Premises after the expiration or earlier termination of the Term without Landlord's prior written consent, (a) Tenant shall become a tenant at sufferance subject to the terms and conditions of this Lease, except that the monthly rent shall be equal to one hundred fifty percent (150%) of the Rent in effect during the last thirty (30) days of the Term, and (b) if such holdover persists for more than thirty (30) days after the earlier of (i) the expiration or earlier termination of the Term and (ii) the date Landlord notifies Tenant that Landlord has procured a tenant that is ready, willing and able to sign a lease for the Premises (or a portion thereof), Tenant shall be liable to Landlord for any and all damages suffered by Landlord as a result of such holdover, including any lost rent or consequential, special and indirect damages (in each case, regardless of whether such damages are foreseeable).

27.3 Acceptance by Landlord of Rent after the expiration or earlier termination of the Term shall not result in an extension, renewal or reinstatement of this Lease.

27.4 The foregoing provisions of this Article are in addition to and do not affect Landlord's right of reentry or any other rights of Landlord hereunder or as otherwise provided by Applicable Laws.

27.5 The provisions of this Article shall survive the expiration or earlier termination of this Lease.

28. Indemnification and Exculpation.

28.1 Tenant agrees to Indemnify the Landlord Indemnitees from and against any and all Claims of any kind or nature, real or alleged, arising from (a) injury to or death of any person or damage to any property occurring within or about the Premises, the Building, the Property or the Project, arising directly or indirectly out of (i) the presence at or use or occupancy of the Premises or Project by a Tenant Party, (ii) an act or omission on the part of any Tenant Party, (b) a breach or default by Tenant in the performance of any of its obligations hereunder (including any Claim asserted by any Lender against any Landlord Indemnitees under any Loan Document as a direct result of such breach or default by Tenant) or (c) injury to or death of persons or damage to or loss of any property, real or alleged, arising from the serving of alcoholic beverages at the Premises or Project, including liability under any dram shop law, host liquor law or similar Applicable Law, except to the extent directly caused by Landlord's negligence or willful misconduct. Tenant's obligations under this Section shall not be affected, reduced or limited by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant under workers' compensation acts, disability benefit acts, employee benefit acts or similar legislation. Tenant's obligations under this Section shall survive the expiration or earlier termination of this Lease. Subject to Sections 23.6, 28.2 and 31.12 and any subrogation provisions contained in the Work Letter, Landlord agrees to Indemnify the Tenant Parties from and against any and all Claims arising from injury to or death of any person or damage to or loss of any physical property occurring within or about the Premises, the Building, the Property or the Project to the extent directly arising out of Landlord's gross negligence or willful misconduct.

28.2 Notwithstanding anything in this Lease to the contrary, Landlord shall not be liable to Tenant for and Tenant assumes all risk of (a) damage or losses arising from fire, electrical malfunction, gas explosion or water damage of any type (including broken water lines, malfunctioning fire sprinkler systems, roof leaks or stoppages of lines), unless any such loss is due to Landlord's willful disregard of written notice by Tenant of need for a repair that Landlord is responsible to make for an unreasonable period of time, and (b) damage to personal property or scientific research, including loss of records kept by Tenant within the Premises (in each case, regardless of whether such damages are foreseeable). Tenant further waives any claim for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property as described in this Section. Notwithstanding anything in the foregoing or this Lease to the contrary, except (x) as otherwise provided herein (including Section 27.2), (y) as may be provided by Applicable Laws or (z) in the event of Tenant's breach of Article 21 or Section 26.1, in no event shall Landlord or Tenant be liable to the other for any consequential, special or indirect damages arising out of this Lease, including lost profits (provided that this Subsection 28.2(z) shall not limit Tenant's liability for Base Rent or Additional Rent pursuant to this Lease).

28.3 Landlord shall not be liable for any damages arising from any act, omission or neglect of any other tenant in the Building or the Project, or of any other third party.

28.4 Tenant acknowledges that security devices and services, if any, while intended to deter crime, may not in given instances prevent theft or other criminal acts. Landlord shall not be liable for injuries or losses arising from criminal acts of third parties, and Tenant assumes the risk that any security device or service may malfunction or otherwise be circumvented by a criminal. If Tenant desires protection against such criminal acts, then Tenant shall, at Tenant's sole cost and expense, obtain appropriate insurance coverage. Tenant's security programs and equipment for the Premises shall be coordinated with Landlord and subject to Landlord's reasonable approval.

28.5 The provisions of this Article shall survive the expiration or earlier termination of this Lease.

29. Assignment or Subletting.

29.1 Except as hereinafter expressly permitted, none of the following (each, a "Transfer"), either voluntarily or by operation of Applicable Laws, shall be directly or indirectly performed without Landlord's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed: (a) Tenant selling, hypothecating, assigning, pledging, encumbering or otherwise transferring this Lease or subletting the Premises or (b) a controlling interest in Tenant being sold, assigned or otherwise transferred (other than as a result of shares in Tenant being sold on a public stock exchange). For purposes of the preceding sentence, "control" means (a) owning (directly or indirectly) more than fifty percent (50%) of the stock or other equity interests of another person or (b) possessing, directly or indirectly, the power to direct or cause the direction of the management and policies of such person. Tenant shall have the right to Transfer, without Landlord's prior written consent, Tenant's interest in this Lease or the Premises or any part thereof to (i) any person that as of the date of determination and at all times thereafter directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with Tenant ("Tenant's Affiliate") or (ii) any person or any entity with which Tenant is merged or consolidated, or to which all or substantially all of Tenant's assets or all or substantially all of the ownership interests in Tenant are sold, or which results from a direct spin-off from Generation Bio Co.; provided that (in each instance under the foregoing clauses (i) and (ii)) Tenant shall notify Landlord in writing at least thirty (30) days prior to the effectiveness of such Transfer (an "Exempt Transfer") and otherwise comply with the requirements of this Lease regarding such Transfer; and provided, further, that the person that will be the tenant under this Lease after the Exempt Transfer has a net worth (as of both the day immediately prior to and the day immediately after the Exempt Transfer) that is equal to or greater than the net worth (as of both the Execution Date and the date of the Exempt Transfer) of the transferring Tenant. For purposes of the immediately preceding sentence, "control" requires both (a) owning (directly or indirectly) more than fifty percent (50%) of the stock or other equity interests of another person and (b) possessing, directly or indirectly, the power to direct or cause the direction of the management and policies of such person. In no event shall Tenant perform a Transfer (other than an Exempt Transfer (a) to or with an entity that is a tenant at the Project, unless, upon Tenant's written request, Landlord confirms in writing to Tenant that Landlord does not have available space at the Project or (b) if the proposed transferee is then in active discussions or negotiations with Landlord or an affiliate of Landlord to lease premises at the Project or a property owned by Landlord or an affiliate of Landlord in Cambridge, Massachusetts.

29.2 In the event Tenant desires to effect a Transfer, then, at least thirty (30) but not more than ninety (90) days prior to the date when Tenant desires the Transfer to be effective (the "Transfer Date"), Tenant shall provide written notice to Landlord (the "Transfer Notice") containing information (including references) concerning the character of the proposed transferee, assignee or sublessee; the Transfer Date; the most recent unconsolidated financial statements of Tenant and of the proposed transferee, assignee or sublessee satisfying the requirements of

Section 40.2 ("Required Financials"); any ownership or commercial relationship between Tenant and the proposed transferee, assignee or sublessee; copies of Hazardous Materials Documents for the proposed transferee, assignee or sublessee; and the consideration and all other material terms and conditions of the proposed Transfer, all in such detail as Landlord shall reasonably require. Without limiting any other factors that Landlord may consider in determining whether to withhold, condition or delay its consent to any Transfer in accordance with Section 29.1 of this Lease, Tenant hereby acknowledges and agrees that (a) if Tenant does not deliver to Landlord the most recent consolidated financial statements of Tenant (or if Tenant is not the ultimate parent company, the unconsolidated financial statements of Tenant) and the most recent unconsolidated financial statements of such proposed transferee, then it shall be reasonable for Landlord to withhold its consent to any Transfer to such proposed transferee, (b) if Landlord reasonably determines that the proposed Transfer will diminish the value of Landlord's interest under this Lease, it shall be reasonable for Landlord to withhold its consent to any such Transfer and (c) if Landlord reasonably determines that such proposed Transferee's financial condition is not satisfactory, it shall be reasonable for Landlord to condition its consent to any such Transfer upon the proposed transferee's ultimate parent company providing a guaranty to Landlord of such transferee's obligations under this Lease, in a form acceptable to Landlord, which guaranty shall be executed and delivered to Landlord by the applicable guarantor prior to the Transfer Date, or upon Tenant or the proposed transferee providing other credit enhancements acceptable to Landlord (including without limitation an increased Security Deposit). For purposes of the immediately foregoing clause (c), such transferee's financial condition will be deemed not satisfactory if Landlord determines that such transferee is not capable of satisfying all of the obligations of the Tenant under this Lease.

29.3 Landlord, in determining whether consent should be given to a proposed Transfer, may give consideration to (a) the financial strength of Tenant and of such transferee, assignee or sublessee (notwithstanding Tenant remaining liable for Tenant's performance), (b) any change in use that such transferee, assignee or sublessee proposes to make in the use of the Premises and (c) Landlord's desire to exercise its rights under Section 29.7 to cancel this Lease. In no event shall Landlord be deemed to be unreasonable for declining to consent to a Transfer if any applicable Loan Document prohibits such assignment or any Lender whose consent is required thereunder withholds its consent, or if the Transfer is to a transferee, assignee or sublessee of poor reputation, lacking financial qualifications or seeking a change in the Permitted Use, or jeopardizing directly or indirectly the status of Landlord or any of Landlord's affiliates as a Real Estate Investment Trust under the Internal Revenue Code of 1986 (as the same may be amended from time to time, the "Revenue Code"). Notwithstanding anything contained in this Lease to the contrary, (w) no Transfer shall be consummated on any basis such that the rental or other amounts to be paid by the occupant, assignee, manager or other transferee thereunder would be based, in whole or in part, on the income or profits derived by the business activities of such occupant, assignee, manager or other transferee; (x) Tenant shall not furnish or render any services to an occupant, assignee, manager or other transferee with respect to whom transfer consideration is required to be paid, or manage or operate the Premises or any capital additions so transferred, with respect to which transfer consideration is being paid; (y) Tenant shall not consummate a Transfer with any person in which Landlord owns an interest, directly or indirectly (by applying constructive ownership rules set forth in Section 856(d)(5) of the Revenue Code); and (z) Tenant shall not consummate a Transfer with any person or in any manner that could cause any portion of the amounts received by Landlord pursuant to this Lease or any sublease, license or other arrangement for the right to

use, occupy or possess any portion of the Premises to fail to qualify as "rents from real property" within the meaning of Section 856(d) of the Revenue Code, or any similar or successor provision thereto or which could cause any other income of Landlord to fail to qualify as income described in Section 856(c)(2) of the Revenue Code. Notwithstanding anything in this Lease to the contrary, if (a) any proposed transferee, assignee or sublessee of Tenant has been required by any prior landlord, Lender or Governmental Authority to take material remedial action in connection with Hazardous Materials contaminating a property if the contamination resulted from such party's action or omission or use of the property in question or (b) any proposed transferee, assignee or sublessee is subject to a material enforcement order issued by any Governmental Authority in connection with the use, disposal or storage of Hazardous Materials, then it shall not be unreasonable for Landlord to withhold its consent to any proposed transfer, assignment or subletting (with respect to any such matter involving a proposed transferee, assignee or sublessee).

