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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED June 30, 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 001-38501

BLACK DIAMOND THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	81-4254660
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
139 Main Street Cambridge, Massachusetts **(Address of principal executive offices)**	02142 **(Zip Code)**

(617) 252-0848

(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, par value $0.0001	BDTX	The Nasdaq Global Select Market

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

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

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

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

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

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

As of August 5, 2020, the registrant had 35,912,705 shares of common stock, $0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "intends", "plans", "anticipates", "believes", "estimates", "predicts", "potential", "continue" or the negative of these terms or other comparable terminology. These statements are not guarantees of future results or performance and involve substantial risks and uncertainties. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials and investigational new drug applications, or IND, and other regulatory submissions;
- our ability to obtain and maintain regulatory approval for BDTX-189 or any of our other current or future product candidates that we may identify or develop;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to identify future product candidates for treatment of additional disease indications;
- our ability to develop our current product candidates for the treatment of various cancers;
- the rate and degree of market acceptance and clinical utility for any current or future product candidates we may develop;
- the effects of competition with respect to BDTX-189 or any of our other current or future product candidates, as well as innovations by current and future competitors in our industry;
- the implementation of our strategic plans for our business, any product candidates we may develop and our MAP platform;
- our ability to successfully develop companion diagnostics for use with our current or future product candidates;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering our product candidates and MAP platform;
- our ability to use the proceeds of our initial public offering in ways that increase the value of your investment;
- our ability to obtain additional funding for our operations, when needed, including funding necessary to complete further development and commercialization of our product candidates, if approved, and to further expand our MAP platform;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance and our ability to effectively manage our anticipated growth;
- our estimates regarding the market opportunities for our product candidates;
- our ability to remediate our existing material weaknesses and to maintain an effective system of internal controls;
- the ultimate impact of the current coronavirus pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole; and
- other risks and uncertainties, including those discussed in Part II, Item 1A, "Risk Factors" in this Quarterly Report.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, “Risk Factors” and elsewhere in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

All of our forward-looking statements are as of the date of this Quarterly Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report that modify or impact any of the forward-looking statements contained in this Quarterly Report will be deemed to modify or supersede such statements in this Quarterly Report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

BLACK DIAMOND THERAPEUTICS, INC.

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We have applied for various trademarks that we use in connection with the operation of our business. This Quarterly Report may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this Quarterly Report is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Quarterly Report may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner of these trademarks, service marks and trade names will not assert, to the fullest extent under applicable law, its rights.

From time to time, we may use our website or our LinkedIn profile at www.linkedin.com/company/black-diamond-therapeutics to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.blackdiamondtherapeutics.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our LinkedIn page is not incorporated into, and does not form a part of, this Quarterly Report.

Part I - FINANCIAL INFORMATION

Item I. Condensed Consolidated Financial Statements (Unaudited)

Black Diamond Therapeutics, Inc.
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	As of	
	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 63,984	$ 154,666
Short-term investments	140,505	—
Prepaid expenses and other current assets	3,756	1,048
Total current assets	208,245	155,714
Equipment, net	166	164
Restricted cash	55	55
Deferred offering costs	—	2,303
Right-of-use asset	382	—
Long-term investments	140,522	—
Other non-current assets	80	59
Total assets	$ 349,450	$ 158,295
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 45	$ 1,964
Amounts due to related party	15	—
Accrued expenses and other current liabilities	6,079	2,899
Total current liabilities	6,139	4,863
Derivative liabilities	—	16
Non-current operating lease liability	186	—
Total liabilities	6,325	4,879
Commitments and contingencies (Note 11)	—	—
Convertible preferred stock (Note 7)	—	200,573
Stockholders' equity (deficit):		
Common stock; $0.0001 par value; 500,000,000 shares authorized at June 30, 2020 and 80,000,000 shares authorized at December 31, 2019; 35,910,705 shares issued and outstanding at June 30, 2020 and 2,236,672 shares issued and outstanding at December 31, 2019	5	1
Additional paid-in capital	419,794	3,812
Accumulated other comprehensive income	1,012	—
Accumulated deficit	(77,686)	(50,970)
Total stockholders' equity (deficit)	343,125	(47,157)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 349,450	$ 158,295

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

Black Diamond Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development (inclusive of $223, $3,077, $2,103 and $5,017 respectively, with a related party)	$ 10,170	$ 5,646	$ 17,524	$ 8,659
General and administrative (inclusive of $0, $170, $0 and $181 respectively, with a related party)	4,858	1,353	10,383	2,181
Total operating expenses	15,028	6,999	27,907	10,840
Loss from operations	(15,028)	(6,999)	(27,907)	(10,840)
Other income (expense):				
Interest expense	(1)	—	(1)	—
Interest income	881	9	1,625	20
Change in fair value of derivative liabilities	—	(5,300)	—	(5,300)
Other (expense) income	(423)	3	(433)	5
Total other income (expense), net	457	(5,288)	1,191	(5,275)
Net loss attributable to common stockholders	$ (14,571)	$ (12,287)	$ (26,716)	$ (16,115)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.41)	$ (5.99)	$ (0.92)	$ (7.86)
Weighted average common shares outstanding, basic and diluted	35,910,718	2,052,056	29,804,987	2,048,239
Comprehensive loss:				
Net loss	$ (14,571)	$ (12,287)	$ (26,716)	$ (16,115)
Other comprehensive income:				
Unrealized gains on investments	1,012	—	1,012	—
Comprehensive loss	$ (13,559)	$ (12,287)	$ (25,704)	$ (16,115)

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

Black Diamond Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (26,716)	$ (16,115)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,296	283
Change in fair value of derivative liabilities	—	5,300
Depreciation expense	23	25
Accretion of discount on investments	(400)	—
Noncash rent expense	94	—
Changes in current assets and liabilities:		
Prepaid expenses and other current assets	(2,708)	(302)
Other non-current assets	(21)	(15)
Accounts payable	(1,359)	270
Amounts due to related party	15	(1,637)
Accrued expenses and other current liabilities	2,994	313
Non-current operating lease liability	(104)	—
Net cash used in operating activities	(24,886)	(11,878)
Cash flows from investing activities:		
Purchases of equipment	(25)	(8)
Purchases of investments	(279,615)	—
Net cash used in investing activities	(279,640)	(8)
Cash flows from financing activities:		
Proceeds from initial public offering, net of issuance costs of $1,275	213,844	—
Payment of deferred offering costs	—	(70)
Net cash provided by (used in) financing activities	213,844	(70)
Net decrease in cash and cash equivalents	(90,682)	(11,956)
Cash, cash equivalents and restricted cash, beginning of period	154,721	51,660
Cash, cash equivalents and restricted cash, end of period	$ 64,039	$ 39,704
Cash and cash equivalents, end of period	$ 63,984	$ 39,649
Restricted cash, end of period	55	55
Cash, cash equivalents and restricted cash, end of period	$ 64,039	$ 39,704
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of preferred stock into common stock upon closing of initial public offering	$ 200,573	$ —
Reclassification of warrants to additional paid-in capital	$ 16	$ —

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

Black Diamond Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit) (Unaudited)
(in thousands, except share data)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Par Value				
BALANCE - December 31, 2018	33,668,075	$ 60,770	2,173,684	$ 1	$ 169	$ —	$ (15,712)	$ (15,542)
Grant of restricted common stock awards	—	—	46,416	—	—	—	—	—
Stock-based compensation	—	—	—	—	91	—	—	91
Net loss	—	—	—	—	—	—	(3,828)	(3,828)
BALANCE - March 31, 2019	33,668,075	60,770	2,220,100	1	260	—	(19,540)	(19,279)
Grant of restricted common stock awards	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	192	—	—	192
Net loss	—	—	—	—	—	—	(12,287)	(12,287)
BALANCE - June 30, 2019	33,668,075	60,770	2,220,100	1	452	—	(31,827)	(31,374)
BALANCE - December 31, 2019	64,839,353	$ 200,573	2,236,672	$ 1	$ 3,812	$ —	$ (50,970)	$ (47,157)
Conversion of preferred stock to common stock upon closing of the initial public offering	(64,839,353)	(200,573)	21,499,770	3	200,570	—	—	200,573
Issuance of common stock, net of issuance costs	—	—	12,174,263	1	212,100	—	—	212,101
Reclassification of warrants to additional paid-in capital	—	—	—	—	16	—	—	16
Stock-based compensation	—	—	—	—	1,877	—	—	1,877
Net loss	—	—	—	—	—	—	(12,145)	(12,145)
BALANCE - March 31, 2020	—	—	35,910,705	5	418,375	—	(63,115)	355,265
Stock-based compensation	—	—	—	—	1,419	—	—	1,419
Unrealized gains on investments	—	—	—	—	—	1,012	—	1,012
Net loss	—	—	—	—	—	—	(14,571)	(14,571)
BALANCE - June 30, 2020	—	$ —	35,910,705	$ 5	$ 419,794	$ 1,012	$ (77,686)	$ 343,125

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

Black Diamond Therapeutics, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)
(Amounts in thousands, except share and per share amounts)

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Black Diamond Therapeutics, Inc. (the "Company") is a precision oncology medicine company pioneering the discovery and development of small molecule, tumor-agnostic therapies. The Company was originally organized as a limited liability company in December 2014 under the name ASET Therapeutics LLC. In September 2016, the Company was converted to a corporation under the laws of the State of Delaware under the name ASET Therapeutics, Inc. The Company changed its name to Black Diamond Therapeutics, Inc. in January 2018. Since its inception, the Company has devoted substantially all of its efforts to raising capital, obtaining financing, and incurring research and development costs related to the development of its mutation, allostery, and pharmacology computational and discovery platform.

The Company is subject to risks and uncertainties common to early stage companies in the biotechnology industry. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any products, if approved, will be commercially viable. The Company operates in an environment of rapid technological innovation and substantial competition from pharmaceutical and biotechnological companies. In addition, the Company is dependent upon the services of its employees, consultants and service providers including a related party Ridgeline Therapeutics GmbH ("Ridgeline"). Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On January 21, 2020, the Company effected a 1-for-3.01581 reverse stock split of the Company's common stock. All shares, stock options, warrants and per share information presented in the condensed consolidated financial statements have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented. There was no change in the par value of the Company's common stock.

On February 3, 2020, the Company completed an initial public offering (the "IPO") of 12,174,263 shares of its common stock, including the exercise in full by the underwriters of their option to purchase up to 1,587,947 additional shares of common stock, for aggregate gross proceeds of $231,311 and its shares started trading on The Nasdaq Global Select Market under the ticker symbol "BDTX." The Company received $212,101 in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. Upon closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 21,499,770 shares of common stock.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. Historically, the Company has funded its operations primarily with proceeds from the sale of convertible preferred stock. The Company expects to continue to generate operating losses for the foreseeable future.

As of August 11, 2020, the issuance date of the condensed consolidated financial statements, the Company expects that its cash, cash equivalents and investments will be sufficient to fund its operating expenses and capital requirements into 2023.

The Company may seek additional funding through private or public equity financings, debt financings, collaborations, strategic alliances and marketing, distribution 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 collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. 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, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. Although management continues 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, if at all.

The ongoing global outbreak of the novel coronavirus disease (“COVID-19”), which began in December 2019 and has spread worldwide, has resulted, and will likely continue to result, in significant governmental measures being implemented to control the spread of the virus through quarantines, travel restrictions, heightened border security and other measures. While the Company cannot predict the scope and severity, these developments and measures have resulted, and will likely continue to result, in disruptions to our business, results of operations and financial condition. The Company is closely monitoring the impact of the COVID-19 pandemic on all aspects of the Company’s business and has taken steps to minimize its impact on the business. In response to these public health directives and orders and to help minimize the risk of the virus to our employees, the Company has taken precautionary measures, including implementing work-from-home policies for certain employees. The effects of these responsive actions and precautionary measures may negatively impact productivity, disrupt our business and delay our clinical programs and timelines. However, the extent to which COVID-19 ultimately impacts the Company’s business, results of operations or financial condition will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain the pandemic or treat its impact, among others. Furthermore, for the safety of the Company’s employees and families, the Company has introduced enhanced safety measures for scientists to be present in our labs and increased the use of third party service providers for the conduct of certain experiments and studies for research programs. Certain of the Company’s third party service providers have also experienced shutdowns or other business disruptions. While states and jurisdictions have started to rollback “stay-at-home” and quarantine orders, it is difficult to predict what the lasting impact of the pandemic will be, and any prolonged material disruption to the Company’s employees or third party service providers could negatively impact the Company’s ability to conduct business in the manner and on the timelines presently planned, which could have a material adverse impact on the Company’s business, results of operations and financial condition.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of consolidation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries, Black Diamond Therapeutics (Canada), Inc. and Black Diamond Therapeutics Security Corporation, after elimination of all significant intercompany accounts and transactions.