29.4 The following are conditions precedent to a Transfer or to Landlord considering a request by Tenant to a Transfer:

(a) Tenant shall remain fully liable under this Lease. Tenant agrees that it shall not be (and shall not be deemed to be) a guarantor or surety of this Lease, however, and waives its right to claim that is it is a guarantor or surety or to raise in any legal proceeding any guarantor or surety defenses permitted by this Lease or by Applicable Laws;

(b) [Intentionally omitted];

(c) In the case of an Exempt Transfer, Tenant shall provide Landlord with evidence reasonably satisfactory to Landlord that the Transfer qualifies as an Exempt Transfer;

(d) Tenant shall provide Landlord with evidence reasonably satisfactory to Landlord that the value of Landlord's interest under this Lease shall not be diminished or reduced by the proposed Transfer. Such evidence shall include evidence respecting the relevant business experience and financial responsibility and status of the proposed transferee, assignee or sublessee;

(e) Tenant shall reimburse Landlord for Landlord's actual costs and expenses, including reasonable attorneys' fees, charges and disbursements incurred in connection with the review, processing and documentation of such request;

(f) Except with respect to an Exempt Transfer, if Tenant's transfer of rights or sharing of the Premises provides for the receipt by, on behalf of or on account of Tenant of any consideration of any kind whatsoever (including a premium rental for a sublease or lump sum payment for an assignment, but excluding Tenant's reasonable costs in marketing and subleasing the Premises) in excess of the rental and other charges due to Landlord under this Lease, Tenant shall pay fifty percent (50%) of all of such excess to Landlord, after making deductions for all costs associated with the subject transfer, including any reasonable marketing expenses, tenant improvement funds expended by Tenant, alterations, cash concessions, brokerage commissions, attorneys' fees and free rent actually paid by Tenant. If such consideration consists of cash paid to Tenant, payment to Landlord shall be made upon receipt by Tenant of such cash payment;

(g) The proposed transferee, assignee or sublessee shall agree that, in the event Landlord gives such proposed transferee, assignee or sublessee notice that Tenant is in default under this Lease, such proposed transferee, assignee or sublessee shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments shall be received by Landlord without any liability being incurred by Landlord, except to credit such payment against those due by Tenant under this Lease, and any such proposed transferee, assignee or sublessee shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, that in no event shall Landlord or its Lenders, successors or assigns be obligated to accept such attornment;

(h) Landlord's consent to any such Transfer shall be effected on Landlord's forms, which shall be commercially reasonable;

(i) Tenant shall not then be in default of any monetary obligation or any material non-monetary obligation hereunder in any respect;

(j) Such proposed transferee, assignee or sublessee's use of the Premises shall be the same as the Permitted Use;

(k) Landlord shall not be bound by any provision of any agreement pertaining to the Transfer, except for Landlord's written consent to the same;

(l) Tenant shall pay all transfer and other taxes (including interest and penalties) assessed or payable for any Transfer;

(m) Landlord's consent (or waiver of its rights) for any Transfer shall not waive Landlord's right to consent or refuse consent to any later Transfer;

(n) Tenant shall deliver to Landlord one executed copy of any and all written instruments evidencing or relating to the Transfer; and

(o) Tenant shall deliver to Landlord a list of Hazardous Materials (as defined below), certified by the proposed transferee, assignee or sublessee to be true and correct, that the proposed transferee, assignee or sublessee intends to use or store in the Premises. Additionally, Tenant shall deliver to Landlord, on or before the date any proposed transferee, assignee or sublessee takes occupancy of the Premises, all of the items relating to Hazardous Materials of such proposed transferee, assignee or sublessee as described in Section 21.2.

29.5 Any Transfer that is not in compliance with the provisions of this Article or with respect to which Tenant does not fulfill its obligations pursuant to this Article shall be void and shall, at the option of Landlord, terminate this Lease.

29.6 Notwithstanding any Transfer, Tenant shall remain fully and primarily liable for the payment of all Rent and other sums due or to become due hereunder, and for the full performance of all other terms, conditions and covenants to be kept and performed by Tenant. The acceptance of Rent or any other sum due hereunder, or the acceptance of performance of any other term, covenant or condition thereof, from any person or entity other than Tenant shall not be deemed a waiver of any of the provisions of this Lease or a consent to any Transfer.

29.7 If Tenant delivers to Landlord a Transfer Notice indicating a desire to transfer all or substantially all of the Premises and/or for all or substantially all of the remainder of the Term to a proposed transferee, assignee or sublessee other than pursuant to an Exempt Transfer, then Landlord shall have the option, exercisable by giving notice to Tenant at any time within fifteen (15) business days after Landlord's receipt of such Transfer Notice, to terminate this Lease as of the date specified in the Transfer Notice as the Transfer Date, except for those provisions that, by their express terms, survive the expiration or earlier termination hereof. If Landlord exercises such option, then Tenant shall have the right to withdraw such Transfer Notice by delivering to Landlord written notice of such election within five (5) business days after Landlord's delivery of notice electing to exercise Landlord's option to terminate this Lease. In the event Tenant withdraws the Transfer Notice as provided in this Section, this Lease shall continue in full force and effect. No failure of Landlord to exercise its option to terminate this Lease shall be deemed to be Landlord's consent to a proposed Transfer.

29.8 If Tenant sublets the Premises or any portion thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any such subletting, and appoints Landlord as assignee and attorney-in-fact for Tenant, and Landlord (or a receiver for Tenant appointed on Landlord's application) may collect such rent and apply it toward Tenant's obligations under this Lease; provided that, until the occurrence of a Default (as defined below) by Tenant, Tenant shall have the right to collect such rent.

29.9 In the event that Tenant enters into a sublease for the entire Premises in accordance with this Article that expires within two (2) days of the Term Expiration Date, the term expiration date of such sublease shall, notwithstanding anything in this Lease, the sublease or any consent to the sublease to the contrary, be deemed to be the date that is two (2) days prior to the Term Expiration Date.

30. Subordination and Attornment.

30.1 This Lease shall be subject and subordinate to the lien of any mortgage, deed of trust, or lease in which Landlord is tenant now or hereafter in force against the Building or the Project and to all advances made or hereafter to be made upon the security thereof without the necessity of the execution and delivery of any further instruments on the part of Tenant to effectuate such subordination.

30.2 Notwithstanding the foregoing, Tenant shall execute and deliver upon demand such further instrument or instruments evidencing such subordination of this Lease to the lien of any such mortgage or mortgages or deeds of trust or lease in which Landlord is tenant as may be required by Landlord. If any Lender so elects, however, this Lease shall be deemed prior in lien to any such lease, mortgage, or deed of trust upon or including the Premises regardless of date and Tenant shall execute a statement in writing to such effect at Landlord's request. If Tenant fails to execute any document required from Tenant under this Section within ten (10) business days after written request therefor, it shall be a default hereunder, subject to applicable notice and cure periods. For the avoidance of doubt, "Lenders" shall also include historic tax credit investors and new market tax credit investors.

30.3 Upon written request of Landlord and opportunity for Tenant to review, Tenant agrees to execute any Lease amendments not materially altering the terms of this Lease or increasing Tenant's monetary obligations or materially increasing Tenant's other material nonmonetary obligations hereunder, if required by a Lender incident to the financing of the real property of which the Premises constitute a part.

30.4 In the event any proceedings are brought for foreclosure, or in the event of the exercise of the power of sale under any mortgage or deed of trust made by Landlord covering the Premises, Tenant shall at the election of the purchaser at such foreclosure or sale attorn to the purchaser upon any such foreclosure or sale and recognize such purchaser as Landlord under this Lease.

30.5 Landlord agrees to use commercially reasonable efforts to request from its current Lender of the Property that such Lender enter into its standard subordination, non-disturbance and attornment agreement (the "SNDA") with Tenant. If Lender so agrees to enter into the SNDA, Tenant shall pay the reasonable charges or fees which may be required by such Lender in order to obtain such agreement.

31. Defaults and Remedies.

31.1 Late payment by Tenant to Landlord of Rent and other sums due shall cause Landlord to incur costs not contemplated by this Lease, the exact amount of which shall be extremely difficult and impracticable to ascertain. Such costs include processing and accounting charges and late charges that may be imposed on Landlord by the terms of any mortgage or trust deed covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within three (3) business days after the date such payment is due, Tenant shall pay to Landlord (a) an additional sum of five percent (5%) of the overdue Rent as a late charge plus (b) interest at an annual rate (the "Default Rate") equal to the lesser of (a) twelve percent (12%) and (b) the highest rate permitted by Applicable Laws. The parties agree that this late charge represents a fair and reasonable estimate of the costs that Landlord shall incur by reason of late payment by Tenant and shall be payable as Additional Rent to Landlord due with the next installment of Rent or within five (5) business days after Landlord's demand, whichever is earlier. Landlord's acceptance of any Additional Rent (including a late charge or any other amount hereunder) shall not be deemed an extension of the date that Rent is due or prevent Landlord from pursuing any other rights or remedies under this Lease, at law or in equity.

31.2 No payment by Tenant or receipt by Landlord of a lesser amount than the Rent payment herein stipulated shall be deemed to be other than on account of the Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as Rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or pursue any other remedy provided in this Lease or in equity or at law. If a dispute shall arise as to any amount or sum of money to be paid by Tenant to Landlord hereunder, Tenant shall have the right to make payment "under protest," such payment shall not be regarded as a voluntary payment, and there shall survive the right on the part of Tenant to institute suit for recovery of the payment paid under protest.

31.3 If Tenant fails to pay any sum of money required to be paid by it hereunder or perform any other act on its part to be performed hereunder, in each case within the applicable cure period (if any) described in Section 31.4, then Landlord may (but shall not be obligated to), without waiving or releasing Tenant from any obligations of Tenant, make such payment or perform such act; provided that such failure by Tenant unreasonably interfered with the use of the Building or the Project by any other tenant or with the efficient operation of the Building or the Project, or resulted or could have resulted in a violation of Applicable Laws or the cancellation of an insurance policy maintained by Landlord. Notwithstanding the foregoing, in the event of an emergency, Landlord shall have the right to enter the Premises and act in accordance with its rights as provided elsewhere in this Lease. In addition to the late charge described in Section 31.1, Tenant shall pay to Landlord as Additional Rent all sums so paid or incurred by Landlord, together with interest at the Default Rate, computed from the date such sums were paid or incurred.

31.4 The occurrence of any one or more of the following events shall constitute a "Default" hereunder by Tenant:

(a) If Tenant (i) abandons the Premises; or (ii)(A) Landlord receives notice of Tenant's vacation of or Tenant's intention to vacate the Premises prior to the scheduled expiration or earlier termination of this Lease, other than in accordance with a right expressly granted to Tenant under this Lease, and such vacation (or intention to vacate) is related to financial hardship or Tenant's inability to pay its debts as they become due, a dissolution of Tenant, or the liquidation or winding up of Tenant's business operations; or (B) Tenant vacates the Premises prior to the scheduled expiration or earlier termination of this Lease, other than in accordance with a right expressly granted to Tenant under this Lease, within the one hundred twenty (120) day period following the filing of any involuntary petition against Tenant or the attachment of Tenant's interest in this Lease (notwithstanding anything to the contrary in Sections 31.4(g) and 31.4(i));

(b) Tenant fails to make any payment of Rent, as and when due, or to satisfy its obligations under Article 19, where such failure shall continue for a period of three (3) business days after written notice thereof from Landlord to Tenant;

(c) Tenant fails to observe or perform any obligation or covenant contained herein (other than described in Sections 31.4(a) and 31.4(b)) to be performed by Tenant, where such failure continues for a period of thirty (30) days after written notice thereof from Landlord to Tenant; provided that, if the nature of Tenant's default is such that it reasonably requires more than thirty (30) days to cure, Tenant shall not be deemed to be in Default if Tenant commences such cure within such thirty (30) day period and thereafter diligently prosecutes the same to completion; and provided, further, that such cure is completed no later than ninety (90) days after Tenant's receipt of written notice from Landlord;

(d) Tenant makes an assignment for the benefit of creditors;

(e) A receiver, trustee or custodian is appointed to or does take title, possession or control of all or substantially all of Tenant's assets;

(f) Tenant files a voluntary petition under the United States Bankruptcy Code or any successor statute (as the same may be amended from time to time, the "Bankruptcy Code") or an order for relief is entered against Tenant pursuant to a voluntary or involuntary proceeding commenced under any chapter of the Bankruptcy Code;

(g) Any involuntary petition is filed against Tenant under any chapter of the Bankruptcy Code and is not dismissed within one hundred twenty (120) days;

(h) Tenant fails to deliver an estoppel certificate in accordance with Article 20;

or

(i) Tenant's interest in this Lease is attached, executed upon or otherwise judicially seized and such action is not released within one hundred twenty (120) days of the action.

Notices given under this Section shall specify the alleged default and shall demand that Tenant perform the provisions of this Lease or pay the Rent that is in arrears, as the case may be, within the applicable period of time, or quit the Premises. No such notice shall be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice.

31.5 In the event of a Default by Tenant, and at any time thereafter, with or without notice or demand and without limiting Landlord in the exercise of any right or remedy that Landlord may have, Landlord has the right to do any or all of the following:

(a) Halt any Tenant Improvements or Alterations and order Tenant's contractors, subcontractors, consultants, designers and material suppliers to stop work;

(b) Terminate Tenant's right to possession of the Premises by written notice to Tenant or by any lawful means, in which case Tenant shall immediately surrender possession of the Premises to Landlord. In such event, Landlord shall have the immediate right to re-enter and remove all persons and property, and such property may be removed and stored in a public warehouse or elsewhere at the cost and for the account of Tenant, all without service of notice or resort to legal process and without being deemed guilty of trespass or becoming liable for any loss or damage that may be occasioned thereby; and

(c) Terminate this Lease, in which event Tenant shall immediately surrender possession of the Premises to Landlord. In such event, Landlord shall have the immediate right to re-enter and remove all persons and property, and such property may be removed and stored in a public warehouse or elsewhere at the cost and for the account of Tenant, all without service of notice or resort to legal process and without being deemed guilty of trespass or becoming liable for any loss or damage that may be occasioned thereby. In the event that Landlord shall elect to so terminate this Lease, then Landlord shall be entitled to recover from Tenant all damages incurred by Landlord by reason of Tenant's default, including the sum of:

(i) The worth at the time of award of any unpaid Rent that had accrued at the time of such termination; plus

(ii) The costs of restoring the Premises to the condition required under the terms of this Lease; plus

(iii) An amount (the "Election Amount") equal to either (A) the positive difference (if any, and measured at the time of such termination) between (1) the then-present value of the total Rent and other benefits that would have accrued to Landlord under this Lease for the remainder of the Term if Tenant had fully complied with the Lease minus (2) the then-present cash rental value of the Premises as determined by Landlord for what would be the then-unexpired Term if the Lease remained in effect, computed using the discount rate of the Federal Reserve Bank of San Francisco at the time of the award plus one (1) percentage point (the "Discount Rate") or (B) twelve (12) months (or such lesser number of months as may then be remaining in the Term) of Base Rent and Additional Rent at the rate last payable by Tenant pursuant to this Lease, in either case as Landlord specifies in such election. Landlord and Tenant agree that the Election Amount represents a reasonable forecast of the minimum damages expected to occur in the event of a breach, taking into account the uncertainty, time and cost of determining elements relevant to actual damages, such as fair market rent, time and costs that may be required to re-lease the Premises, and other factors; and that the Election Amount is not a penalty.

As used in Section 31.5(c)(i), "worth at the time of award" shall be computed by allowing interest at the Default Rate.

31.6 In addition to any other remedies available to Landlord at law or in equity and under this Lease, Landlord may continue this Lease in effect after Tenant's Default or abandonment and recover Rent as it becomes due. In addition, Landlord shall not be liable in any way whatsoever for its failure or refusal to relet the Premises. For purposes of this Section, the following acts by Landlord will not constitute the termination of Tenant's right to possession of the Premises:

(a) Acts of maintenance or preservation or efforts to relet the Premises, including alterations, remodeling, redecorating, repairs, replacements or painting as Landlord shall consider advisable for the purpose of reletting the Premises or any part thereof; or

(b) The appointment of a receiver upon the initiative of Landlord to protect Landlord's interest under this Lease or in the Premises.

Notwithstanding the foregoing, in the event of a Default by Tenant, Landlord may elect at any time to terminate this Lease and to recover damages to which Landlord is entitled.

31.7 If Landlord does not elect to terminate this Lease as provided in Section 31.5, then Landlord may, from time to time, recover all Rent as it becomes due under this Lease. At any time thereafter, Landlord may elect to terminate this Lease and to recover damages to which Landlord is entitled.

31.8 In the event Landlord elects to terminate this Lease and relet the Premises, Landlord may execute any new lease in its own name. Tenant hereunder shall have no right or authority whatsoever to collect any Rent from such tenant. The proceeds of any such reletting shall be applied as follows:

(a) First, to the payment of any indebtedness other than Rent due hereunder from Tenant to Landlord, including storage charges or brokerage commissions owing from Tenant to Landlord as the result of such reletting;

(b) Second, to the payment of the costs and expenses of reletting the Premises, including (i) alterations and repairs that Landlord deems reasonably necessary and advisable and (ii) reasonable attorneys' fees, charges and disbursements incurred by Landlord in connection with the retaking of the Premises and such reletting;

(c) Third, to the payment of Rent and other charges due and unpaid hereunder; and

(d) Fourth, to the payment of future Rent and other damages payable by Tenant under this Lease.

31.9 All of Landlord's rights, options and remedies hereunder shall be construed and held to be nonexclusive and cumulative. Landlord shall have the right to pursue any one or all of such remedies, or any other remedy or relief that may be provided by Applicable Laws, whether or not stated in this Lease. No waiver of any default of Tenant hereunder shall be implied from any acceptance by Landlord of any Rent or other payments due hereunder or any omission by Landlord to take any action on account of such default if such default persists or is repeated, and no express waiver shall affect defaults other than as specified in such waiver. Notwithstanding any provision of this Lease to the contrary, in no event shall Landlord be required to mitigate its damages with respect to any default by Tenant, except as required by Applicable Laws. Any such obligation imposed by Applicable Laws upon Landlord to relet the Premises after any termination of this Lease shall be subject to the reasonable requirements of Landlord to (a) lease to high quality tenants on such terms as Landlord may from time to time deem appropriate in its discretion and (b) develop the Project in a harmonious manner with a mix of uses, tenants, floor areas, terms of tenancies, etc., as determined by Landlord. Landlord shall not be obligated to relet the Premises to (y) any Tenant's Affiliate or (z) any party (i) unacceptable to a Lender, (ii) that requires Landlord to make improvements to or re-demise the Premises, (iii) that desires to change the Permitted Use, (iv) that desires to lease the Premises for more or less than the remaining Term or (v) to whom Landlord or an affiliate of Landlord may desire to lease other available space in the Project or at another property owned by Landlord or an affiliate of Landlord.

31.10 Landlord's termination of (a) this Lease or (b) Tenant's right to possession of the Premises shall not relieve Tenant of any liability to Landlord that has previously accrued or that shall arise based upon events that occurred prior to the later to occur of (y) the date of Lease termination and (z) the date Tenant surrenders possession of the Premises.

31.11 To the extent permitted by Applicable Laws, Tenant waives any and all rights of redemption granted by or under any present or future Applicable Laws if Tenant is evicted or dispossessed for any cause, or if Landlord obtains possession of the Premises due to Tenant's default hereunder or otherwise.

31.12 Landlord shall not be in default or liable for damages under this Lease unless Landlord fails to perform obligations required of Landlord within a reasonable time, but in no event shall such failure continue for more than thirty (30) days after written notice from Tenant specifying the nature of Landlord's failure; provided, however, that if the nature of Landlord's obligation is such that more than thirty (30) days are required for its performance, then Landlord shall not be in default if Landlord commences performance within such thirty (30) day period and

thereafter diligently prosecutes the same to completion. If Landlord fails to commence to cure any default by Landlord within the period provided above in this paragraph and if, as a result the default, Tenant is incapable despite commercially reasonable efforts to continue operations within the Premises, Tenant may give Landlord an additional written notice confirming that the default has not been cured and that Tenant intends to cure such default, and, if Landlord fails to cure such default within thirty (30) days after such notice, Tenant may take such steps within the confines of its Premises as are reasonably appropriate to cure the default and seek to recover from Landlord the reasonable cost of such cure. Tenant shall have no right to perform any obligation of Landlord in lieu of Landlord to the extent the same involves or may impact any base building system, any structural element of the Building, or any area of the Building outside of the Premises, including, without limitation, the Common Area or the premises of any other tenant or occupant of the Building (collectively, the "Excluded Systems/Areas"). Landlord's liability to keep, maintain, and repair shall always be limited to the cost of making such repair or accomplishing such maintenance or repair and Landlord shall not be liable for any consequential or any indirect damages. In no event shall Tenant have the right to terminate or cancel this Lease or offset from Rent as a result of Landlord's default. Notwithstanding the above provisions of this Section 31.12 to the contrary, in emergency situations such that the prior written notice to Landlord provided for above is not practical, Tenant may, upon such shorter period of written notice or contemporaneous written and oral notice as is appropriate under the circumstances, and excluding in all instances any work or access to Excluded Systems/Areas, take such steps as are reasonably appropriate to cure the default, in which event Tenant's rights with respect to recovering the cost of such cure shall be as provided above.

31.13 In the event of any default by Landlord, Tenant shall give notice by registered or certified mail to any (a) beneficiary of a deed of trust or (b) mortgagee under a mortgage covering the Premises, the Building or the Project and to any landlord of any lease of land upon or within which the Premises, the Building or the Project is located, and shall offer such beneficiary, mortgagee or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Building or the Project by power of sale or a judicial action if such should prove necessary to effect a cure; provided that Landlord shall furnish to Tenant in writing, upon written request by Tenant, the names and addresses of all such persons who are to receive such notices.