Unaudited interim financial information

The condensed consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this Quarterly Report, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company’s Annual Report on Form 10-K. The results for any interim period are not necessarily indicative of results for any future period.

Use of estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses, the valuation of common stock and the valuation of stock-based awards. 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. Estimates are periodically reviewed in light of 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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. The Company has considered the impact of COVID-19 on estimates within its financial statements and there may be changes to those estimates in future periods. As of the date of issuance of these unaudited condensed consolidated financial statements, the Company has not experienced material business disruptions or incurred impairment losses in the carrying value of its assets as a result of the pandemic and is not aware of any specific related event or circumstance that would require it to update its estimates.

Deferred offering costs

As of December 31, 2019, the Company recorded deferred offering costs of $2,303. The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process preferred stock or common stock financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should a planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. After consummation of the IPO, which closed on February 3, 2020, these costs were recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering.

Investments

The Company determines the appropriate classification of its investments in debt securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company classifies its marketable securities as current or non-current based on each instrument's underlying effective maturity date. Marketable securities with maturities of greater than three months as available-for-sale are classified as current and are included in investments in the condensed consolidated balance sheets. Marketable securities with maturities greater than one year are classified as non-current and are included in investments, non-current in the condensed consolidated balance sheets. The Company's marketable securities consist of U.S. government agency securities, corporate bonds, and commercial paper. Debt securities are carried at fair value with unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity (deficit) until realized. Amortization and accretion of premiums and discounts are recorded in interest income (expense). Realized gains and losses on debt securities are included in other income (expense), net.

If any adjustment to fair value reflects a decline in value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is other than temporary and, if so, marks the investment to market on the Company's statement of operations and comprehensive income (loss).

Comprehensive loss

Comprehensive loss is composed of net loss and other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains and losses on investments.

Leases

Effective January 1, 2020, the Company adopted Accounting Standards Updated ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "ASC 842"), using the modified retrospective method and utilized the effective date as its date of initial application, with prior periods presented in accordance with previous guidance under ASC 840, Leases ("ASC 840"). At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date. The Company has elected not to recognize leases with an original term of one year or less on the condensed consolidated balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

The Company elected the following practical expedients, which must be elected as a package and applied consistently to all of its leases at the transition date (including those for which the entity is a lessee or a lessor): i) the Company did not reassess whether any expired or existing contracts are or contain leases; ii) the Company did not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases, and all existing leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases); and iii) the Company did not reassess initial direct costs for any existing leases.

For leases that existed prior to the date of initial application of ASC 842 (which were previously classified as operating leases), a lessee may elect to use either the total lease term measured at lease inception under ASC 840 or the remaining lease term as of the date of initial application of ASC 842 in determining the period for which to measure its incremental borrowing rate. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

In accordance with ASC 842, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Entities may elect not to separate lease and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

Recently issued accounting pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes-Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for annual periods beginning after December 15, 2020 and interim periods within, with early adoption permitted. Adoption of the standard requires certain changes to be made prospectively, with some changes to be made retrospectively. The Company is currently assessing the impact of this standard on our financial condition and results of operations.

3. FAIR VALUE MEASUREMENTS

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair value measurements at June 30, 2020 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 59,764	$ —	$ —	$ 59,764
Investments:				
Commercial paper	—	74,400	—	74,400
Corporate bonds	—	186,608	—	186,608
U.S. Government agencies	—	20,019	—	20,019
Total	$ 59,764	$ 281,027	$ —	$ 340,791

	Fair value measurements at December 31, 2019 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 24,157	$ —	$ —	$ 24,157
Total	$ 24,157	$ —	$ —	$ 24,157
Liabilities:				
Derivative liabilities	$ —	$ —	$ 16	$ 16
Total	$ —	$ —	$ 16	$ 16

When developing fair value estimates, the Company maximizes the use of observable inputs and minimizes the use of unobservable inputs. When available, the Company uses quoted market prices to measure fair value. The valuation technique used to measure fair value for the Company's Level 1 and Level 2 assets is a market approach, using prices and other relevant information generated by market transactions involving identical or comparable assets. If market prices are not available, the fair value measurement is based on models that use primarily market-based parameters including yield curves, volatilities, credit ratings and currency rates. In certain cases where market rate assumptions are not available, the Company is required to make judgments about assumptions market participants would use to estimate the fair value of a financial instrument.

There were no transfers in or out of Level 3 categories in the periods presented.

Valuation of derivative liabilities

The fair value of the derivative liabilities related to the warrants to purchase series A convertible preferred stock is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

Upon completion of the IPO in February 2020, the warrants to purchase series A convertible preferred stock converted to warrants to purchase 10,757 shares of common stock and the fair value of the derivative liability was reclassified to additional paid-in capital. As a result, we will no longer remeasure the fair value of the warrant liability at each reporting date. Derivative liabilities consisted of the following:

	June 30, 2020
Balance - December 31, 2019	$ 16
Reclassification to additional paid-in capital in connection with IPO	(16)
Balance - June 30, 2020	$ —

4. INVESTMENTS

As of June 30, 2020, investments were comprised of the following:

	June 30, 2020	
	Amortized Cost	Fair Value
Due within one year or less	$ 140,093	$ 140,505
Due after one year through three years	139,922	140,522
Total investments	$ 280,015	$ 281,027

The amortized cost and estimated fair value of marketable securities, by contractual maturity:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Current	Non-Current
Commercial paper	$ 74,208	$ 192	$ —	$ 74,400	$ 74,400	$ —
Corporate bonds	185,789	819	—	186,608	66,105	120,503
U.S. Government agencies	20,018	1	—	20,019	—	20,019
Total	$ 280,015	$ 1,012	$ —	$ 281,027	$ 140,505	$ 140,522

As of December 31, 2019, the Company did not hold any investments.

5. PROPERTY AND EQUIPMENT

Equipment, net consisted of the following:

	June 30, 2020	December 31, 2019
Laboratory equipment	$ 218	$ 218
Computer and office equipment	83	58
Equipment	301	276
Less: accumulated depreciation	(135)	(112)
Total Equipment, net	$ 166	$ 164

Depreciation expense for the six months ended June 30, 2020 and 2019 was $23 and $25, respectively.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2020	December 31, 2019
Contracted research services	$ 2,276	$ 434
Payroll and related expenses	1,779	1,182
Professional and consulting fees	1,736	984
Legal fees	74	299
Current portion of operating lease liability	214	—
Total accrued expenses and other current liabilities	$ 6,079	$ 2,899

7. STOCKHOLDERS' EQUITY

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.

Upon closing of the IPO on February 3, 2020, all of the preferred stock converted into an aggregate of 21,499,770 shares of common stock.

On January 3, 2020, in connection with the IPO, the Company filed a restated Certificate of Incorporation, which, among other things, restated the number of shares of all classes of stock that the Company has authority to issue to 510,000,000 shares, of which (i) 500,000,000 shares shall be a class designated as common stock, par value $0.0001 per share, and (ii) 10,000,000 shares shall be a class designated as undesignated preferred stock, par value $0.0001 per share.

8. STOCK-BASED COMPENSATION

2017 Equity Incentive Plan

The Company's 2017 Employee, Director and Consultant Equity Incentive Plan, as amended (the "2017 Plan"), provided for the Company to grant qualified incentive options, nonqualified options, stock grants and other stock-based awards to employees and non-employees to purchase the Company's common stock. Upon the effectiveness of the 2020 Plan (as defined below), no further issuances will be made under the 2017 Plan.

2020 Stock Option and Incentive Plan

The 2020 Stock Option and Incentive Plan (the "2020 Plan") was approved by our board of directors on December 5, 2019, and the Company's stockholders on January 14, 2020 and became effective on the date immediately prior to the date on which the registration statement for the Company's IPO was declared effective. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares initially reserved for issuance under the 2020 Plan is 6,665,891, which shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation, nomination, and corporate governance committee of the board of directors.

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the "2020 ESPP") was approved by the Company's board of directors on December 5, 2019, and our stockholders on January 14, 2020, and became effective on the date immediately prior to the date on which the registration statement for the Company's IPO was declared effective. A total of 326,364 shares of common stock were initially reserved for issuance under this plan, which shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation, nomination and corporate governance committee of the board of directors.

Stock-based compensation expense

The Company recorded stock-based compensation expense in the following expense categories of its condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 655	$ 166	$ 1,219	$ 246
General and administrative	764	26	2,077	37
	$ 1,419	$ 192	$ 3,296	$ 283

Options

During the six months ended June 30, 2020, the Company granted options to purchase 901,651 shares of common stock. The total fair value of options vested during the six months ended June 30, 2020 was $1,110. As of June 30, 2020, there were 3,240,362 options outstanding, 39,763 options were forfeited during the period. The weighted-average grant-date fair value per share of options granted during the six months ended June 30, 2020 was $13.08.

For the six months ended June 30, 2020, total unrecognized compensation cost related to the unvested stock-options was $20,337, which is expected to be recognized over a weighted average period of 3.1 years.

9. NET LOSS PER SHARE

Net loss per share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss attributable to common stockholders	$ (14,571)	$ (12,287)	$ (26,716)	$ (16,115)
Weighted average common shares outstanding, basic and diluted	35,910,718	2,052,056	29,804,987	2,048,239
Net loss per share, basic and diluted	$ (0.41)	$ (5.99)	$ (0.92)	$ (7.86)

The Company had no unvested restricted common shares outstanding at June 30, 2020. Unvested restricted common shares at June 30, 2019 have been excluded from the computation of basic net loss per share attributable to common stockholders.

The Company's potentially dilutive securities, which include options, unvested restricted stock, convertible preferred stock and warrants to purchase convertible preferred stock, have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be to reduce the net loss per share attributable to common stockholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Six Months Ended June 30,	
	2020	2019
Options to purchase common stock	3,240,362	503,666
Unvested restricted stock	—	164,582
Preferred stock (as converted to common stock)	—	11,163,838
Warrants to purchase shares of series A preferred stock (as converted to common stock)	—	10,757
	3,240,362	11,842,843

10. LEASES

The Company has historically entered into lease arrangements for its facilities. As of June 30, 2020, the Company had one operating lease with required future minimum payments. In applying the transition guidance under ASC 842, the Company determined the classification of this lease to be an operating lease and recorded a right-of-use asset and lease liability as of the effective date. The Company's leases generally do not include termination or purchase options.

Operating Leases

In February 2019, the Company entered into an agreement to lease approximately 2,357 square feet of office space for its principal office, which is located in Cambridge, MA. The lease expires on April 30, 2022, subject to an option to extend the lease for three additional years.

In July 2020, the Company entered into a seven-year agreement with an option to extend for five additional years to lease two floors totaling approximately 25,578 square feet of office space in Cambridge, MA. The lease on the first floor commenced on August 1, 2020 and the Company currently expects the lease of the second floor to commence in Q4 2020 when the landlord delivers the space in accordance with the lease terms. The Company is in the process of assessing the impacts to the financial statements, but currently expect to recognize the respective lease balances on the condensed consolidated balance sheets when the lease of each floor has commenced. Under the terms of the lease, the Company is required to make up to $17,048 in total minimum payments during the term and is required to issue a $1,168 letter of credit as security for the lease.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating lease for the three and six months ended June 30, 2020:

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Lease Cost		
Operating lease cost	$ 56	$ 112
Short-term lease cost	105	265
Variable lease cost	10	22
Total lease cost	$ 171	$ 399

Other Operating Lease Information	June 30, 2020
Cash paid for amounts included in the measurement of lease liability	$ 111
Weighted-average remaining lease term	1.8
Weighted-average discount rate	8.6 %

The variable lease costs for the three and six months ended June 30, 2020 include common area maintenance and other operating charges. As the Company's leases do not provide an implicit rate, the Company utilized its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

Future minimum lease payments under the Company's operating leases as of June 30, 2020 were as follows:

	As of June 30, 2020
2020 (excluding the six months ended June 30, 2020)	$ 112
2021	228
2022	77
Thereafter	—
Total lease payments	417
Less: interest	(29)
Total lease liability	$ 388

As of December 31, 2019, future minimum lease payments under the Company's lease obligations under ASC 840 were as follows:

Years Ending December 31,		
2020	$	223
2021		228
2022		77
2023		—
Total	$	528

11. COMMITMENTS AND CONTINGENCIES

We enter into contracts in the normal course of business with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other third parties for preclinical research studies, Clinical Trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancelable upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of service providers, up to the date of cancellation.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, 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 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. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of June 30, 2020 or December 31, 2019.

Legal proceedings

The Company is not currently party to and is not aware of any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

12. BENEFIT PLANS

In 2018 the Company established a Simplified Employee Pension ("SEP") defined-contribution savings plan. This plan covers substantially all employees who meet minimum age and service requirements. The Company provides contributions of 6% of each participant's salary. Employees are immediately and fully vested in the Company's contribution. During the three and six months ended June 30, 2020 and 2019, the Company contributed $118, $267, $38 and $61 to the plan, respectively.

13. RELATED-PARTY TRANSACTIONS

The Company is party to a services agreement, which was entered into in March 2017 and amended in November 2017 and March 2020, with Ridgeline. Ridgeline is an entity owned by one of its investors, whereby an individual who is a Company director and was executive officer until September 2019 and other employees of Ridgeline provide the Company with scientific consulting services. The services agreement is effective until December 31, 2020. Under the November 2017 amended services agreement the Company paid Ridgeline $950 per month, and reconciled on a quarterly basis with the actual expenses incurred by Ridgeline on its behalf. In connection with the March 2020 amendment to the services agreement, the Company transitioned to a more limited consulting arrangement where Ridgeline invoices the Company for services performed on an ongoing monthly basis. Total amounts due to related party were $15 as of June 30, 2020. Total prepaids with related party were $916 as of December 31, 2019. Total service fees incurred were $223, $2,103, $3,247 and $5,198, for the three and six months ended June 30, 2020 and 2019, respectively.

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

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report and our audited consolidated financial statements and related notes thereto for the year ended December 31, 2019 included in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on March 24, 2020. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

We are a precision oncology medicine company pioneering the discovery and development of small molecule, tumor-agnostic therapies. We target undrugged oncogenic driver mutations in patients with genetically defined cancers. The foundation of our company is built upon a deep understanding of cancer genetics, protein structure and function, and medicinal chemistry. Our proprietary technology platform, which we refer to as our Mutation-Allostery-Pharmacology, or MAP, platform, is designed to allow us to analyze population-level genetic sequencing data to discover oncogenic mutations that promote cancer across tumor types. Our goal is to identify families of mutations that can be inhibited with a single small molecule therapy in a tumor-agnostic manner. We have designed our lead product candidate, BDTX-189, to potently and selectively inhibit a family of oncogenic proteins defined by mutations which occur outside the adenosine triphosphate, or ATP, site, and which we refer to as non-canonical mutations. Non-canonical mutations occur across a range of tumor types that affect both the epidermal growth factor receptor, or EGFR, and the tyrosine-protein kinase ErbB-2, or HER2. We have designed BDTX-189 to bind to the active site of these mutant kinases and inhibit their function. BDTX-189 is also designed to spare normal, or wild type, EGFR, which we believe will improve upon the toxicity profiles of current ErbB kinase inhibitors. We are also leveraging our MAP platform to identify other families of non-canonical mutations in validated oncogenes beyond ErbB, which has the potential to expand the reach of targeted therapies.

Since our inception in 2014, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, acquiring, discovering product candidates and securing related intellectual property rights and conducting research and development activities for our programs. We do not have any products approved for sale and have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product. We have not yet successfully completed any pivotal clinical trials, obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities. Through June 30, 2020, we have received net proceeds of $200.6 million from sales of our preferred stock.

We submitted our IND for BDTX-189 in November 2019, which was allowed by the U.S. Food and Drug Administration ("FDA") on December 13, 2019. We have since begun enrollment and dosing of patients in the Phase 1 portion of our MasterKey-01 trial to pursue a tumor-agnostic development strategy and expect to complete the Phase 1 portion of the trial by the first half of 2021. In July 2020, we were granted Fast Track designation for BDTX-189 for the treatment of adult patients with solid tumors harboring an allosteric human epidermal growth factor receptor 2 (HER2) mutation or an epidermal growth factor receptor (EGFR) or HER2 Exon 20 insertion mutation who have progressed following prior treatment and who have no satisfactory treatment options.

In December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease ("COVID-19"), was reported to have surfaced in Wuhan, China, and has since spread to other regions and countries worldwide. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed restrictions on travel between the United States, Europe and certain other countries. Almost all U.S. states and many local jurisdictions have issued "shelter-in-place" orders, quarantines, executive orders and similar government orders, restrictions, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and recommendations, and the perception that additional orders, restrictions or recommendations could occur, have resulted in widespread closures of businesses not deemed "essential," work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events. Although some states are starting to relax "shelter-in-place" orders, quarantines and similar restrictions, the regulations vary on a state by state basis and the impact of loosening of those restrictions is not yet known.

We are closely monitoring the impact of the COVID-19 pandemic on all aspects of our business, including how it has and will continue to impact our operations and the operations of our suppliers, vendors and business partners, and may take further precautionary and preemptive actions as may be required by federal, state or local authorities. In addition, we have taken steps to minimize the current environment's impact on our business and strategy, including devising contingency plans and securing additional resources from third party service providers. For the safety of the Company's employees and families, the Company has introduced enhanced safety measures for scientists to be present in our labs and increased the use of third party service providers for the conduct of certain experiments and studies for research programs. Certain of our third party service providers have also experienced shutdowns or other business disruptions. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy and we cannot presently predict the scope and severity of any potential business shutdowns or disruptions. In particular, our ability to conduct our MasterKey-01 trial in a timely manner that meets our current projected timelines could be adversely impacted. While the Phase 1 portion of the trial currently remains on track to complete by the first half of 2021, potential COVID-19-associated risks include delays in patient recruitment and principal investigator availability, clinical trial site shutdowns or other interruptions and potential limitations on the quality, completeness and interpretability of data we are able to collect. Additionally, our drug product supply chain, early stage research & development programs and activities and other aspects of our business operations could be negatively impacted by the pandemic and COVID-19-related delays or disruptions.

Beyond the impact on our pipeline, the extent to which COVID-19 ultimately impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others. If we or any of the third parties with whom we engage, however, were to experience any additional shutdowns or other prolonged business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, results of operations and financial condition.

Since inception we have incurred significant operating losses. Our net losses were $26.7 million and $16.1 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $77.7 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- continue preclinical studies and initiate or advance clinical trials for BDTX-189, our glioblastoma (GBM) program and other product candidates;
- advance the development of our product candidate pipeline;
- continue to develop and expand our proprietary MAP platform to identify additional product candidates;

- obtain, maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- hire additional clinical, scientific and commercial personnel;
- acquire or in-license additional product candidates;
- expand our infrastructure and facilities to accommodate our growing employee base; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private 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 the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. 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 as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to 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.

As of June 30, 2020, we had cash, cash equivalents and investments of $345.0 million, which we believe will fund our operating expenses and capital expenditure requirements into 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and capital resources.” To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. 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.

Components of our results of operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating expenses

Research and development expenses (inclusive of amounts with a related party)

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- expenses incurred to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with contract research organizations, or CROs, that are primarily engaged in the oversight and conduct of our drug discovery efforts and preclinical studies, clinical trials and contract manufacturing organizations, or CMOs, that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- payments made in cash or equity securities under third-party licensing, acquisition and option agreements;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred under our services agreement with Ridgeline Therapeutics GmbH, or Ridgeline;
- costs related to compliance with regulatory requirements; and
- allocated facilities-related costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Any nonrefundable 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. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

We do not track our research and development expenses on a program-by-program basis. Our direct external research and development expenses consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses also include fees incurred under license, acquisition and option agreements. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years as we commence our planned clinical trials for BDTX-189, as well as conduct other preclinical and clinical development, including submitting regulatory filings for our other product candidates. Historically, many of our research and development activities were conducted pursuant to our services agreement with Ridgeline, a related party, and we have transitioned many of these activities internally as we've increased our internal capacity. While the service fee we have historically paid under our Ridgeline Services Agreement has been reduced significantly as a result of this transition, we expect that we will incur increased personnel and overhead costs associated with moving those functions in-house, which we expect will offset that reduction in Ridgeline services fees. In addition, we expect our discovery research efforts and our related personnel costs will increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, will increase above historical levels. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of the following:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety and efficacy profile with IND enabling studies;
- successful patient enrollment in and the initiation and completion of clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and administrative expenses (inclusive of amounts with a related party)

General and administrative expenses consist primarily of salaries and benefits, travel and stock-based compensation expense for personnel in executive, business development, finance, human resources, legal, information technology, pre-commercial and support personnel functions. General and administrative expenses also include direct and allocated facility-related costs as well as insurance costs and professional fees for legal, patent, consulting, investor and public relations, accounting and audit services.

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 product candidates and prepare for potential commercialization activities. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

Other income (expense)

Other income (expense) consists primarily of interest income earned on our cash equivalents and investment balances, realized and unrealized foreign currency transaction gains and losses, and changes in fair value of derivative liabilities.

Our issuance of Series B preferred stock provided investors the right to participate in subsequent offerings of Series B preferred stock, in the event specified developmental and regulatory milestones were achieved. We classified the tranche right as a derivative liability on our condensed consolidated balance sheets. We remeasured the derivative liability associated with tranche right to fair value at each reporting date, and recognized change in the fair value of the derivative liability in the condensed consolidated statements of operations.

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 (inclusive of $223 and $3,077 respectively, with a related party)	$ 10,170	$ 5,646	$ 4,524
General and administrative (inclusive of $0 and $170, respectively, with a related party)	4,858	1,353	3,505
Total operating expenses	15,028	6,999	8,029
Loss from operations	(15,028)	(6,999)	(8,029)
Other income (expense):			
Interest expense	(1)	—	(1)
Interest income	881	9	872
Change in fair value of derivative liabilities	—	(5,300)	5,300
Other (expense) income	(423)	3	(426)
Total other income (expense), net	457	(5,288)	5,745
Net loss attributable to common stockholders	$ (14,571)	$ (12,287)	$ (2,284)

Research and development (inclusive of amounts with a related party)

Research and development expenses were $10.2 million for the three months ended June 30, 2020, compared to $5.6 million for the three months ended June 30, 2019. The increase of $4.5 million was primarily due to an increase in headcount and external fees related to the continued development of our MAP platform and our product candidates, including BDTX-189. We do not currently track expenses on a program-by-program basis.

General and administrative (inclusive of amounts with a related party)

General and administrative expenses were $4.9 million for the three months ended June 30, 2020, compared to $1.4 million for the three months ended June 30, 2019. The increase of $3.5 million was primarily a result of higher personnel-related costs due to additional headcount and higher legal and other professional fees due to operating as a public company.

Other income (expense)

Other income was $0.5 million for the three months ended June 30, 2020, compared to other expense of $5.3 million for the three months ended June 30, 2019. The increase was primarily attributable to no derivative liability in 2020 and then interest income on investments in 2020 and none in 2019.

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 (inclusive of $2,103 and $5,017 respectively, with a related party)	$ 17,524	$ 8,659	$ 8,865
General and administrative (inclusive of $0 and $181, respectively, with a related party)	10,383	2,181	8,202
Total operating expenses	27,907	10,840	17,067
Loss from operations	(27,907)	(10,840)	(17,067)
Other income (expense):			
Interest expense	(1)	—	(1)
Interest income	1,625	20	1,605
Change in fair value of derivative liabilities	—	(5,300)	5,300
Other (expense) income	(433)	5	(438)
Total other income (expense), net	1,191	(5,275)	6,466
Net loss attributable to common stockholders	$ (26,716)	$ (16,115)	$ (10,601)

Research and development (inclusive of amounts with a related party)

Research and development expenses were $17.5 million for the six months ended June 30, 2020, compared to $8.7 million for the six months ended June 30, 2019. The increase of $8.9 million was primarily due to an increase in headcount and external fees related to the continued development of our MAP platform and our product candidates, including BDTX-189. We do not currently track expenses on a program-by-program basis.