32. Bankruptcy. In the event a debtor, trustee or debtor in possession under the Bankruptcy Code, or another person with similar rights, duties and powers under any other Applicable Laws, proposes to cure any default under this Lease or to assume or assign this Lease and is obliged to provide adequate assurance to Landlord that (a) a default shall be cured, (b) Landlord shall be compensated for its damages arising from any breach of this Lease and (c) future performance of Tenant's obligations under this Lease shall occur, then such adequate assurances shall include any or all of the following, as designated by Landlord in its sole and absolute discretion:

32.1 Those acts specified in the Bankruptcy Code or other Applicable Laws as included within the meaning of "adequate assurance," even if this Lease does not concern a shopping center or other facility described in such Applicable Laws;

32.2 A prompt cash payment to compensate Landlord for any monetary defaults or actual damages arising directly from a breach of this Lease;

32.3 A cash deposit in an amount at least equal to the then-current amount of the Security Deposit; or

32.4 The assumption or assignment of all of Tenant's interest and obligations under this Lease.

33. Brokers.

33.1 Landlord and Tenant each represents and warrants to the other that it has had no dealings with any real estate broker or agent in connection with the negotiation of this Lease other than CBRE | New England ("Broker"), and that it knows of no other real estate broker or agent that is or might be entitled to a commission in connection with this Lease. Landlord shall compensate Broker in relation to this Lease pursuant to a separate agreement between Landlord and Broker.

33.2 Tenant represents and warrants that no broker or agent has made any representation or warranty relied upon by Tenant in Tenant's decision to enter into this Lease, other than as contained in this Lease.

33.3 Tenant acknowledges and agrees that the employment of brokers by Landlord is for the purpose of solicitation of offers of leases from prospective tenants and that no authority is granted to any broker to furnish any representation (written or oral) or warranty from Landlord unless expressly contained within this Lease. Landlord is executing this Lease in reliance upon Tenant's representations, warranties and agreements contained within Sections 33.1 and 33.2.

33.4 Landlord and Tenant each agree to Indemnify, respectively, the Tenant Indemnitees and the Landlord Indemnitees harmless from any and all cost or liability for compensation claimed by any broker or agent, other than Broker, employed or engaged by Landlord and Tenant or claiming to have been employed or engaged by Landlord or Tenant.

34. Definition of Landlord. With regard to obligations imposed upon Landlord pursuant to this Lease, the term "Landlord," as used in this Lease, shall refer only to Landlord or Landlord's then-current successor-in-interest. In the event of any transfer, assignment or conveyance of Landlord's interest in this Lease or in Landlord's fee title to or leasehold interest in the Property, as applicable, Landlord herein named (and in case of any subsequent transfers or conveyances, the subsequent Landlord) shall be automatically freed and relieved, from and after the date of such transfer, assignment or conveyance, from all liability for the performance of any covenants or obligations contained in this Lease thereafter to be performed by Landlord and, without further agreement, the transferee, assignee or conveyee of Landlord's in this Lease or in Landlord's fee title to or leasehold interest in the Property, as applicable, shall be deemed to have assumed and agreed to observe and perform any and all covenants and obligations of Landlord hereunder during the tenure of its interest in the Lease or the Property. Landlord or any subsequent Landlord may transfer its interest in the Premises or this Lease without Tenant's consent.

35. Limitation of Landlord's Liability.

35.1 If Landlord is in default under this Lease and, as a consequence, Tenant recovers a monetary judgment against Landlord, the judgment shall be satisfied only out of (a) the proceeds of sale received on execution of the judgment and levy against the right, title and interest of Landlord in the Building and the Project, (b) rent or other income from such real property receivable by Landlord or (c) the consideration received by Landlord from the sale, financing, refinancing or other disposition of all or any part of Landlord's right, title or interest in the Building or the Project.

35.2 Neither Landlord nor any of its affiliates, nor any of their respective partners, shareholders, directors, officers, employees, members or agents shall be personally liable for Landlord's obligations or any deficiency under this Lease, and service of process shall not be made against any shareholder, director, officer, employee or agent of Landlord or any of Landlord's affiliates. No partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates shall be sued or named as a party in any suit or action, and service of process shall not be made against any partner or member of Landlord except as may be necessary to secure jurisdiction of the partnership, joint venture or limited liability company, as applicable. No partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates shall be required to answer or otherwise plead to any service of process, and no judgment shall be taken or writ of execution levied against any partner, shareholder, director, officer, employee, member or agent of Landlord or any of its affiliates.

35.3 Tenant's directors, officers or employees shall not be personally liable for Tenant's obligations or any deficiency under this Lease. No director, officer or employee of Tenant shall be sued or named as a party in any suit or action, and service of process shall not be made against any director, officer or employee. No director, officer or employee of Tenant shall be required to answer or otherwise plead to any service of process, and no judgment shall be taken or writ of execution levied against any director, officer or employee.

35.4 Each of the covenants and agreements of this Article shall be applicable to any covenant or agreement either expressly contained in this Lease or imposed by Applicable Laws and shall survive the expiration or earlier termination of this Lease.

36. Joint and Several Obligations. If more than one person or entity executes this Lease as Tenant, then:

36.1 Each of them is jointly and severally liable for the keeping, observing and performing of all of the terms, covenants, conditions, provisions and agreements of this Lease to be kept, observed or performed by Tenant, and such terms, covenants, conditions, provisions and agreements shall be binding with the same force and effect upon each and all of the persons executing this Agreement as Tenant; and

36.2 The term "Tenant," as used in this Lease, shall mean and include each of them, jointly and severally. The act of, notice from, notice to, refund to, or signature of any one or more of them with respect to the tenancy under this Lease, including any renewal, extension, expiration, termination or modification of this Lease, shall be binding upon each and all of the persons executing this Lease as Tenant with the same force and effect as if each and all of them had so acted, so given or received such notice or refund, or so signed.

37. Representations. Tenant warrants and represents that (a) Tenant is duly incorporated or otherwise established or formed and validly existing under the laws of its state of incorporation, establishment or formation, (b) Tenant has and is duly qualified to do business in the state in which the Property is located, (c) Tenant has full corporate, partnership, trust, association or other appropriate power and authority to enter into this Lease and to perform all Tenant's obligations hereunder, (d) each person (and all of the persons if more than one signs) signing this Lease on behalf of Tenant is duly and validly authorized to do so and (e) neither (i) the execution, delivery or performance of this Lease nor (ii) the consummation of the transactions contemplated hereby will violate or conflict with any provision of documents or instruments under which Tenant is constituted or to which Tenant is a party. In addition, Tenant represents that Tenant, and to Tenant's current, actual knowledge, its members, shareholders or other equity owners (without duty of inquiry) is not an entity with whom U.S. persons or entities are restricted from doing business under regulations of the Office of Foreign Asset Control ("OFAC") of the Department of the Treasury (including those named on OFAC's Specially Designated and Blocked Persons List) or under any statute, executive order (including the September 24, 2001, Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism) or other similar governmental action. Landlord represents that, to its current, actual knowledge (without duty of inquiry), it is not an entity with whom U.S. persons or entities are restricted from doing business under regulations of OFAC of the Department of the Treasury (including those named on OFAC's Specially Designated and Blocked Persons List) or under any statute, executive order (including the September 24, 2001, Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism) or other similar governmental action.

38. Confidentiality. Tenant shall keep the terms and conditions of this Lease and any information provided to Tenant or its employees, agents or contractors pursuant to Article 9 confidential and shall not (a) disclose to any third party any terms or conditions of this Lease or any other Lease-related document (including subleases, assignments, work letters, construction contracts, letters of credit, subordination agreements, non-disturbance agreements, brokerage agreements or estoppels) or the contents of any documents, reports, surveys or evaluations related to the Project or any portion thereof or (b) provide to any third party an original or copy of this Lease (or any Lease-related document) or another document referenced in Subsection 38(a). Landlord shall not release to any third party any non-public financial information or non-public information about Tenant's ownership structure that Tenant gives Landlord. Notwithstanding the foregoing, confidential information under this Section may be released by Landlord or Tenant under the following circumstances: (x) if required by Applicable Laws or in any judicial proceeding; provided that the releasing party has given the other party reasonable notice of such requirement, if feasible, (y) to a party's attorneys, accountants, brokers, lenders, potential lenders, investors, potential investors and other bona fide consultants or advisers (with respect to this Lease only); provided such third parties agree to be bound by this Section or (z) to bona fide prospective assignees or subtenants of this Lease; provided they agree in writing to be bound by this Section.

39. Notices. Except as otherwise stated in this Lease, any notice, consent, demand, invoice, statement or other communication required or permitted to be given hereunder shall be in writing and shall be given by (a) personal delivery or (b) overnight delivery with a reputable international overnight delivery service, such as FedEx, or (c) email transmission, so long as such transmission is followed within one (1) business day by delivery utilizing one of the methods described in

Subsection 39(a) or (b). Any such notice, consent, demand, invoice, statement or other communication shall be deemed delivered (x) upon receipt, if given in accordance with Subsection 39(a); (y) one (1) business day after deposit with a reputable international overnight delivery service, if given in accordance with Subsection 39(b); or (z) upon transmission, if given in accordance with Subsection 39(c). Except as otherwise stated in this Lease, any notice, consent, demand, invoice, statement or other communication required or permitted to be given pursuant to this Lease shall be addressed to Tenant at the Premises, or to Landlord or Tenant at the addresses shown in Sections 2.9 and 2.10 or 2.11, respectively. Either party may, by notice to the other given pursuant to this Section, specify additional or different addresses for notice purposes.

40. Miscellaneous.

40.1 Landlord reserves the right to change the name of the Building or the Project in its sole discretion.

40.2 To induce Landlord to enter into this Lease, Tenant agrees that it shall promptly furnish to Landlord, from time to time, upon Landlord's written request, the most recent year-end unconsolidated financial statements reflecting Tenant's current financial condition audited by a nationally recognized accounting firm. In addition, upon Landlord's written request, Tenant shall provide copies of its latest quarterly financial reports. Additionally, Tenant shall, within one hundred twenty (120) days after the end of Tenant's financial year, furnish Landlord with Tenant's year-end unconsolidated financial statements for the previous year audited by a nationally recognized accounting firm. Tenant represents and warrants that all financial statements, records and information furnished by Tenant to Landlord in connection with this Lease are true, correct and complete in all respects. If audited financials are not otherwise prepared, unaudited financials complying with generally accepted accounting principles and certified by the chief financial officer of Tenant as true, correct and complete in all respects shall suffice for purposes of this Section. The provisions of this Section shall not apply at any time while Tenant is a corporation whose shares are traded on any nationally recognized stock exchange. If Tenant fails to deliver to Landlord any financial statement within the time period required under this Section, then Tenant shall be required to pay to Landlord an administrative fee equal to Five Hundred Dollars ($500) within ten (10) business days after receiving written notice from Landlord advising Tenant of such failure (provided, however, that Landlord's acceptance of such fee shall not prevent Landlord from pursuing any other rights or remedies under this Lease, at law or in equity).

40.3 Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease or otherwise until execution by and delivery to both Landlord and Tenant.

40.4 The terms of this Lease are intended by the parties as a final, complete and exclusive expression of their agreement with respect to the terms that are included herein, and may not be contradicted or supplemented by evidence of any other prior or contemporaneous agreement.

40.5 Upon the request of either Landlord or Tenant, the parties shall execute a document in recordable form containing only such information as is necessary to constitute a Notice of Lease under Massachusetts law. All costs of preparing and recording such notice shall be borne by the requesting party. Within ten (10) days after receipt of written request from Landlord after the expiration or earlier termination of this Lease, Tenant shall execute a termination of any Notice of Lease recorded with respect hereto. Neither party shall record this Lease.