General and administrative (inclusive of amounts with a related party)

General and administrative expenses were $10.4 million for the six months ended June 30, 2020, compared to $2.2 million for the six months ended June 30, 2019. The increase of $8.2 million was primarily a result of higher personnel-related costs due to additional headcount and higher legal and other professional fees due to preparing to operate as a public company.

Other income (expense)

Other income was $1.2 million for the six months ended June 30, 2020, compared to other expense of $5.3 million for the six months ended June 30, 2019. The increase was primarily attributable to the change in fair value of derivative liabilities period over period.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have not generated any revenue from any product sales or any other sources and have incurred significant operating losses and negative cash flows from our operations. 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. We have funded our operations to date primarily with proceeds from the sale of preferred stock. On February 3, 2020, we completed an IPO of 12,174,263 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to 1,587,947 additional shares of common stock, for aggregate gross proceeds of $231.3 million. The Company received $212.1 million in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. Through June 30, 2020, we had previously received net cash proceeds of $200.6 million from sales of our preferred stock and as of June 30, 2020, we had cash, cash equivalents and investments of $345.0 million.

Cash flows

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

	Six Months Ended June 30,	
	2020	2019
Cash used in operating activities	$ (24,886)	$ (11,878)
Cash used in investing activities	(279,640)	(8)
Cash provided by (used in) financing activities	213,844	(70)
Net decrease in cash and cash equivalents	$ (90,682)	$ (11,956)

Operating activities

During the six months ended June 30, 2020, we used cash in operating activities of $24.9 million, primarily resulting from our net loss of $26.7 million, partially offset by the non-cash charge related to stock compensation expense of $3.3 million.

During the six months ended June 30, 2019, we used cash in operating activities of $11.9 million, primarily resulting from our net loss of $16.1 million, partially offset by a decrease in accrued expenses and an increase in prepaid expenses.

Changes in accounts payable and accrued expenses in all periods were generally due to growth in our business, the advancement of our product candidates, and the timing of vendor invoicing and payments.

Investing activities

During the six months ended June 30, 2020, we had cash used in investing activities of $279.6 million for the purchase of investments.

During the six months ended June 30, 2019, we used cash in investing activities of less than $0.1 million, consisting solely of purchases of equipment.

Financing activities

During the six months ended June 30, 2020, we had cash provided by financing activities of $213.8 million, consisting primarily of proceeds from the initial public offering.

During the six months ended June 30, 2019, we had cash used in financing activities of less than $0.1 million consisting of payments of deferred offering costs.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. The timing and amount of our operating expenditures will depend largely on our ability to:

- advance BDTX-189 through the clinic;
- advance preclinical development of our early stage programs, including in GBM;
- manufacture, or have manufactured on our behalf, our preclinical and clinical drug material and develop processes for late state and commercial manufacturing;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; and
- obtain, maintain, expand and protect our intellectual property portfolio.

As of June 30, 2020, we had cash, cash equivalents and investments of $345.0 million, which we believe will fund our operating expenses and capital expenditure requirements into 2023. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We anticipate that we will require additional capital as we seek regulatory approval of our product candidates and if we choose to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for BDTX-189 or our other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;

- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

If we raise additional funds through collaborations, strategic partnerships and alliances or marketing, distribution 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, we may be required to delay, limit, reduce or terminate our research, 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.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Critical accounting policies and significant judgments and use of estimates

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

Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Use of Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on March 24, 2020. During the three and six months ended June 30, 2020, there were no material changes to our critical accounting policies from those previously disclosed.

Recently issued 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 appearing elsewhere in this Quarterly Report.

Emerging growth company and smaller reporting company status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us 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 not "opt out" of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Quarterly Report were not effective at a reasonable assurance level due to the material weaknesses in internal control over financial reporting described below. The Company's disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Internal Control Over Financial Reporting

In preparation of our financial statements to meet the requirements of our IPO, we determined that material weaknesses in our internal control over financial reporting existed during fiscal 2017 and remain unremediated as of June 30, 2020. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

The material weaknesses we identified are related to the design and maintenance of an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately and we did not design and maintain controls to ensure adequate segregation of duties within our financial reporting function including the preparation and review of journal entries.

The material weaknesses contributed to the restatement of our previously issued 2017 annual financial statements. Specifically, the material weaknesses resulted in errors in our accounting for and reporting of derivative liabilities, loss on extinguishment of convertible promissory notes and expense classification.

Remediation Activities

Management has been actively engaged in remediating the above described material weaknesses. The following remedial actions have been taken during the quarter ended June 30, 2020:

- strengthened our internal policies, processes and reviews, including drafting of related documentation thereof;
- selected an enterprise resource planning system to support key financial processes and controls, and the implementation began in the second quarter of 2020; and
- Engaged outside consultants to assist in the design, implementation, and documentation of internal controls that address the relevant risks.

The process of implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may take additional actions to address control deficiencies or modify certain of the remediation measures described above.

While progress has been made to enhance our internal control over financial reporting, we are still in the process of implementing these processes, procedures and controls. Additional time is required to complete implementation and to assess and ensure the sustainability of these procedures. We believe the above actions will be effective in remediating the material weaknesses described above and we will continue to devote significant time and attention to these remedial efforts. However, the material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded that these controls are operating effectively.

Changes in Internal Control over Financial Reporting

The items described in “Remediation Activities” above are considered a change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the second quarter of 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

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report and in other documents that we file with the SEC, in evaluating the Company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks that we face. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations. Certain statements in this Quarterly Report are forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Risks related to our financial position and capital requirements

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

We are a biotechnology company with a limited operating history. We commenced operations in December 2014, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. Most of our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully conduct 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 you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates. We have begun enrollment and dosing of patients in the Phase 1 portion of our MasterKey-01 trial to pursue a tumor-agnostic development strategy. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through private placements of our preferred stock.

We have incurred significant net losses in each period since we commenced operations in December 2014. For the six months ended June 30, 2020, we reported a net loss of $26.7 million. As of June 30, 2020, we had an accumulated deficit of $77.7 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts and submit INDs for our lead product candidates;
- conduct preclinical studies and clinical trials for our current and future product candidates based on our Mutation—Allostery—Pharmacology, or MAP, platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- operate as a public company.

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 we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for 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. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have not generated any revenue from our product candidates and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any of our product candidates. We do not expect to generate significant revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. Most of our product candidates are in the preclinical stages of development and will require additional preclinical studies, clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We have begun enrollment and dosing of patients in the Phase 1 portion of our MasterKey-01 trial to pursue a tumor-agnostic development strategy. Our other product candidates are in various stages of preclinical development. We face significant translational risk as our product candidates in preclinical development advance to the clinical stage, as promising results in preclinical studies may not be replicated in subsequent clinical trials and testing on animals may not accurately predict human experience. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete IND-enabling studies and successfully submit INDs or comparable applications;
- whether we are required by the U.S. Food and Drug Administration, or the FDA, or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, potency, purity, efficacy and acceptable risk to benefit profile of our product candidates or any future product

candidates and such regulatory authorities' acceptance of our tumor-agnostic development strategy (i.e., our pursuit of approval based on a biomarker rather than a specific cancer indication);

- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies, such as chemotherapy, to treat solid tumors;
- the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative cancer therapies and competitive product candidates and technologies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if approved; and
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

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

We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue our discovery and preclinical development activities to identify new product candidates and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. However, we have estimated our current additional funding needs based on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our discovery and preclinical development programs or any future commercialization efforts.

We had cash, cash equivalents and investments of $345.0 million as of June 30, 2020. Our net proceeds from our initial public offering were $212.1 million, based the initial public offering price of $19.00 per share, after deducting underwriting discounts and commissions and offering expenses payable by us. We believe that, based upon our current operating plan, our existing capital resources, including net proceeds from our initial public offering will be sufficient to fund our anticipated operations into 2023, including the Phase 1/2 clinical trial of BDTX-189 and the identification of a lead product candidate and IND-enabling studies in our glioblastoma program, with additional resources for continued development of our MAP platform. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of discovery, preclinical development and clinical trials for our product candidates;
- the extent to which we enter into collaboration arrangements with regard to product discovery or acquire or in-license products or technologies;
- our ability to establish discovery collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, enforcing and protecting our intellectual property rights and defending intellectual property-related claims.

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, our product candidates, if approved, 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. 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.

Risks related to the development of our product candidates

Our discovery and preclinical development is focused on the development of precision medicines for patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop drugs is novel and may never lead to marketable products.

The discovery and development of precision medicines for patients with genetically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work, that the mutations targeted by our programs are oncogenic drivers, clinical results may not confirm this hypothesis or may only confirm it for certain mutations or certain tumor types. The patient populations for our product candidates are limited to those with specific target mutations and may not be completely defined but are substantially smaller than the general treated cancer population, and we will need to screen and identify these patients with the targeted mutations. Successful identification of patients is dependent on several factors, including achieving certainty as to how specific genetic alterations respond to our product candidates and developing companion diagnostics to identify such genetic alterations. Furthermore, even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each mutation will be large enough to allow us to successfully obtain approval for each mutation type and commercialize our products and achieve profitability. In addition, even if our approach is successful in showing clinical benefit for tumors harboring the targeted mutations affecting the ErbB proteins EGFR and HER2, we may never successfully identify additional oncogenic mutations for other receptor tyrosine kinases.

Therefore, we do not know if our approach of treating patients with genetically defined cancers will be successful, and if our approach is unsuccessful, our business will suffer.

In addition, we are pursuing a tumor-agnostic development strategy (i.e., pursuing approval based on a biomarker rather than a specific cancer indication). There is currently a limited number of approved tumor-agnostic therapies. We may not receive approval for a tumor-agnostic indication or may be delayed in receiving tumor-agnostic approval.

We are very early in our development efforts and are substantially dependent on our lead product candidate, BDTX-189. If we are unable to advance BDTX-189 or any of our other product candidates through clinical development, obtain regulatory approval and ultimately commercialize BDTX-189 or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts. Most of our product candidates are still in preclinical development and have never been tested in human subjects. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of BDTX-189 and one or more of our other product candidates. In addition, our drug development programs contemplate the development of companion diagnostics, which are assays or tests to identify an appropriate patient population. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- approval of INDs for our planned clinical trials or future clinical trials;
- FDA acceptance of our tumor-agnostic development strategy;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- successful development of companion diagnostics for use with our product candidates;
- safety, tolerability and efficacy profiles for our product candidates that are satisfactory to the FDA or any foreign regulatory authority for marketing approval;
- receipt of marketing approvals for our product candidates and any companion diagnostics from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other cancer therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following approval.

There is no guarantee that the results obtained in current preclinical studies or our open-label Phase 1/2 clinical trial of BDTX-189 will be sufficient to obtain regulatory approval or marketing authorization for such product candidate. Negative results in the development of our lead product candidate may also impact our ability to obtain regulatory approval for our other product candidates, either at all or within anticipated timeframes because, although other product candidates may target different indications, the underlying technology platform, manufacturing process and development process is the same for all of our product candidates. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates. For example, although we believe based on our preclinical studies that the conformational change to the active site receptor is similar for all of the genetic mutations we are targeting and therefore the chemical structure of BDTX-189 will suffice to bind adequately to such receptor for all such mutations, this may not prove true in clinical testing of BDTX-189 for all or any of the targeted mutations. Moreover, anti-tumor activity may be different in each of the different tumor types we plan on evaluating in the clinical trial. Therefore, even though we plan on pursuing tumor-agnostic clinical development of BDTX-189, the tumor response may be low in patients with some cancers compared to others. This may result in discontinuation of development of BDTX-189 for patients with these tumor types and/or mutations due to insufficient clinical benefit while continuing development for a more limited population of patients more likely to benefit. As a consequence, we may have to negotiate with the FDA to reach agreement on defining the optimal patient population, study design and size in order to obtain regulatory approval, any of which may require significant additional resources and delay the timing of our clinical trials and ultimately the approval, if any, of any of our product candidates.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidate, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. 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 other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to those future product candidates 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 future product candidates.

Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates. We may find it difficult to enroll patients in our open-label Phase 1/2 clinical trial for BDTX-189 with the genetic mutations that BDTX-189 is designed to target.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of completion of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because we are focused on patients with specific genetic mutations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, with respect to BDTX-189, we cannot be certain how many patients will have each of the genetic mutations that BDTX-189 is designed to target or that the number of patients enrolled for each mutation will suffice for regulatory approval and inclusion of each such mutation in the approved label. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

In addition to the potentially small populations, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their disease is either severe enough or not too advanced to include them in a study. Additionally, the process of finding and diagnosing patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, the availability of genetic sequencing information for patient tumors so that we can identify patients with the targeted genetic mutations, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

We intend to engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials. Further, if we are unable to include patients with the targeted genetic mutations, this could compromise our ability to seek participation in FDA's expedited review and development programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise seek to accelerate clinical development and regulatory timelines.

The enrollment of patients further depends on many factors, including:

- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment and because most of our product candidates have not been tested in humans before, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in any future clinical trial. Additionally, because our clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented.

We have no experience as a company in conducting clinical trials.

We have no experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies will be completed on time or if the planned preclinical studies and clinical trials will begin or be completed on time, if at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations, or CROs, and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs and consultants on a timely basis or at all. For our lead product candidate, BDTX-189, we entered in to a master services agreement with a CRO to lead our first-in-human open-label Phase 1/2 clinical trial. There can be no assurance that we will be able to negotiate and enter into any additional master services agreement with other CROs, as necessary, on terms that are acceptable to us on a timely basis or at all.

Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency, purity and efficacy of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, including BDTX-189, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict human experience. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, potency, purity and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency, purity and efficacy necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, potency, purity and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety, potency, purity or efficacy results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. As is the case with all oncology drugs, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. For example, other EGFR inhibitors have experienced dose limiting toxicities due to rash in patients and, although we have designed BDTX-189 to be "wild-type" sparing to limit the risk of similar toxicities, clinical results may differ and patients may also experience similar or different toxicities that limit the dose and/or efficacy of BDTX-189. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We submitted an IND for BDTX-189 in November 2019, which was allowed by the FDA on December 13, 2019, but we may not be able to file INDs for our other product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our product candidates could harm our drug development strategy and operational results.

As one of the central elements of our business strategy and approach, we seek to screen and identify subsets of patients with a genetic alteration who may derive meaningful benefit from our development product candidates. To achieve this, our product development program is dependent on the development and commercialization of a companion diagnostic by us or by third party collaborators. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices. Each agency that approves a product candidate will independently need to approve the companion diagnostic before or concurrently with its approval of the product candidate, and before a product can be commercialized. The approval of a companion diagnostic as part of the product label will also limit the use of the product candidate to only those patients who express the specific genetic alteration it was developed to detect.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate clearance or approval prior to their commercialization. To date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. We and our third-party collaborators may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third- party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval of our related product candidates.

Since the number of patients that we plan to dose in our open-label Phase 1/2 clinical trial of BDTX-189 is small, the results from such a clinical trial, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.

In our open-label Phase 1/2 clinical trial of BDTX-189, we are evaluating the safety profile of BDTX-189 and establishing the recommended Phase 2 dose in patients with bladder cancer, endometrial cancer, breast cancer, gastric cancer, colon cancer and non-small cell lung cancer, or NSCLC, and other solid tumors. The Phase 1 portion of the trial is expected to enroll up to 100 patients with solid tumors that have alterations likely to be associated with anti-tumor activity based on preclinical studies as well as some patients with the targeted genetic mutations and is designed to establish the recommended dose for the Phase 2 portion of the trial. The Phase 1 portion may have to

evaluate different dosing schedules if the pharmacokinetic or safety data suggest once daily dosing is suboptimal. This may delay initiation of the Phase 2 portion. The open-label Phase 2 portion of the trial is expected to enroll up to 100 patients with the targeted mutations to evaluate efficacy as determined by objective response rate, or ORR, a measure of tumor response and tumor duration response, or DOR. This portion may need to be expanded to provide additional safety and efficacy data to support an application for accelerated approval even if tumor response and duration is adequate. The preliminary results of clinical trials with smaller sample sizes, such as our ongoing open-label Phase 1/2 clinical trial of BDTX-189, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of BDTX-189, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our initial open-label Phase 1/2 clinical trial.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses.

Broad-based business or economic disruptions could adversely affect our ongoing or planned research and development activities. For example, in December 2019, an outbreak of a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease (COVID-19) was reported to have surfaced in Wuhan, China, and has since spread to other regions and countries worldwide. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed restrictions on travel between the United States, Europe and certain other countries. Almost all U.S. states and many local jurisdictions have issued “shelter-in-place” orders, quarantines, executive orders and similar government orders, restrictions, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and recommendations, and the perception that additional orders, restrictions or recommendations

could occur, have resulted in widespread closures of businesses not deemed "essential," work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, as well as record declines in stock prices, among other effects. There is a risk that government actions will not be effective at containing COVID-19 or other infectious diseases, and that government actions, including the orders and restrictions described above, that are intended to contain the spread of COVID-19 will have a devastating negative impact on the world economy at large, in which case the risks to our sales, operating results and financial condition described herein would be elevated significantly.

The continued spread of COVID-19 or other global health matters, such as pandemics, could also impact our target patient populations as well as the hospitals and clinical sites in which we conduct any of our clinical trials, which could lead to delays in completing enrollment of our clinical trials. For instance, the COVID-19 outbreak may continue to impair our ability to recruit and retain patients and engage principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography or due to prioritization of hospital resources toward the outbreak and restrictions on travel. Furthermore, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. COVID-19 already has affected and may further negatively affect the operations of third party contract research organizations that we rely upon to carry out our discovery work, clinical trials or the operations of our third party manufacturers, which could result in delays or disruptions in the supply of our product candidates and the conduct of experiments and studies. Any negative impact COVID-19 has to patient enrollment or treatment or the timing and execution of our preclinical studies or clinical trials could cause costly delays to our development programs, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business and financial results. COVID-19 has also caused, and may continue to cause for an extended period, volatility in the global financial markets and threatened a slowdown in the global economy, reducing our ability to access capital, which would negatively affect our liquidity.

Although some states are starting to relax "shelter-in-place" orders, quarantines and similar restrictions, the regulations vary on a state by state basis and the impact of loosening of those restrictions is not yet known. While our lab-based employees have returned to our labs with enhanced safety measures, our office-based employees continue to work primarily from home and this may continue for an extended period despite the loosening of restrictions, due to the complexities of re-entering the workplace and concerns of individual employees. Furthermore, there has been a resurgence of COVID-19 cases, which could prompt a reinstatement of "shelter-in-place" orders and restrictions at the state and local levels impacting our reentry to the workplace and causing hospital and clinical sites to suspend our clinical trials or could deter patients from continuing to participate in our trials.

The global outbreak of COVID-19 continues to rapidly evolve. The extent to which COVID-19 impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, duration of the outbreak, travel restrictions, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken in the United States and other countries to contain COVID-19 or treat its impact, among others. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, service providers, regulators and other third parties with whom we conduct business, were to experience prolonged business shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

All of our lead product candidates are in preclinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. 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 product candidates. Our preclinical studies and future clinical trials may not be successful.

We cannot be certain that our preclinical study and clinical trial results will be sufficient to support regulatory approval of our product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process.

Additionally, some of the clinical trials we conduct may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that our Phase 1/2 clinical trial of BDTX-189 includes an open-label dosing design, the results from this clinical trial may not be predictive of future clinical trial results with this or other product candidates for which we conduct an open-label clinical trial when studied in a controlled environment with a placebo or active control.

We may experience delays in obtaining the FDA’s authorization to initiate clinical trials under future INDs, completing ongoing preclinical studies of our other product candidates, and initiating our planned preclinical studies and clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with our tumor-agnostic development strategy;
- delays in obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- having subjects complete a clinical trial or return for post-treatment follow-up;

- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- clinical trials of our product candidates may not produce differentiated or clinically significant results across tumor types or indications;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, for example, if we experiences delays or challenges in identifying patients with the mutations required for our clinical trials, we may have to reimburse sites for genetic sequencing costs in order to encourage sequencing of additional patients;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our entire pipeline and MAP platform could have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We may in the future conduct clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our MAP platform to build a pipeline of product candidates with commercial value.

A key element of our strategy is to use and expand our MAP platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of various cancers. Although our research and development efforts to date have resulted in our discovery and preclinical development of BDTX-189, BDTX-189 may not be safe or effective as a cancer treatment, and we may not be able to develop any other product candidates. Our MAP platform is evolving and may not reach a state at which building a pipeline of product candidates is possible. For example, we may not be successful in identifying additional genetic mutations which are oncogenic and which can be "basketed" into a group that is large enough to present a sufficient commercial opportunity or that is druggable with one chemical compound. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

We will rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our product candidates, if approved.

We do not currently own any facility that may be used as our clinical scale manufacturing facility and expect to rely on outside vendors to manufacture supplies of our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

Manufacturing our product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.

The process of manufacturing of our product candidates is complex and highly regulated.

We rely on third parties for the manufacture of our product candidates. These third-party manufacturers may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our product candidates.

As our product candidates progress through preclinical studies and clinical trials towards approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates and additional bridging studies or trials may be required.

We do not have our own clinical-scale manufacturing facility and are currently reliant on a limited number of manufacturers for our product candidates. These third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs.

The market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in most instances at least as a second or third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved as a second or third or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, who may have their tumors genetically sequenced, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third-party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third-party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries, for example, no country other than the United States has a pathway for accelerated drug approval and so obtaining regulatory approvals outside of the United States will take longer and be more costly than obtaining approval in the United States;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on 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 must focus on a limited number of research programs and product candidates and on specific indications. 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. 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 discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products.

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

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge, platform technology and development expertise provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, and public and private research institutes that conduct research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, regulatory approvals and product marketing than we do. Our competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Specifically for BDTX-189, we expect competition primarily in the EGFR and HER2 Exon 20 insertion NSCLC patient populations, including: mobocertinib (TAK-788), which is under development by Takeda Pharmaceutical Company Ltd; amivantamab (JNJ-61186372), which is under development by Janssen Research & Development, LLC; trastuzumab deruxtecan (DS-8201), marketed by Daiichi Sankyo Company Ltd. and AstraZeneca plc under the trade name Enhertu, which is currently approved for HER2+ breast cancer, but under development for HER2 mutan t solid tumors; poziotinib, which is under development by Spectrum Pharmaceuticals, Inc; CLN-081 (formerly TAS6417), which is under development by Cullinan Oncology, LLC; and DZD9008, which is under development by Dizal Pharmaceutical Co., Ltd. In addition, there are other small molecule and precision oncology-focused companies with whom we may eventually compete, including Loxo Oncology, Inc. (recently acquired by Eli Lilly and Company), Blueprint Medicines Corporation, Deciphera Pharmaceuticals, Inc., Turning Point Therapeutics, Inc., and Mirati Therapeutics, Inc.

If our drug candidates, including BDTX-189, are approved for the indications for which we are currently planning clinical trials, they will likely compete with the competitor drugs mentioned above and with other drugs that are currently in development. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also 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. For additional information regarding our competition, see “Business—Competition.”