40.6 Where applicable in this Lease, the singular includes the plural and the masculine or neuter includes the masculine, feminine and neuter. The words “include,” “includes,” “included” and “including” mean “‘include,’ etc., without limitation.” The word “shall” is mandatory and the word “may” is permissive. The section headings of this Lease are not a part of this Lease and shall have no effect upon the construction or interpretation of any part of this Lease. Landlord and Tenant have each participated in the drafting and negotiation of this Lease, and the language in all parts of this Lease shall be in all cases construed as a whole according to its fair meaning and not strictly for or against either Landlord or Tenant.

40.7 Except as otherwise expressly set forth in this Lease, each party shall pay its own costs and expenses incurred in connection with this Lease and such party’s performance under this Lease; provided that, if either party commences an action, proceeding, demand, claim, action, cause of action or suit against the other party arising out of or in connection with this Lease, then the substantially prevailing party shall be reimbursed by the other party for all reasonable costs and expenses, including reasonable attorneys’ fees and expenses, incurred by the substantially prevailing party in such action, proceeding, demand, claim, action, cause of action or suit, and in any appeal in connection therewith (regardless of whether the applicable action, proceeding, demand, claim, action, cause of action, suit or appeal is voluntarily withdrawn or dismissed).

40.8 Time is of the essence with respect to the performance of every provision of this Lease.

40.9 Each provision of this Lease performable by Tenant shall be deemed both a covenant and a condition.

40.10 Notwithstanding anything to the contrary contained in this Lease, Tenant’s obligations under this Lease are independent and shall not be conditioned upon performance by Landlord.

40.11 Whenever consent or approval of either party is required, that party shall not unreasonably withhold, condition or delay such consent or approval, except as may be expressly set forth to the contrary.

40.12 Any provision of this Lease that shall prove to be invalid, void or illegal shall in no way affect, impair or invalidate any other provision hereof, and all other provisions of this Lease shall remain in full force and effect and shall be interpreted as if the invalid, void or illegal provision did not exist.

40.13 Each of the covenants, conditions and agreements herein contained shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs; legatees; devisees; executors; administrators; and permitted successors and assigns. This Lease is for the sole benefit of the parties and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns, and nothing in this Lease shall give or be construed to give any other person or entity any legal or equitable rights. Nothing in this Section shall in any way alter the provisions of this Lease restricting assignment or subletting.

40.14 This Lease shall be governed by, construed and enforced in accordance with the laws of the state in which the Premises are located, without regard to such state's conflict of law principles.

40.15 Each party hereto guarantees, warrants and represents that the individual or individuals signing this Lease have the power, authority and legal capacity to sign this Lease on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

40.16 This Lease may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document. The parties acknowledge and agree that this Lease may be executed via .pdf format (including computer-scanned or other electronic reproduction of the actual signatures) and that delivery of a signature by electronic or physical means shall be effective to the same extent as delivery of an original signature. Notwithstanding the foregoing, originally signed documents shall be provided upon either party's request.

40.17 No provision of this Lease may be modified, amended or supplemented except by an agreement in writing signed by Landlord and Tenant.

40.18 No waiver of any term, covenant or condition of this Lease shall be binding upon Landlord unless executed in writing by Landlord. The waiver by Landlord of any breach or default of any term, covenant or condition contained in this Lease shall not be deemed to be a waiver of any preceding or subsequent breach or default of such term, covenant or condition or any other term, covenant or condition of this Lease.

40.19 To the extent permitted by Applicable Laws, the parties waive trial by jury in any action, proceeding or counterclaim brought by the other party hereto related to matters arising out of or in any way connected with this Lease; the relationship between Landlord and Tenant; Tenant's use or occupancy of the Premises; or any claim of injury or damage related to this Lease or the Premises.

41. Rooftop Installation Area.

41.1 Tenant may use a portion of the Building allocated by Landlord and depicted on Exhibit A (the "Rooftop Installation Area") solely to operate, maintain, repair and replace rooftop antennae, mechanical equipment, communications antennas, a generator, and other equipment installed by Tenant in the Rooftop Installation Area in accordance with this Article ("Tenant's Rooftop Equipment"). Tenant's Rooftop Equipment shall be only for Tenant's use of the Premises for the Permitted Use.

41.2 Tenant shall install Tenant's Rooftop Equipment at its sole cost and expense, at such times and in such manner as Landlord may reasonably designate, and in accordance with this Article and the applicable provisions of this Lease regarding Alterations. Tenant's Rooftop Equipment and the installation thereof shall be subject to Landlord's prior written approval, which approval shall not be unreasonably withheld, delayed or conditioned. Among other reasons, Landlord may withhold approval if the installation or operation of Tenant's Rooftop Equipment could reasonably be expected to damage the structural integrity of the Building or to transmit vibrations or noise or cause other adverse effects beyond the Premises to an extent not customary in first class laboratory buildings, unless Tenant implements measures that are acceptable to Landlord in its reasonable discretion to avoid any such damage or transmission.

41.3 Tenant shall comply with any roof or roof-related warranties. Tenant shall obtain a letter from Landlord's roofing contractor within thirty (30) days after completion of any Tenant work on the rooftop stating that such work did not affect any such warranties. Tenant, at its sole cost and expense, shall inspect the Rooftop Installation Area at least annually, and correct any loose bolts, fittings or other appurtenances and repair any damage to the roof arising from the installation or operation of Tenant's Rooftop Equipment. Tenant shall not permit the installation, maintenance or operation of Tenant's Rooftop Equipment to violate any Applicable Laws or constitute a nuisance. Tenant shall pay Landlord within thirty (30) days after demand (a) all applicable taxes, charges, fees or impositions imposed on Landlord by Governmental Authorities as the result of Tenant's use of the Rooftop Installation Areas in excess of those for which Landlord would otherwise be responsible for the use or installation of Tenant's Rooftop Equipment and (b) the amount of any increase in Landlord's insurance premiums as a result of the installation of Tenant's Rooftop Equipment. Upon Tenant's written request to Landlord, Landlord shall use commercially reasonable efforts to cause other tenants to remedy any interference in the operation of Tenant's Rooftop Equipment arising from any such tenants' equipment installed after the applicable piece of Tenant's Rooftop Equipment; provided, however, that Landlord shall not be required to request that such tenants waive their rights under their respective leases.

41.4 If Tenant's Equipment (a) causes physical damage to the structural integrity of the Building, (b) interferes with any telecommunications, mechanical or other systems located at or near or servicing the Building or the Project that were installed prior to the installation of Tenant's Rooftop Equipment, (c) interferes with any other service provided to other tenants in the Building or the Project by rooftop or penthouse installations that were installed prior to the installation of Tenant's Rooftop Equipment or (d) interferes with any other tenants' business, in each case in excess of that permissible under Federal Communications Commission regulations, then Tenant shall cooperate with Landlord to determine the source of the damage or interference and promptly repair such damage and eliminate such interference, in each case at Tenant's sole cost and expense, within ten (10) business days after receipt of notice of such damage or interference (which notice may be oral; provided that Landlord also delivers to Tenant written notice of such damage or interference within twenty-four (24) hours after providing oral notice).

41.5 Landlord reserves the right to cause Tenant to relocate Tenant's Rooftop Equipment to comparably functional space on the roof or in the penthouse of the Building by giving Tenant prior written notice thereof. Landlord agrees to pay the reasonable costs thereof. Tenant shall arrange for the relocation of Tenant's Rooftop Equipment within sixty (60) days after receipt of Landlord's notification of such relocation. In the event Tenant fails to arrange for relocation within such sixty (60)-day period, Landlord shall have the right to arrange for the relocation of Tenant's Rooftop Equipment in a manner that does not unnecessarily interrupt or interfere with Tenant's use of the Premises for the Permitted Use.

42. Option to Extend Term. Tenant shall have one (1) option (the "Option") to extend the Term by five (5) years with respect to either the entire Fourth Floor Premises or the entire Premises upon the following terms and conditions. Any extension of the Term pursuant to the Option shall be on all the same terms and conditions as this Lease, except as follows:

42.1 Base Rent at the commencement of the Option term shall equal the greater of the then-current Base Rent, or (b) the then-current fair market value for comparable office and laboratory space in the East Cambridge submarket of comparable age, quality, level of finish and proximity to amenities and public transit, and containing the systems and improvements present in the Premises as of the date that Tenant gives Landlord written notice of Tenant's election to exercise the Option. Such fair market value shall be determined for such initial year of the Option term assuming the initial Base Rent shall be subject to 3% annual increases as provided in Section 8 of this Lease (and for the avoidance of doubt, such annual increase is not intended to double count, or to have the Base Rent during the Option term multiplied by an additional 3% in excess of market). Tenant may, no more than eighteen (18) months prior to the date the Term is then scheduled to expire, request Landlord's estimate of the FMV for the Option term. Landlord shall, within fifteen (15) days after receipt of such request, give Tenant a written proposal of such FMV. If Tenant gives written notice to exercise the Option, such notice shall specify whether Tenant accepts Landlord's proposed estimate of FMV. If Tenant does not accept the FMV, then the parties shall endeavor to agree upon the FMV, taking into account all relevant factors, including (v) the size of the Premises, (w) the length of the Option term, (x) rent in comparable buildings in the relevant submarket, including concessions offered to new tenants, such as free rent, tenant improvement allowances and moving allowances, (y) Tenant's creditworthiness and (z) the quality and location of the Building and the Project. In the event that the parties are unable to agree upon the FMV within thirty (30) days after Tenant notifies Landlord that Tenant is exercising the Option, then either party may request that the same be determined as follows: a senior officer of a nationally recognized leasing brokerage firm with local knowledge of the East Cambridge laboratory/research and development leasing submarket (the "Baseball Arbitrator") shall be selected and paid for jointly by Landlord and Tenant. If Landlord and Tenant are unable to agree upon the Baseball Arbitrator, then the same shall be designated by the local chapter of the Judicial Arbitration and Mediation Services or any successor organization thereto (the "JAMS"). The Baseball Arbitrator selected by the parties or designated by JAMS shall (y) have at least ten (10) years' experience in the leasing of laboratory/research and development space in the East Cambridge submarket and (z) not have been employed or retained by either Landlord or Tenant or any affiliate of either for a period of at least ten (10) years prior to appointment pursuant hereto. Each of Landlord and Tenant shall submit to the Baseball Arbitrator and to the other party its determination of the FMV. The Baseball Arbitrator shall grant to Landlord and Tenant a hearing and the right to submit evidence. The Baseball Arbitrator shall determine which of the two (2) FMV determinations more closely represents the actual FMV. The arbitrator may not select any other FMV for the Premises other than one submitted by Landlord or Tenant. The FMV selected by the Baseball Arbitrator shall be binding upon Landlord and Tenant and shall serve as the basis for determination of Base Rent payable for the Option term. If, as of the commencement date of the Option term, the amount of Base Rent payable during the Option term shall not have been determined, then, pending such determination, Tenant shall pay Base Rent equal to the Base Rent payable with respect to the last year of the then-current Term. After the final determination of Base Rent payable for the Option term, the parties shall promptly execute a written amendment to this Lease specifying the amount of Base Rent to be paid during the Option term. Any failure of the parties to execute such amendment shall not affect the validity of the FMV determined pursuant to this Section.