Risks related to government regulation

We are very early in our development efforts. Most of our product candidates are still in preclinical development. 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 are very early in our development efforts, and most of our product candidates are still in preclinical development. We have invested substantially all of our efforts and financial resources in the identification and preclinical development of our product candidates, including the development of our initial product candidate, BDTX-189. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend on the successful development, approval and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies;
- approval of INDs for our planned clinical trials or future clinical trials;
- FDA acceptance of our tumor-agnostic development strategy;
- successful enrollment in future clinical trials;
- positive results from future clinical trials that are supportive of safety and efficacy in the intended patient populations;
- successful development of companion diagnostics for use with certain of our product candidates;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- obtaining, enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Depending on results from our open-label Phase 1/2 clinical trial for BDTX-189, we expect, subject to discussions with FDA, to either expand the Phase 2 portion of the trial or initiate a second Phase 2 trial in order to seek accelerated approval from the FDA for the treatment of patients with advanced solid tumors that harbor one or more of the targeted genetic mutations detected by an NGS test requiring contemporaneous FDA clearance or approval, who have progressed or relapsed following prior treatment and who have no satisfactory treatment options. Whether the results from our open-label Phase 1/2 clinical trial and other trials will suffice to obtain accelerated approval will be a review issue and the FDA may not grant accelerated approval and may require that we conduct one or more controlled, randomized Phase 3 clinical trials to obtain approval. In addition, because there is limited experience of the FDA with the approval of tumor-agnostic cancer treatments and since we will need to show that there is no available therapy for each of the tumors tested in our open-label Phase 1/2 clinical trial, we may experience challenges in obtaining accelerated approval across all such tumor types. To date, we have had no interactions with regulatory authorities outside of the United States. We intend to engage with the EMA following the results of the Phase 2 portion of the planned trial regarding regulatory requirements for registration in the EU. There is limited experience of regulatory authorities outside of the United States with the approval of tumor-agnostic precision cancer medicines.

Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates 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 regulatory 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 IND, NDA, or equivalent application types, 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 are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including our Phase 1/2 clinical trial design for BDTX-189;
- the FDA or comparable foreign regulatory authorities may disagree with our tumor-agnostic development strategy;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including BDTX-189 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. Our product candidates may fail to demonstrate efficacy in humans, and particularly across tumor types. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, the EMA, or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA, the EMA or other comparable foreign regulatory authorities will view our product candidates as having sufficient efficacy to support a tumor-agnostic indication even if positive results are observed in clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA or other comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Additionally, any safety or efficacy concerns observed in any tumor-specific subgroup of our clinical trials could limit the prospects for regulatory approval of our product candidates for a tumor-agnostic indication, which could have a material adverse effect on our business, financial condition and results of operations.

We may in the future seek orphan drug status for BDTX-189 and some of our other future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for BDTX-189 and some or all of our other future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these products. Even when we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations. For example, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tissue agnostic therapies, and the FDA may interpret the FD&C Act and regulations promulgated thereunder in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications.

On August 3, 2017, the Congress passed the FDA Reauthorization Act of 2017, or 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 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.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek Breakthrough Therapy designation for BDTX-189 and some or all of our future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for BDTX-189 and some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation.

A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We have been granted Fast Track designation for BDTX-189 for the treatment of adult patients with solid tumors harboring an allosteric human epidermal growth factor receptor 2 (HER2) mutation or an epidermal growth factor receptor (EGFR) or HER2 Exon 20 insertion mutation who have progressed following prior treatment and who have no satisfactory treatment options. We may seek Fast Track designation for other indications or for certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our other proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. 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. In addition, the FDA may withdraw any Fast Track designation at any time.

Accelerated approval by the FDA, even if granted for BDTX-189 or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We plan to seek approval of BDTX-189 and may seek approval of future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our drug candidates that are required or experience significant delays in doing so, we may not realize the full commercial potential of these drug candidates.

In connection with the clinical development of our drug candidates for certain indications, we intend to engage third parties to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our drug candidates. Such companion diagnostics would be used during our clinical trials as well as in connection with the FDA approval of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA regulates *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will require the test to be analytically validated and used for patient selection in the clinical trial, which we expect will require separate regulatory clearance or approval prior to commercialization if not already approved.

We intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic drug candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic drug candidates, or experience delays in doing so, the development of these therapeutic drug candidates may be adversely affected, these therapeutic drug candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with applicable cGMP, GLP and GCP requirements, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they

will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, 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 reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. 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.

Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, 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 our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe 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. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of 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.

Additionally, we may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval. Our inability to promptly obtain coverage and adequate reimbursement from both third-party payors for the companion diagnostic tests that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale

discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been judicial, administrative, executive and Congressional legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example. various portions of the ACA are currently undergoing constitutional challenges in the Fifth Circuit Court and the United States Supreme Court, and the Trump Administration has issued various Executive Orders eliminating cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended, and we cannot predict what affect further changes to the ACA would have on our business.

Members of the U.S. Congress and the Trump administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the Affordable Care Act. While Congress has not passed repeal legislation to date, the Tax Cuts and Jobs Act of 2017, or TCJA, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The Trump Administration and CMS have both stated that the ruling will have no immediate effect, and on December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. The Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. 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. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay to third-party payors more than $12 billion in ACA risk corridor payments that they argued were owed to them. On December 10, 2019, the U.S. Supreme Court heard arguments in *Moda Health Plan, Inc. v. United States*, which will determine whether the government must make risk corridor payments. The U.S. Supreme Court's decision will be released in the coming months, but we cannot predict how the U.S. Supreme Court will rule. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Moreover, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. However, on December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar

taxes could be instated in the future. The Bipartisan Budget Act of 2018, also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently published a final rule that would give states greater flexibility, starting in 2020, 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 ACA for plans sold through such marketplaces. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act 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. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2029 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, or ATRA, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget for fiscal year 2020 contains further drug price control measures that could be enacted during the 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. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020.

Further, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Additionally, in December 2019, the FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada. FDA also issued a Draft Guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the notice of proposed rulemaking and Draft Guidance are unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs, if enacted and implemented, could decrease the price we receive for our products and adversely affect our future revenues and prospects for profitability.

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 health care 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 health care 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 our product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the Affordable Care Act. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil “qui tam” or “whistleblower” actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; 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 that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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. 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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 also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010, or the Bribery Act. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU 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 EU Member States.

These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States.

Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 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 also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also 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 includes restrictions on cross-border data transfers. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject

to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

In addition, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

If we 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 are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. 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. We also could incur significant costs associated with civil or criminal fines and penalties.

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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Risks related to our intellectual property

We do not currently own or in-license any issued patents relating to our product candidates or technology, including BDTX-189. If we are unable to obtain and maintain patent and other intellectual property protection for BDTX-189, our MAP platform and our other product candidates and technology, or any other product candidates or technology we may develop, or if the scope of 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 commercialize BDTX-189 or any other product candidates or technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our product candidates, including BDTX-189, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business, as well as successfully defending these patents against third-party challenges. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We intend to rely upon a combination of patent applications, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our product candidates and technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to establish our patent position.

To protect our proprietary position, we plan to file patent applications in the United States and abroad relating to our product candidates and MAP platform that are important to our business; we may in the future also license or purchase patents or patent applications owned by others. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure or maintain patent protection with respect to BDTX-189, our MAP platform or any other proprietary products and technology we develop, our business, financial condition, results of operations, and prospects would be materially harmed.

We do not currently own or in-license any issued patents relating to BDTX-189, including its composition of matter, and we do not currently own or in-license any issued patents relating to any of our other product candidates or technology. We own one Patent Cooperation Treaty, or PCT, patent application that covers the composition of matter for BDTX-189, as well as methods of using and making BDTX-189. This PCT application may never result in an issued patent. This pending PCT patent application is not eligible to become an issued patent until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent application and any patent protection on the inventions disclosed in such PCT patent application. While we intend to timely file a national stage patent application relating to our PCT patent application, we cannot predict whether any of our future patent applications for BDTX-189 or any of our other product candidates will result in the issuance of patents that effectively protect BDTX-189 or our other product candidates. If we do not successfully obtain patent protection, or, even if we do obtain patent protection, if the scope of the patent protection we or our potential licensors obtain with respect to BDTX-189 or our other product candidates and technology is not sufficiently broad, we will be unable to prevent others from using 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 BDTX-189 and our other product candidates would have a material adverse effect on our business, financial condition, results of operations and prospects.

The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any patents we may own or in-license in the future will have, or that any of our patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot assure you that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan, and the term of any patents we may own or in-license in the future may be inadequate to protect our competitive position of our product candidates or technology for an adequate amount of time. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life 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 candidates might expire before or shortly after such candidates are commercialized.

Even if they are unchallenged, our patent applications, if issued, and any patents we may own or in-license in the future, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent any patents we may own or in-license in the future by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of any patent protection we may have in the future. If the patent protection provided by our patent applications or any patents we may pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Although we currently own our patent applications, similar risks would apply to any patents or patent applications that we may own or in-license in the future.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patent applications or any patents we may own or in-license in the future.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. Patent license negotiations also can be complex and protracted, with uncertain results. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose results before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind 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. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patent applications.

It is possible that defects of form in the preparation or filing of our patent applications, or any patents we may own or in-license in the future, may exist or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patent applications or patents we may own or in-license in the future, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Additionally, we cannot be certain that the claims in our patent applications covering composition of matter of our product candidates or technology will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any issued patents we may own or in-license in the future will be considered patentable by courts in the United States or foreign countries.

Method of use patents protect the use of a product for the specified method. These types of patents do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may induce or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any rights we may have from our patent applications are highly uncertain. Our patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Moreover, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art, including our own previously filed patent applications and scientific publications, allow our inventions to be patentable over the prior art. Even if our patent applications issue as patents, third parties could challenge the validity of such patents based on such scientific publications and we could potentially lose valuable patent rights. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even where patent applications we currently own or that we may license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade any rights we may have from our patent applications by developing new compounds or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and any patents we may own or in-license in the future may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of any patents we may own or in-license being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and

other similar proceedings challenging any rights we may have from our patent applications or the patent rights of others in the U.S. Patent and Trademark Office, or USPTO, or other foreign patent office, or in declaratory judgment actions or counterclaims. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, any rights we may have from our patent applications, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Moreover, some of our intellectual property, including any patents we may own or in-license in the future, may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such intellectual property, including patents or patent applications, such 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. In addition, we or our future licensors may need the cooperation of any such co-owners of our owned and in-licensed intellectual property, including patents and patent applications, in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us or our future licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our future licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If we fail to comply with our obligations in any future agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.

In the future, we may be party to license or collaboration agreements with third parties to advance our research or allow commercialization of product candidates. Such future agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our future licensors might conclude that we have materially breached our future license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties in the future 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 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. Moreover, if disputes over intellectual property that we may license in the future prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, 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 may own or in-license in the future, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes, including our MAP platform that involve proprietary know-how, information, or technology that is not covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our MAP platform, including aspects of oncogenicity computational algorithms, in vivo experiments to validate mechanisms and pharmacology, drug design, and related processes, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. 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 from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions 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. 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. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations may be costly and time consuming and may prevent or delay our product discovery and development efforts.

The intellectual property landscape around precision medicine is crowded, and 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 have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, including BDTX-189, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our product candidates or processes so they do not infringe, misappropriate or violate third party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- 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.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block

our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license in the future is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we own one PCT patent application related to BDTX-189. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, 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 others, potentially blocking our ability to pursue our program and allowing third parties to compete with us. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash 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 or at all. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business, results of operations, financial condition and prospects could suffer.

We may be involved in lawsuits to protect or enforce our intellectual property rights, including any patents we may own or in-license in the future, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any patents we may own or in-license in the future. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license in the future is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license in the future do not cover the technology in question or that such third party's activities do not infringe our patent applications or any patents we may own or in-license in the future. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license in the future at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. 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 conduct such litigation or proceedings adequately. Some of our competitors 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 have a material adverse effect on our ability to compete in the marketplace.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license in the future. These proceedings are expensive and an unfavorable outcome could result in a loss our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the European Patent Office, or EPO, or similar proceedings in other foreign patent offices, where either our foreign patents are challenged. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. 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.

We may not be able to detect infringement against any patents we may own or in-license in the future. Even if we detect infringement by a third party of any patents we may own or in-license in the future, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third party.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and 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 any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

Any issued patents we may own or in-license in the future covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

If we or our future licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in the future in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any

rights we may have from our patent applications or any patents we may own or in-license in the future, allow third parties to commercialize our product candidates or other technologies 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 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 our or priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. Such challenges may result in loss of patent rights, loss of exclusivity, 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 product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. For 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. Any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce any rights we may have in our patent applications or any patents we may own or in-license in the future.