42.2 The Option is not assignable separate and apart from this Lease.

42.3 The Option is conditional upon Tenant giving Landlord written notice of its election to exercise the Option at least fifteen (15) months prior to the end of the expiration of the then-current Term. Time shall be of the essence as to Tenant's exercise of the Option. Tenant assumes full responsibility for maintaining a record of the deadlines to exercise the Option. Tenant acknowledges that it would be inequitable to require Landlord to accept any exercise of the Option after the date provided for in this Section.

42.4 Notwithstanding anything contained in this Article to the contrary, Tenant shall not have the right to exercise the Option:

(a) During the time commencing from the date Landlord delivers to Tenant a written notice that Tenant is in default under any provisions of this Lease and continuing until Tenant has cured the specified default;

(b) At any time after any Default as described in Article 31 of the Lease (provided, however, that, for purposes of this Section 42.4(b), Landlord shall not be required to provide Tenant with notice of such Default other than any notice from Landlord that may be required under Article 31 of this Lease) and continuing until Tenant cures any such Default, if such Default is susceptible to being cured;

(c) In the event that Tenant has defaulted in the performance of its obligation to pay Base Rent, Operating Expenses or the Property Management Fee two (2) or more times during the twelve (12)-month period immediately prior to the date that Tenant intends to exercise the Option, whether or not Tenant has cured such defaults;

(d) In the event that Tenant has been in Default of any material nonmonetary obligations under this Lease or its obligations to pay Additional Rent (excluding Operating Expenses and the Property Management Fee) two (2) or more times during the twelve (12) month period immediately prior to the date that Tenant intends to exercise the Option, whether or not Tenant has cured such defaults; and

(e) At the time Tenant exercises its Option and as of the last day of the initial Term, Tenant has not (i) subleased more than 50% of the Rentable Area of the Premises, and (ii) assigned this Lease, except in connection with an Exempt Transfer.

42.5 The period of time within which Tenant may exercise the Option shall not be extended or enlarged by reason of Tenant's inability to exercise such Option because of the provisions of Section 42.4.

42.6 All of Tenant's rights under the provisions of the Option shall terminate and be of no further force or effect even after Tenant's due and timely exercise of the Option if, after such exercise, but prior to the commencement date of the new term, (a) Tenant fails to pay to Landlord a monetary obligation of Tenant for a period of twenty (20) days after written notice from Landlord to Tenant, (b) Tenant fails to commence to cure a default (other than a monetary default) within thirty (30) days after the date Landlord gives notice to Tenant of such default or (c) Tenant has been in Default under this Lease two (2) or more times and a service or late charge under Section 31.1 has become payable for any such Default, whether or not Tenant has cured such Defaults.

43. Right of First Offer. Subject to any other parties' pre-existing rights with respect to Available ROFO Premises (as defined below), Tenant shall have a one-time right of first offer ("ROFO") as to any rentable premises on the fourth (4th) floor in the Building for which Landlord is seeking a Tenant ("Available ROFO Premises"); provided, however, that in no event shall Landlord be required to lease any Available ROFO Premises to Tenant for any period past the date on which this Lease expires or is terminated pursuant to its terms. To the extent that Landlord renews or extends a then-existing lease with any then-existing tenant or subtenant of any space, or enters into a new lease with such then-existing tenant or subtenant, the affected space shall not be deemed to be Available ROFO Premises. In the event Landlord intends to market and lease Available ROFO Premises (and in any event prior to Landlord's marketing thereof), Landlord shall provide written notice thereof to Tenant (the "Notice of Availability"). The Notice of Availability shall include as Base Rent for the Available ROFO Premises, the then-current fair market value for comparable office and laboratory space in the East Cambridge submarket of comparable age, quality, level of finish and proximity to amenities and public transit, and containing the systems and improvements present in the Premises.

43.1 Within ten (10) business days following its receipt of a Notice of Availability, Tenant shall advise Landlord in writing whether Tenant elects to lease all (not just a portion) of the Available ROFO Premises upon the terms and conditions set forth therein. If Tenant fails to notify Landlord of Tenant's election within such ten (10) business day period, then Tenant shall be deemed to have elected not to lease the Available ROFO Premises.

43.2 If Tenant timely notifies Landlord that Tenant elects to lease all of the Available ROFO Premises upon the terms and conditions set forth in the Notice of Availability ("Tenant's Notice") (provided that Tenant shall be required to lease the Available ROFO Premises for at least the remainder of the then-current Term), then Landlord shall lease the Available ROFO Premises to Tenant upon the terms and conditions set forth in the Notice of Availability, and Tenant's ROFO under this Lease shall expire.

43.3 If (a) Tenant notifies Landlord that Tenant elects not to lease the Available ROFO Premises, or (b) Tenant fails to notify Landlord of Tenant's election within the ten (10) business day period described above, then Landlord shall have the right to consummate a lease of the Available ROFO Premises at base rent not less than ninety-five percent (95%) of that stated in Tenant's Offer, if applicable, and Tenant's ROFO under this Lease shall expire.

43.4 Notwithstanding anything in this Article to the contrary, Tenant shall not exercise the ROFO during such period of time that Tenant is in Default under any provision of this Lease. Any attempted exercise of the ROFO during a period of time in which Tenant is so in Default shall be void and of no effect.

43.5 Notwithstanding anything in this Lease to the contrary, Tenant shall not assign or transfer the ROFO, either separately or in conjunction with an assignment or transfer of Tenant's interest in the Lease, without Landlord's prior written consent (except in connection with an Exempt Transfer), which consent Landlord shall not unreasonably withhold, condition, or delay if such consent is requested in connection with a proposed assignment to an assignee that has the financial capacity and wherewithal to perform the remaining obligations of Tenant under this Lease.

43.6 If Tenant exercises the ROFO, Landlord does not guarantee that the Available ROFO Premises will be available on the anticipated commencement date for the Lease as to such Premises due to a holdover by the then-existing occupants of the Available ROFO Premises or for any other reason beyond Landlord's reasonable control.

43.7 At the time Tenant exercises the ROFO, Tenant shall not have subleased more than thirty percent (30%) of the Premises or assigned this Lease, except in connection with an Exempt Transfer.

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IN WITNESS WHEREOF, the parties hereto have executed this Lease as a sealed Massachusetts instrument as of the date first above written.

LANDLORD:

BMR-ROGERS STREET LLC,
a Delaware limited liability company

By: /s/ William Kane
Name: William Kane
Title: Senior Vice President, East Coast Leasing

TENANT:

GENERATION BIO CO.,
a Delaware corporation

By: /s/ Geoffrey McDonough
Name: Geoffrey McDonough
Title: Chief Executive Officer

FIRST AMENDMENT TO LEASE

THIS FIRST AMENDMENT TO LEASE (this "Amendment") is entered into as of this 12th day of July, 2019 (the "Effective Date"), by and between BMR-ROGERS STREET LLC, a Delaware limited liability company ("Landlord"), and GENERATION BIO CO., a Delaware corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant are parties to that certain Lease dated as of August 2, 2018 (as the same may have been amended, supplemented or modified from time to time, the "Existing Lease"), whereby Tenant leases certain Premises from Landlord located at 301 Binney Street, Cambridge, Massachusetts;

B. WHEREAS, Landlord and Tenant desire to increase the tenant improvement allowance and Base Rent, and substitute the Premises plans attached to the Existing Lease; and

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

AGREEMENT

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

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

45. Base Rent for First Floor Premises. Notwithstanding anything to the contrary set forth in the Existing Lease, from and after the Effective Date, monthly and annual installments of Base Rent for the First Floor Premises as of July 1, 2019 and through the Term of the Lease shall be as set forth in the chart below, which chart shall replace in its entirety the chart set forth in Section 2.4 of the Existing Lease. Furthermore, the provisions of Article 8 of the Existing Lease shall not apply to the Base Rent for the First Floor Premises for the period commencing on July 1, 2019 and ending on April 30, 2029.

Dates	Square Feet of Rentable Area	Base Rent per Square Foot of Rentable Area	Monthly Base Rent	Annual (or Annualized) Base Rent
7/1/2019-7/17/2019	19,310	$ 6.18	$ 9,944.65	$ 5,558.11
7/18/2019-7/17/2020	19,310	$ 89.18 annually	$143,505.48	$1,722,065.80
7/18/2020-7/17/2021	19,310	$ 91.67 annually	$147,512.31	$1,770,147.70
7/18/2021-7/17/2022	19,310	$ 94.23 annually	$151,631.78	$1,819,581.30
7/18/2022-7/17/2023	19,310	$ 96.88 annually	$155,896.07	$1,870,752.80
7/18/2023-7/17/2024	19,310	$ 99.60 annually	$160,273.00	$1,923,276.00
7/18/2024-7/17/2025	19,310	$102.40 annually	$164,778.67	$1,977,344.00
7/18/2025-7/17/2026	19,310	$105.28 annually	$169,413.07	$2,032,956.80
7/18/2026-7/17/2027	19,310	$108.26 annually	$174,208.38	$2,090,500.60
7/18/2027-7/17/2028	19,310	$111.32 annually	$179,132.43	$2,149,589.20
7/18/2028-4/30/2029	19,310	$114.48 annually	$184,217.40*	$2,210,608.80*

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

46. Base Rent for Fourth Floor Premises. Notwithstanding anything to the contrary set forth in the Existing Lease, from and after the Effective Date, monthly and annual installments of Base Rent for the Fourth Floor Premises as of July 1, 2019 and through the Term of the Lease shall be as set forth in the chart below, which chart shall replace in its entirety the chart set forth in Section 2.3 of the Existing Lease. Furthermore, the provisions of Article 8 of the Existing Lease shall not apply to the Base Rent for the Fourth Floor Premises for the period commencing on July 1, 2019 and ending on April 30, 2029.

Dates	Square Feet of Rentable Area	Base Rent per Square Foot of Rentable Area	Monthly Base Rent	Annual (or Annualized) Base Rent
7/1/2019-4/3/2020	52,252	$ 92.18 annually	$401,382.45	$3,639,200.85
4/4/2020-4/3/2021	52,252	$ 94.76 annually	$412,616.63	$4,951,399.52
4/4/2021-4/3/2022	52,252	$ 97.42 annually	$424,199.15	$5,090,389.84
4/4/2022-4/3/2023	52,252	$100.15 annually	$436,086.48	$5,233,037.80
4/4/2023-4/3/2024	52,252	$102.97 annually	$448,365.70	$5,380,388.44
4/4/2024-4/3/2025	52,252	$105.88 annually	$461,036.81	$5,532,441.76
4/4/2025-4/3/2026	52,252	$108.87 annually	$474,056.27	$5,688,675.24
4/4/2026-4/3/2027	52,252	$111.95 annually	$487,467.62	$5,849,611.40
4/4/2027-4/3/2028	52,252	$115.12 annually	$501,270.85	$6,015,250.24
4/4/2028-4/3/2029	52,252	$118.39 annually	$515,509.52	$6,181,877.20
4/4/2029-4/30/2029	52,252	$121.76 annually	$530,183.63*	$6,362,203.52*

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

47. First Floor Additional TI Allowance.

47.1 Notwithstanding the provisions of the Existing Lease, Landlord shall provide to Tenant an additional tenant improvement allowance for additional work to be performed to the First Floor Premises in accordance with the plans attached as Exhibit B to this Amendment (the "Additional First Floor Tenant Improvements") in an amount equal to Two Million Eight Hundred Ninety-Six Thousand Five Hundred and 00/100 Dollars ($2,896,500.00) (based upon One Hundred Fifty and No/100 Dollars ($150.00) per square foot of Rentable Area of the First Floor Premises) (the "Additional First Floor TI Allowance"), which funds shall be available to Tenant upon the Effective Date. Tenant shall, at its sole cost and expense (but subject to the Additional First Floor TI Allowance) cause the Additional First Floor Improvements to be constructed in the First Floor Premises. The Additional First Floor Premises TI Allowance may be applied to the costs of (a) construction, including demising the Premises and submetering, (b) actual out-of-pocket costs incurred in connection with project review by Landlord, (c) commissioning of mechanical, electrical and plumbing systems by a licensed, qualified commissioning agent hired by Tenant, and review of such party's commissioning report by a licensed, qualified

commissioning agent hired by Landlord, (d) space planning, architect, engineering and other related professional or consulting services performed by third parties unaffiliated with, Tenant, (e) building permits and other taxes, fees, charges and levies by Governmental Authorities for permits, approvals or for inspections of the Tenant Improvements, and (f) costs and expenses for labor, material, equipment and fixtures. In no event shall the Additional First Floor TI Allowance be used for (u) the cost of work that is not authorized by the Approved Plans for the Additional First Floor Tenant Improvements or the First Floor Tenant Improvements or otherwise approved in writing by Landlord, (v) payments to Tenant or any affiliates of Tenant, (w) the purchase of any furniture, personal property or other non-building system equipment, (x) costs resulting from any default by Tenant of its obligations under the Lease, (y) costs that are recoverable by Tenant from a third party (e.g., insurers, warrantors, or tortfeasors), or (z) costs related to the Fourth Floor Tenant Improvements. In addition, and in addition to the First Floor A/E Allowance described by Section 4.5 of the Existing Lease, Landlord shall provide an allowance to Tenant to be used solely for architectural and engineering costs related to the First Floor Premises in an amount not to exceed Two Thousand Three Hundred Seventeen and 20/100 Dollars ($2,317.20) (based upon 12/100 Dollars ($0.12) per square foot of Rentable Area for the First Floor Premises) (the "Additional First Floor A/E Allowance"; together with the Additional First Floor TI Allowance, the "Additional First Floor Allowance").

47.2 Tenant shall have until the First Floor TI Deadline to submit Fund Requests (as defined in the Work Letter) to Landlord for disbursement of the unused portion of the Additional First Floor Allowance, after which date Landlord's obligation to fund any such costs for which Tenant has not submitted a Fund Request to Landlord shall expire. In no event shall any unused Additional First Floor Allowance entitle Tenant to a credit against Rent payable under the Lease.

47.3 For the avoidance of doubt, the provisions of the Work Letter shall govern the Additional First Floor Tenant Improvements and the disbursement of the Additional First Floor Allowance, except to the extent that such provisions are directly inconsistent with the provisions of this Amendment. Landlord has previously approved (x) the construction plans for the First Floor Tenant Improvements pursuant to that certain letter dated May 22, 2019 (subject to the conditions set forth therein), and (y) the schedule and budget for the Additional First Floor Tenant Improvements pursuant to that certain letter dated May 23, 2019. Tenant shall submit separate Fund Requests for the Additional First Floor Allowance. As of the Effective Date, the term "Tenant Improvements" as used in the Existing Lease (including the Work Letter) shall be deemed to mean collectively, the Fourth Floor Tenant Improvements, the First Floor Tenant Improvements, and the Additional First Floor Tenant Improvements. The Existing Lease (including the Work Letter) shall be amended to include: (i) the Additional First Floor Tenant Improvements in any reference to the First Floor Tenant Improvements and the Fourth Floor Tenant Improvements, as applicable, and (ii) the Additional First Floor Allowance in any reference to the First Floor Allowance and the Fourth Floor Allowance, as applicable. The Additional First Floor Tenant Improvements shall not constitute a Change to the Tenant Improvements (as such term is defined in Section 2.3 of the Work Letter).

48. Premises. The parties acknowledge and agree that the Premises plans attached to the Existing Lease as Exhibit A are hereby deleted in their entirety and replaced with the plans attached hereto and incorporated herein as Exhibit A.

49. Notices. Tenant confirms that, notwithstanding anything in the Lease to the contrary, notices delivered to Tenant pursuant to the Lease should be sent to:

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

50. Broker. Tenant represents and warrants to Landlord that Tenant has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment other than CBRE, Inc. (the "Broker") and agrees to reimburse, indemnify, save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord, at Tenant's sole cost and expense) and hold harmless the Landlord Parties for, from and against any and all cost or liability for compensation claimed by any such broker or agent employed or engaged by Tenant or claiming to have been employed or engaged by Tenant other than Broker. Landlord represents and warrants to Tenant that Landlord has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment other than Broker and agrees to reimburse, indemnify, save, defend (at Tenant's option and with counsel reasonably acceptable to Tenant, at Landlord's sole cost and expense) and hold harmless the Tenant Parties for, from and against any and all cost or liability for compensation claimed by any such broker or agent employed or engaged by Landlord or claiming to have been employed or engaged by Landlord other than Broker. The parties acknowledge and agree that no commissions are due to Broker based on this Amendment.

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

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

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

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

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

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

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

LANDLORD:

BMR-ROGERS STREET LLC,
a Delaware limited liability company

By: /s/ Kevin M. Simonsen
Name: Kevin M. Simonsen
Title: Sr. VP, General Counsel & Secretary

TENANT:

GENERATION BIO CO.,
a Delaware corporation

By: /s/ Geoffrey McDonough
Name: Geoffrey McDonough
Title: Chief Executive Officer

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE (this "Amendment") is entered into as of this 17th day of June, 2020 (the "Effective Date"), by and between BMR-ROGERS STREET LLC, a Delaware limited liability company ("Landlord"), and GENERATION BIO CO., a Delaware corporation ("Tenant").

RECITALS

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

B. WHEREAS, Tenant has requested and Landlord has agreed to switch a portion of shaft space within the Premises in the shaft identified on the Premises plans as "W25" with another tenant in the Building, and to substitute the Premises plans attached to the Existing Lease accordingly; and

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

AGREEMENT

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

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

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

3. Notices. Tenant confirms that, notwithstanding anything in the Lease to the contrary, notices delivered to Tenant pursuant to the Lease should be sent to:

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

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

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

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

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

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

9. Counterparts; Facsimile and PDF Signatures. This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the

same document. A portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

[Remainder of page intentionally left blank]

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

LANDLORD:

BMR-ROGERS STREET LLC,
a Delaware limited liability company

By: /s/ Colleen O'Connor
Name: Colleen O'Connor
Title: Vice President, East Coast and U.K. Markets

TENANT:

GENERATION BIO CO.,
a Delaware corporation

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

By Electronic Mail

July 6, 2020

Matthew Norkunas
***
***

RE: Offer of Employment

Dear Matthew:

We are very excited to offer you the position of Chief Financial Officer where you will play an essential role in building Generation Bio's foundation and long-term business and scientific success. Below are the terms of employment for your review and execution. If these terms are acceptable, please sign and return a copy to us within five business days.

Position: Your initial position with Generation Bio will be as Chief Financial Officer where you will be initially reporting to Chief Executive Officer. This is a full-time position with a principal workplace at Generation Bio's headquarters in Cambridge, Massachusetts. In this role you will be responsible for Generation Bio's finance function, leading our financial and capital strategy and helping to shape our strategic planning, capital-raising, and corporate development activities, as well as other related activities as directed by the Company from time to time. 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 and officer of the Company, and shall not engage in any other employment, consulting or other business activity without the prior written consent of the Company. Please review and sign the attached job description, which provides additional details about the position.

1. **Start Date:** Your employment will begin on July 22, 2020 (the "Start Date").

2. **Salary:** Generation Bio will pay you an annual Base Salary of $400,000, payable in accordance with Generation Bio's standard payroll schedule and subject to applicable deductions and withholdings. This salary will be subject to periodic review and adjustments at Generation Bio's discretion. Because this is an exempt position, you will not be eligible for any overtime pay.

3. **Bonus:** During the term of your employment with Generation Bio, you will be eligible for an annual incentive bonus ("Bonus") for each fiscal year of your employment with Generation Bio. The amount, terms and conditions of such bonus are to be determined at the sole discretion of the Board of Directors of Generation Bio (the "Board"), and such terms may be changed and conditions may be changed at any time with or without notice to you. Your target annual Bonus shall be up to 40% of your annual salary. Your actual Bonus percentage is discretionary and will be subject to Generation Bio's assessment of your performance as well as the performance of Generation Bio during the applicable

fiscal year. Any Bonus payable for the year in which you begin working for the Company shall be prorated based on your Start Date. Payment of the Bonus shall be contingent upon you being employed by Generation Bio as of the last day of the fiscal year in which it was earned. The annual Bonus, if any, shall be paid on or before March 15th of the calendar year following the fiscal year for which such Bonus is earned.

In addition, the Company will pay you a $70,000 one-time bonus within one month of your start date less appropriate payroll taxes. The bonus is deemed fully earned after twelve (12) months of active employment. Should you leave the company for any reason, voluntarily or involuntarily other than due to your termination by the Company without cause or your death, before you have completed twelve (12) months of active employment, 100% of the bonus is required to be repaid. Any repayment must be made on or before your final date of active employment and shall be by certified check to the Company or may be deducted from your final payroll.

4. **Incentive Equity Grant:** You will be eligible to participate in the Company's stock incentive program. Subject to the approval of the Board, you will be granted options to purchase 330,000 shares of Generation Bio's common stock (the "Option Grant"). The options subject to the Option Grant ("Options") 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. 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.

5. **Benefits:** You may participate in the benefit programs offered by the Company to its employees, 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 and sick leave each year in accordance with the terms and conditions set forth in the Company's policies. You will also be entitled to receive reimbursement for all reasonable business expenses incurred by you in performing your services to the Company in keeping with Company policies. In addition, you may be eligible for other benefits offered by the Company as set forth in the Employee Guide, which can be accessed on the Company's intranet portal.

6. **Accrued Obligations:** If your employment terminates for any reason, including for Cause or as a result of Involuntary Termination, the Company will pay you the Accrued Obligations earned through your last day of employment (the "Separation Date") on or before the time required by law or applicable policy, except to the extent any such payments would accelerate compensation in a manner inconsistent with compliance with Section 409A of the Internal Revenue Code of 1986, as amended (the "Code").