Recent or future patent reform legislation could also increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we may own or in-license in the future. The United States has enacted and implemented wide-ranging patent reform legislation. On September 16, 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law, which includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, establish a new post-grant review system and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a

patent on the invention regardless of whether another inventor had made the invention earlier. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our patent applications or any patents we may own or in-license. These changes also allow third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products 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. Accordingly, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents we may own or in-license in the future, all of which could have a material adverse effect on our business and financial condition.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We may not be able to pursue generic coverage of our product candidates or MAP platform outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our 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. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license in the future or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in the future in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license in the future 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 may not prevail in any lawsuits that we 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 countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents we may own or license in the future that are relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may be subject to claims challenging the inventorship or ownership of any intellectual property, including any patents we may own or in-license in the future.

We may be subject to claims that former employees, collaborators or other third parties have an interest in any patents we may own or in-license in the future, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. Litigation may be necessary to defend against these and other claims challenging inventorship of any patents we may own or in-license in the future, trade secrets or other intellectual property. If we were unsuccessful, in addition to paying monetary damages, we could lose valuable rights in intellectual property that we regard as our own, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. 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.

We are party to a services agreement with Ridgeline Therapeutics GmbH, or the Ridgeline Services Agreement, pursuant to which Ridgeline provides certain drug discovery and development services. Pursuant to the Ridgeline Services Agreement, we own all rights in and to all patent, copyright and other intellectual property rights generated by Ridgeline in the course of performing the specified services. If it is unclear whether certain intellectual property generated by Ridgeline is our property, we may be subject to conflicting claims of ownership.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We have received confidential and proprietary information from third parties. In addition, as is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information or trade secrets of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation or arbitration 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 personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims and possible aftermath could result in substantial cost and be a distraction to our management and employees. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

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. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates we may develop, one or more U.S. patents we may own or in-license in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension 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 drug, a method for using it, or a method for manufacturing it may be extended. 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. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following expiration of any patents that issue from our patent applications, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license in the future may not lead to issued patents;
- patents, should they issue, that we may own or in-license in the future, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;

- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license in the future, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks related to our reliance on third parties

We plan to rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract manufacturing organizations, or CMOs, and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us. For example, we contract with Ridgeline for services related to our drug discovery and preclinical work, but we are continuing to build our internal chemistry, manufacturing and controls, biology and preclinical development capabilities to assume activities conducted by Ridgeline on our behalf. We have transitioned from our old service model to a more limited consulting arrangement with Ridgeline. As part of this transition, we may incur additional costs or experience delays in engaging directly with other third-party CROs and CMOs.

We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and 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. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory

requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and non-clinical product candidates. These third parties 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, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships 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 face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results,

changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, 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 our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- 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; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, 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, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or third parties to manufacture our product candidates. Our business could be harmed if we are unable to use third-party manufacturing suites or if the third party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must inspect any manufacturers for current cGMP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;

- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and we have no control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks related to managing growth and employee matters

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer and President, our Chief Financial Officer and Chief Scientific Officer, our Executive Vice President of Discovery and Translational Sciences and our Senior Vice President, Clinical Development. Our Senior Vice President, Clinical Development, Karsten Witt, M.D., is not our employee and provides services under a consulting agreement. We have transitioned from our old service model with Ridgeline to a more limited consulting arrangement. While we have engaged in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. In addition, the loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facilities in Cambridge, MA, New York, NY, Stony Brook, NY, and Toronto, Canada. The Massachusetts region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2020, we had 49 full-time employees. We intend to hire new employees to conduct our research and development activities in the future. Any delay in hiring such new employees could result in delays in our research and development activities and would harm our business. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of precision medicines as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other cancer medicines;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other precision medicine approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the planned clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership by 5% stockholders over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. As a result of our most recent private placements and other transactions that have occurred over the past three years, we may have experienced, and may experience, an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2019, we had U.S. federal and state net operating loss carryforwards of $39,596 and U.S. federal research and development tax credit carryforwards of $1,014, each of which will begin to expire at various dates through 2039 and which could be limited if we experience an "ownership change."

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, 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 these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our MAP platform and product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data

could result in significant liability under state (*e.g.*, state breach notification laws), federal (*e.g.*, HIPAA, as amended by HITECH), and international law (*e.g.*, the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

In addition, the computer systems of various third parties on which we rely, including our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Risks related to ownership of our common stock

The price of our stock is volatile, and you could lose all or part of your investment.

Similar to the trading prices of the common stock of other biopharmaceutical companies, the trading price of our common stock is subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report, these factors include:

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, financial condition, results of operation and future prospects.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

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

Our management will have broad discretion in the application of our existing cash, cash equivalents and marketable securities. Because of the number and variability of factors that will determine our use of the net proceeds from our IPO, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase or maintain the value of your investment.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

Based upon our common stock outstanding as of June 30, 2020, our executive officers, directors, and their affiliates beneficially owned over a majority of our outstanding voting stock. These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval. For example, these stockholders are able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this Quarterly Report and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to not “opt out” of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Quarterly Report and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the Securities and Exchange Commission, or SEC, annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this Quarterly Report lapse, the trading price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2020 Plan and our 2020 Employee Stock Purchase Plan, each of which became effective upon the effectiveness of the registration statement of which this Quarterly Report forms a part, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our bylaws designate a certain court as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision

of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clause in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they 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 even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

In preparation of our financial statements to meet the requirements of our initial public offering, we determined that material weaknesses in our internal control over financial reporting existed during fiscal 2017 and remained unremediated as of June 30, 2020. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

The material weaknesses we identified are related to the design and maintenance of an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately and we did not design and maintain controls to ensure adequate segregation of duties within our financial reporting function including the preparation and review of journal entries.

The material weaknesses contributed to the restatement of our previously issued 2017 annual financial statements. Specifically, the material weaknesses resulted in errors in our accounting for and reporting of derivative liabilities, loss on extinguishment of convertible promissory notes and expense classification.

We are in the process of building a finance organization and implementing measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses, including hiring additional finance and accounting personnel and the establishment of controls to account for and disclose complex transactions. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and applicable Nasdaq Global Select Market listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result. In addition, we could become subject to investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Adequate internal control over financial reporting are necessary for us to provide reliable financial reports and, together with effective disclosure controls and procedures, are designed to prevent or detect material misstatements due to fraud or error. 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 conducted by us in connection with Section 404 of the Sarbanes-Oxley Act, 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. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Set forth below is information regarding shares of equity securities sold, and options granted, by us during the three months ended March 31, 2019 that were not registered under the Securities Act.

Recent Sales of Unregistered Equity Securities

On February 3, 2020, upon the closing of our IPO all 64,839,353 shares of our then-outstanding redeemable convertible preferred stock automatically converted into 21,499,770 shares of common stock. The issuance of such common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

During the period between January 1, 2020 and March 31, 2020, we issued to certain of our employees and advisors, options to purchase an aggregate of 901,651 shares of our common stock at an exercise price ranging from $19.00-$43.05 per share. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit.

Use of Proceeds from IPO of Common Stock

On February 3, 2020, we completed the IPO of our common stock pursuant to which we issued and sold 12,174,263 shares of our common stock, including the exercise in full by the underwriters of their option to purchase up to 1,587,947 additional shares of common stock, at a public offering price of $19.00 per share.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333-235789), which was declared effective by the SEC on January 29, 2020. J.P. Morgan Securities LLC, Jefferies LLC, Cowen and Company, LLC and Canaccord Genuity LLC acted as joint book-running managers of the offering and as representatives of the underwriters.

We received aggregate gross proceeds from our IPO of $231.3 million, or aggregate net proceeds of $212.1 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus dated January 30, 2020.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report.

Exhibit No.	Exhibit Index
10.1†	Lease Agreement, dated as of July 24, 2020, by and between RREEF America REIT II Corp. PPP and the Registrant.
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, 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) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101SCH	Inline XBRL Taxonomy Extension Schema Document.
101CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

+ This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

† Non-material schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company hereby undertakes to furnish supplementally copies of any of the omitted schedules and exhibits upon request by the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Black Diamond Therapeutics, Inc.

Date: August 11, 2020

By: /s/ David M. Epstein

David M. Epstein
President and Chief Executive Officer
(Principal Executive Officer)

Black Diamond Therapeutics, Inc.

Date: August 11, 2020

By: /s/ Thomas Leggett

Thomas Leggett
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

11/02 SOG(BY)-INS
Revised 12/05

LEASE

RREEF AMERICA REIT II CORP. PPP,

Landlord,

and

BLACK DIAMOND THERAPEUTICS, INC.,

Tenant

Riverfront Office Park

Cambridge, Massachusetts

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(continued)

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GROSS (BY)-INS OFFICE LEASE

REFERENCE PAGES

BUILDING:	Riverfront Office Park One Main Street Cambridge, Massachusetts 02142
LANDLORD:	**RREEF AMERICA REIT II CORP. PPP**, a Maryland corporation
LANDLORD'S ADDRESS:	c/o CB Richard Ellis New England One Main Street Cambridge, MA 02142
WIRE INSTRUCTIONS AND/OR ADDRESS FOR RENT PAYMENT:	RREEF America REIT II CORP. PPP, Riverfront 61.J15 Riverfront Office - 1 Main PO Box 9046 Addison, TX 75001-9046
LEASE REFERENCE DATE:	July 24, 2020
TENANT:	**BLACK DIAMOND THERAPEUTICS, INC.**, a Delaware corporation
TENANT'S NOTICE ADDRESS:	
(a) As of beginning of Term:	One Main Street 10th Floor Cambridge, Massachusetts 02142
(b) Prior to beginning of Term (if different):	139 Main Street, Suite 301, Cambridge, MA 02142
PREMISES ADDRESS:	One Main Street 10th Floor Cambridge, Massachusetts 02142
PREMISES RENTABLE AREA:	Approximately 25,578 rentable square feet comprised of 11,139 rentable square feet on the fourteenth (14th) floor (the "**14th Floor Premises**") and 14,439 rentable square feet on the tenth (10th) floor (the "**10th Floor Premises**")
PREMISES:	Collectively, the 14th Floor Premises and the 10th Floor Premises containing the Premises Rentable Area, as applicable, referenced above and located in the Building and approximately as shown on the floor plans attached hereto as Exhibit A.
PREMISES COMPONENT:	Each of (i) the portion of the Premises identified in this Lease as being the 14th Floor Premises, and (ii) the portion of the Premises being identified in this Lease as being the 10th Floor Premises shall each constitute a "Premises Component" for purposes of this lease.
COMMENCEMENT DATE:	The date set forth as the Applicable Commencement Date for the applicable Premises Component of the Premises pursuant to Section 2.1 of this Lease.