7. **Severance Benefits:** If you are subject to an Involuntary Termination, in addition to the Accrued Obligations, you will be eligible to receive severance benefits as described under Sections 2(A) or (B) below, as applicable ("Severance Benefits"), provided you have: (i) returned all Company property in your possession on or prior to the Separation Date, (ii) resigned as a member of the Board of Directors of the Company (the "Board") or of any subsidiary of the Company, to the extent you are then a Director of the Company or of any such subsidiary, and (iii) entered into a separation agreement that has become enforceable and irrevocable and includes a general release of all claims you may have against the Company or persons affiliated with the Company (the "Separation Agreement"). Notwithstanding the foregoing, except as set forth in Section 8(B)(iv), no term of this Agreement or the Separation Agreement shall impact or affect in any way your rights with respect to, and the Separation Agreement shall not include a waiver or release of any claims related to: (x) your status as a stockholder or equity holder of the Company or any rights you have under the terms of any equity award agreement between you and the Company, including any claims with respect to any options or other equity awards owned or held by you at the time your employment is terminated, or (y) any rights to indemnification from the Company, pursuant to any applicable governing documents of the Company or any applicable written agreement between you and the Company, rights under ERISA or rights which, as a matter of law, cannot be waived. The Separation Agreement, in a form to be provided to you by the Company, must be executed and become enforceable and irrevocable within 52 days following the Separation Date, or such shorter period of time prescribed by the Company (the date by which the Separation Agreement must become enforceable and irrevocable, the "Prescribed Deadline"). If the Separation Agreement is not executed or is executed but has not become enforceable and irrevocable by the Prescribed Deadline, you shall be entitled to the Accrued Obligations only and not to any Severance Benefits. Any Severance Benefits shall be paid, or begin to be paid, in the first regular payroll beginning after the Separation Agreement becomes enforceable and irrevocable, provided that if the foregoing 52-day period begins in the year in which your Separation Date occurs and ends in the following year, the Company will not make any payments before the first payroll date falling after the later of (A) January 1 of the year following the year in which your Separation Date occurs and (B) the date on which Separation Agreement becomes enforceable and irrevocable (the date the Severance Benefits are paid or commence pursuant to this sentence, the "Payment Date"). The first payroll shall include, however, all amounts that would otherwise have been paid to you between the Separation Date and your receipt of the first payment.

   A. Involuntary Termination Prior to or More than 12 months Following a Change in Control In the event of your Involuntary Termination prior to or more than 12 months following a Change in Control, you are eligible to receive the following Severance Benefits:

      i. Salary. The Company shall continue to pay you your base salary as in effect on the Separation Date for a period of nine (9) months, payable in accordance with the Company's standard payroll schedule;

ii. Bonus Payment. The Company may pay you an amount determined by reference to your target annual incentive bonus for the year in which the Separation Date occurs, based on Company and individual performance for such year, as determined by the Board in its sole discretion, and pro-rated based on the number of days you were employed by the Company in such year, which payment (if any) will be paid to you in a single lump sum amount on the later of (1) the Payment Date or (2) the date on which bonuses are paid to other executives of the Company but no later than two and one-half (2.5) months following the end of the year in which the Separation Date occurs; and

iii. Health Insurance. If you are participating in the Company's group health plan immediately prior to the Separation Date and you are eligible for and timely elect COBRA health and dental continuation, then the Company will continue to pay the share of the premium the Company would have paid to provide health and dental coverage to you and your eligible dependents if you had remained employed by the Company for a period ending on the earlier of the date that is nine (9) months following the Separation Date or the date COBRA eligibility ends, as such premiums become due, provided that the Company's payment for COBRA coverage shall only apply if and while permitted under applicable tax or other laws as nondiscriminatory.

B. Involuntary Termination On or Within 12 Months Following a Change in Control

In the event of your Involuntary Termination on or within 12 months following a Change in Control (including the one-year anniversary thereof), you are eligible to receive the following Severance Benefits:

i. Salary. The Company shall pay you a lump sum amount on the Payment Date equal to twelve (12) months of your base salary as in effect on the Separation Date;

ii. Bonus Payment. The Company shall pay you a lump sum amount on the Payment Date equal to your target annual incentive bonus for the year in which your Separation Date occurs;

iii. Health Insurance. If you are participating in the Company's group health plan immediately prior to the Separation Date and you are eligible for and timely elect COBRA health and dental continuation, then the Company will continue to pay the share of the premium the Company would have paid to provide health and dental coverage to you and your eligible dependents if you had remained employed by the Company for a period ending on the earlier of the date that is twelve (12) months following the Separation Date or the date COBRA eligibility ends, as such premiums become due, provided that the Company's payment for COBRA coverage shall only apply if and while permitted under applicable tax or other laws as nondiscriminatory; and iv. Equity. One hundred percent (100%) of the unvested portion of any then-outstanding Equity Grant shall vest and become fully exercisable or non-forfeitable as of the Separation Date, provided however, that:

a. no such acceleration shall be effective until the Separation Agreement has become enforceable and irrevocable; and

b. if the Separation Agreement does not become enforceable and irrevocable, the portions of the Equity Grants that would have vested as a result of this provision shall not vest and shall be treated in accordance with the terms and conditions of the applicable award agreement.

8. **Representation Regarding Other Obligations.** Your employment is contingent upon your signing the Company's Invention, Non-Disclosure, Non-Competition and Non-Solicitation Agreement (the "Non-Disclosure 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 represent and agree that you will not disclose to the Company, use, 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 postemployment obligations to any former employer.

9. Taxes

A. Withholding.

All forms of compensation referred to in this 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. Payments Subject to Section 409A.

Notwithstanding anything to the contrary in this Agreement, no severance payments that may be due under this Agreement may begin prior to the date of your Separation (determined as set forth below) which may occur on or after the termination of your employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to you under this Agreement, as applicable:

i. It is intended that each installment of the severance payments provided under this Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Code ("Section 409A"). Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

ii. If, as of the date of your Separation from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in this Agreement.

iii. If, as of the date of your Separation from the Company, you are a "specified employee" (within the meaning of Section 409A), then:

1. Each installment of the severance payments due under this Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when your Separation occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth this Agreement; and

2. Each installment of the severance payments due under this Agreement that is not described in this Section 3(B)(iii)(1) and that would, absent this subsection, be paid within the six-month period following your Separation from the Company shall not be paid until the date that is six months and one day after such Separation (or, if earlier, as soon as practicable following your death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following your Separation and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the Separation occurs.

The determination of whether and when your Separation from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Section 10, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in this letter agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

The Company makes no representation or warranty and shall have no liability to you or to any other person if any of the provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

10. **Interpretation, Amendment and Enforcement.** This offer letter, along with the Non-Disclosure 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.

11. **Other Terms.** This offer 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, except as may be required by, and subject to the conditions set forth in, Section 8. You have the right to consult with counsel before signing this offer letter.

12. **Definitions**: The following terms have the meaning set forth below wherever they are used in this letter:

a. “Accrued Obligations” means: (i) any earned but unpaid base salary as of the Separation Date, (ii) any accrued, but unused vacation time as of the Separation Date, (iii) any vested benefits you may have under any employee benefit plan of the Company as of the Separation Date in accordance with the terms of the applicable benefit plan, (iv) any unpaid expense reimbursements accrued prior to the Separation Date for which you have timely submitted appropriate documentation in accordance with Company policy, and (v) any unpaid but earned bonus approved by the Board for a fiscal year preceding the year in which your employment is terminated.

b. “Cause” means (i) your material breach of the Non-Disclosure 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 the Company, 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; provided, however, that “Cause” shall not be deemed to have occurred pursuant to subsection (iii), (iv), or (v) hereof unless you have first received written notice from the Company specifying in reasonable detail the particulars of such grounds and that the Company intends to terminate your employment hereunder for such grounds, and you have failed to cure such grounds to the Company’s satisfaction within a period of thirty (30) days from the date of such notice.

c. “Change in Control” means the occurrence of any one or more of the following events, in each case only to the extent that such event also constitutes a “change in ownership” of the Company or a “change in the ownership of a substantial part of the Company’s assets” for the purposes of Section 409A: (i) the consummation of a merger or consolidation of the Company with any other entity, other than a merger or consolidation in which voting securities of the Company outstanding immediately prior thereto continue to represent more than fifty percent (50%) percent of the total voting power entitled to vote generally in the election of directors: (A) the surviving or resulting corporation; or (B) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation immediately after such merger or consolidation; (ii) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (a “Person”) of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the total voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors; provided, however, that for purposes of this subsection (ii), the following acquisitions shall not constitute a Change in Control: (A) any acquisition directly from the Company or (B) any acquisition by any corporation pursuant to a merger or consolidation which falls within the exception provided in subsection (i) above; or (iii) the sale, transfer or exclusive license of all or substantially all of the assets of the Company.

d. “Involuntary Termination” means either (i) your Termination Without Cause, or (ii) your Resignation for Good Reason.

e. “Resignation for Good Reason” means a Separation as a result of your resignation within three (3) months after one of the following conditions has come into existence without your consent: (i) a reduction in your base salary by more than 10% (unless such reduction is part of a broad-based salary reduction program at the Company); (ii) a material diminution of your authority, duties or responsibilities; or (iii) a relocation of your principal workplace by more than forty (40) miles.

A Resignation for Good Reason will not be deemed to have occurred unless you give the Company written notice of the condition within thirty (30) days after the condition comes into existence and the Company fails to remedy the condition within thirty (30) days after receiving your written notice.

f. “Separation” means a “separation from service,” as defined in the regulations under Section 409A.

g. “Termination Without Cause” means a Separation as a result of a termination of your employment by the Company without Cause, provided you are willing and able to continue performing services within the meaning of Treasury Regulation 1.409A-1(n)(1).

13. General Provisions

A. Severability. If any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement shall remain be valid and enforceable to the fullest extent permitted under applicable law.

B. Jurisdiction. You and the Company hereby agree that the state and federal courts in the Commonwealth of Massachusetts shall have the exclusive jurisdiction to consider any matters related to this Agreement, including without limitation any claim of a violation of this Agreement. With respect to any such court action, you submit to the jurisdiction of such courts and you acknowledge that venue in such courts is proper.

C. Governing Law; Interpretation. This Agreement shall be interpreted and enforced under the laws of the Commonwealth of Massachusetts, without regard to conflict of law principles. In the event of any dispute, this Agreement is intended by the parties to be construed as a whole, to be interpreted in accordance with its fair meaning, and not to be construed strictly for or against either you or the Company or the “drafter” of all or any portion of this Agreement.

D. Entire Agreement. This Agreement shall be effective as of the date first set forth above. This Agreement constitutes the entire agreement between you and the Company with respect to the subject matter herein. This Agreement supersedes any previous agreements or understandings between you and the Company with respect to the subject matter herein, except for the Non-Disclosure Agreement, which remain in full force and effect.

We are excited about welcoming you to the Generation Bio team. We are eager to add your talent and energy to building a company capable of transforming patients’ lives around the world. This offer is valid for five business days from the date of this letter; we look forward to receiving a response from you acknowledging, by signing below, that you have accepted this offer of employment.

Very truly yours,

Generation Bio Co.

By: /s/ Geoff McDonough

Name: Geoff McDonough
Title: Chief Executive Officer

I have read and accept this employment offer

/s/ Matthew Norkunas
Signature

Name: Matthew Norkunas

Dated: July 6, 2020

Exhibit 31.1

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

I, Geoff McDonough, hereby certify that:

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2020

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

Exhibit 31.2

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

I, Matthew Norkunas, hereby certify that:

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2020

/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 fiscal quarter ended June 30, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Generation Bio Co.

/s/ Geoff McDonough
Geoff McDonough, M.D.
President and Chief Executive Officer
(Principal Executive Officer)
August 11, 2020

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 fiscal quarter ended June 30, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Generation Bio Co.

/s/ Matthew Norkunas
Matthew Norkunas, M.D., M.B.A.
Chief Financial Officer
(Principal Financial and Accounting Officer)
August 11, 2020