14th FLOOR COMMENCEMENT DATE:	The date that is four (4) months following the 14th Floor Delivery Date, as defined below, plus the number of days attributable to Landlord Delay and Excused Construction Delay (as such terms are hereinafter defined); estimated to be February 1, 2021.
10th FLOOR COMMENCEMENT DATE:	The later of (i) August 1, 2020, and (ii) the 10th Floor Delivery Date.
APPLICABLE COMMENCEMENT DATE:	Shall refer, as the context may require, to the commencement date set forth above in this Lease for each of the 14th Floor Premises Component, and the 10th Floor Premises Component, as the case may be.
14TH FLOOR DELIVERY DATE:	As defined in Section 2.1.
10TH FLOOR DELIVERY DATE:	As defined in Section 2.1.
SCHEDULED DELIVERY DATE:	August 1, 2020 for the 10th Floor Premises and October 1, 2020 for the 14th Floor Premises.
14th FLOOR RENT COMMENCEMENT DATE:	The date that is four (4) months after the 14th Floor Commencement Date.
10th FLOOR RENT COMMENCEMENT DATE:	The date that is three (3) months after the 10th Floor Commencement Date.
APPLICABLE RENT COMMENCEMENT DATE:	Shall refer, as the context may require, with respect to Annual Rent only (with Additional Rent commencing as of the Applicable Commencement Date for each Premises Component), to the rent commencement date set forth above in this Lease for each of the 14th Floor Premises Component, and the 10th Floor Premises Component, as the case may be.
TERM OF LEASE:	With respect to the 14th Floor Premises, the period beginning on the 14th Floor Delivery Date and ending on the Termination Date. With respect to the 10th Floor Premises, the period beginning on the 10th Floor Commencement Date and ending on the Termination Date.
TERMINATION DATE:	The last day of the seventh (7th) Rent Year for the 14th Floor Premises, unless extended or earlier terminated as provided in this Lease.
ANNUAL RENT and MONTHLY INSTALLMENT OF RENT(Article 3):	
14th Floor Premises:	

Period	Rentable Square Footage	Annual Rent Per Square Foot	Annual Rent	Monthly Installment of Rent
First Rent Year**	11,139	$97.00	$1,080,483.00	$90,040.25
Second Rent Year	11,139	$99.43	$1,107,550.77	$92,295.90
Third Rent Year	11,139	$101.92	$1,135,286.88	$94,607.24
Fourth Rent Year	11,139	$104.47	$1,163,691.33	$96,974.28
Fifth Rent Year	11,139	$107.08	$1,192,764.12	$99,397.01
Sixth Rent Year	11,139	$109.76	$1,222,616.64	$101,884.72
Seventh Rent Year	11,139	$112.50	$1,253,137.50	$104,428.13
10th Floor Premises:				
Period	**Rentable Square Footage**	**Annual Rent Per Square Foot**	**Annual Rent**	**Monthly Installment of Rent**
First Rent Year**	14,439	$87.00	$1,256,193.00	$104,682.75
Second Rent Year	14,439	$89.18	$1,287,670.02	$107,305.84
Third Rent Year	14,439	$91.41	$1,319,868.99	$109,989.08
Fourth Rent Year	14,439	$93.70	$1,352,934.30	$112,744.53
Fifth Rent Year	14,439	$96.04	$1,386,721.56	$115,560.13
Sixth Rent Year	14,439	$98.44	$1,421,375.16	$118,447.93
Seventh Rent Year	14,439	$100.90	$1,456,895.10	$121,407.93

**Notwithstanding anything to the contrary contained herein, provided and so long as there is no Event of Default in existence, the monthly installment of Annual Rent due under this Lease for each Premises Component will be abated during the period commencing on the Applicable Commencement Date for such Premises Component and ending on the day immediately preceding the Applicable Rent Commencement Date for such Premises Component (the "Abatement Period"). The foregoing rent abatement shall apply to and affect only the monthly installments of Annual Rent due under this Lease during the Abatement Period and Tenant shall be obligated to pay all Additional Rent and all other charges which accrue and are due under this Lease with respect to the applicable Premises Component during the Abatement Period. If at any time during the Abatement Period there occurs any Event of Default under this Lease, Tenant's right to abate the Annual Rent for the Abatement Period shall be suspended until such time that Tenant cures such Event of Default, provided that any reinstatement will be applied at the rental rate that would have applied during the Abatement Period.

For purposes of this Lease, the term "Rent Year" shall mean each consecutive twelve (12) month period beginning on the Applicable Rent Commencement Date or on each anniversary of the Applicable Rent Commencement Date for such Premises Component, provided, however, that if the Applicable Rent Commencement Date for such Premises Component does not fall on the first day of a calendar month, then the first Rent Year for such Premises Component shall begin on the Applicable Rent Commencement Date and end on the last day of the month containing the first anniversary of the Applicable Rent Commencement Date for such Premises Component, and each succeeding Rent Year shall begin on the day following the expiration of the prior Rent Year. Notwithstanding the foregoing, if the 10th Floor Rent Commencement Date occurs prior to the 14th Floor Rent Commencement Date, then the first Rent Year for the 10th Floor Premises shall be extended to expire on the same date as the first Rent Year for the 14th Floor Premises expires. By way of example of the foregoing, if the 10th Floor Rent Commencement Date is November 1, 2020 and the 14th Floor Rent Commencement Date is December 1, 2020 then the first Rent Year for the 10th Floor Premises will commence on November 1, 2020 and expires on November 30, 2021.

All rental amounts are net of Tenant electricity, as more particularly described in Section 13 below.

BASE YEAR (EXPENSES):	Calendar year 2020.
BASE YEAR (TAXES):	Taxes for July 1, 2019 to June 30, 2020 (fiscal 2020)
TENANT'S PROPORTIONATE SHARE:	8.001% (25,578/319,672), provided, however, if the Applicable Commencement Dates for both Premises Components does not occur on the same date, then such Tenant's Proportionate Share shall be temporarily calculated based only on the Premises Rentable Area of the Premises Component for which the Term of this Lease has commenced, i.e. 3.485% (11,139/319,672) for the 14th Floor Premises; and 4.516% (14,439/319,672) for the 10th Floor Premises.
SECURITY DEPOSIT:	$1,168,338.00 in the form of an irrevocable letter of credit; See Article 5.
ASSIGNMENT/SUBLETTING FEE:	$1,500.00
AFTER-HOURS HVAC COST:	$2.00 per heat pump per hour with a minimum charge of $30.00 per request, subject to change at any time.
PARKING	Thirteen (13) passes at $350.00 per month (see Article 39), based on a ratio of one (1) pass per two thousand (2,000) rentable square feet in the Premises.

REAL ESTATE BROKER DUE COMMISSION:	Newmark Knight Frank and CBRE
BUILDING BUSINESS HOURS:	Monday through Friday 8:00 a.m. – 6:00 p.m. (excluding Massachusetts state holidays) Saturdays 8:00 a.m. – 12:00 p.m. (HVAC to be provided at no additional cost to Tenant only upon Tenant advance request.)

The Reference Pages information is incorporated into and made a part of the Lease. In the event of any conflict between any Reference Pages information and the Lease, the Lease shall control. This Lease includes Exhibits A through E, all of which are made a part of this Lease.

LANDLORD:

RREEF AMERICA REIT II CORP. PPP, a Maryland corporation

By: /s/ David F Crane

Name: David F. Crane
Title: Vice President

By: /s/ Gerald F. Ianetta

Name: Gerald F. Ianetta
Title: Vice President

TENANT:

BLACK DIAMOND THERAPEUTICS, INC., a Delaware corporation

By: /s/ David M Epstein

Name: David M. Epstein
Title: President & CEO

LEASE

By this Lease Landlord leases to Tenant and Tenant leases from Landlord the Premises in the Building as set forth and described on the Reference Pages. The Premises are depicted on the floor plans attached hereto as Exhibit A, and the Building is depicted on the site plan attached hereto as Exhibit A-1. The Building is located on the Lot legally described on Exhibit A-2. The Reference Pages, including all terms defined thereon, are incorporated as part of this Lease.

1. USE AND RESTRICTIONS ON USE**.**

1.1 The Premises are to be used solely for general office purposes. Tenant shall not do or permit anything to be done in or about the Premises which will in any way obstruct or interfere with the rights of other tenants or occupants of the Building or injure, annoy, or disturb them, or allow the Premises to be used for any improper, immoral, unlawful, or objectionable purpose, or commit any waste. Tenant shall not do, permit or suffer in, on, or about the Premises the sale of any alcoholic liquor without the written consent of Landlord first obtained. Tenant shall comply with all governmental laws, ordinances, regulations, mandates and directives (the "Legal Requirements") applicable to the use of the Premises and its occupancy and shall promptly comply with all governmental orders and directions for the correction, prevention and abatement of any violations in the Building or appurtenant land, caused by, or resulting from the specific use by, Tenant, or in or upon, or in connection with, the Premises, all at Tenant's sole expense. Landlord shall, as part of Expenses, maintain the common areas of the Building, the structural elements of the Building and the base building systems serving the Building in general in compliance with applicable Legal Requirements. Tenant shall not do or permit anything to be done on or about the Premises or bring or keep anything into the Premises which will in any way increase the rate of, invalidate or prevent the procuring of any insurance protecting against loss or damage to the Building or any of its contents by fire or other casualty or against liability for damage to property or injury to persons in or about the Building or any part thereof. Notwithstanding anything in this Lease to the contrary, Tenant shall not be obligated to make structural repairs or alterations to the Premises in order to comply with any Legal Requirements unless the need for such repairs or alterations arises from the specific manner and nature of Tenant's use or occupancy of the Premises (as distinguished from mere general office use or requirements being imposed on a building-wide basis to all tenants in the Building), the manner of conduct of Tenant's business or operation of its installations, equipment or other property therein (to the extent in excess of or inconsistent with the normal conduct of a general office use), any condition created by or at the instance of the Tenant, including, without limitation, Tenant's Work and/or any other Alterations made by Tenant if and to the extent that such Tenant's Work and/or Alterations are not, in Landlord's sole but reasonable discretion, of a nature customarily performed by tenants of comparable size in comparable buildings in the Cambridge area, or a breach by Tenant of any provisions of this Lease.

Subject to Tenant first obtaining all necessary governmental permits and approvals and Landlord's approval of Tenant's plans and specifications therefor, Tenant shall have the right, as part of the Tenant's Work and at Tenant's sole cost and expense, to construct, fixture and furnish an outdoor roof terrace in a location on the 14th floor roof immediately adjacent to the Premises (the "**Roof Terrace**") in a location and of a size approved by Landlord in Landlord's sole but reasonable discretion. The Roof Terrace will be a minimum of 400 square feet and the size and occupancy capacity must not exceed what the applicable building code allows based on there being only one means of egress to the Premises. There will be a 5-foot buffer zone between the deck railing and the existing parapet walls to allow unlimited access to the davit arm receivers. All deck railings shall be constructed in a manner that shall not impede the use of the roof anchor system and safety lines. All roof penetrations shall be coordinated with the Building's designated roofing contractor and all repairs will be in compliance with the existing roof warranty. Improvements to the Roof Terrace must be modular to enable access to the roof deck for repairs. Subject to compliance with all applicable Laws, and provided and so long as Tenant leases the entire 14th Floor Premises initially leased hereunder (collectively, the "**Roof Terrace Threshold**"), Tenant will have the exclusive right, at no additional rental charge, to access and use the Roof Terrace for outdoor seating and other outdoor activities ancillary to Tenant's office uses of the Premises. Landlord may require that Tenant, at Tenant's sole cost and expense, contract with Landlord's roof contractor to ensure that the roof warranty for the Building is not invalidated or adversely affected and to provide Landlord with a certification to such effect following installation of the Roof Terrace. Tenant shall have the right to install, at Tenant's sole cost and expense, tables, chairs, and other furniture in

the Roof Terrace (the "**Terrace FF&E**") subject to Landlord's prior written approval, which shall not be unreasonably withheld or delayed, provided, however, Landlord's determination of matters relating to aesthetic issues relating to the Terrace FF&E and the Roof Terrace shall be in Landlord's sole discretion and Landlord may require that moveable Terrace FF&E be secured in a manner reasonably acceptable to Landlord. The Roof Terrace shall be considered part of the Premises for all purposes of the Lease except for the payment of Annual Rent and the determination of Tenant's Proportionate Share. Tenant's use of the Roof Terrace and the Terrace FF&E shall be upon and subject to all of the terms and conditions of this Lease, including, without limitation, Tenant's indemnification and insurance obligations under this Lease. Tenant may use the Roof Terrace for Tenant's own use or the use of any subtenants or assignees to which Landlord has consented pursuant to this Lease and Tenant's rights under this Section 1.2 shall not be assignable or otherwise transferable (including by sublease, license or other means) by Tenant separately from this Lease. In no event shall Tenant permit use of the Roof Terrace by the general public (exclusive of Tenant's invitees having a business relationship with Tenant). Tenant's use of the Roof Terrace and the Terrace FF&E shall be subject to rules and regulations reasonably issued from time to time by Landlord and of which Tenant has been given prior notice and Tenant shall comply with all Legal Requirements and governmental approvals applicable to the Roof Terrace. Tenant shall be responsible for maintenance and daily cleaning and janitorial services to the Roof Terrace and shall maintain the Roof Terrace and the Terrace FF&E in a safe, clean and first class condition consistent with first class office building standards for comparable buildings in Cambridge, Massachusetts. Landlord shall not have any obligations (including any compliance with Legal Requirements obligation) with respect to the Roof Terrace or the Terrace FF&E and Landlord shall not be required to provide any services or utilities to the Roof Terrace, provided, however, the foregoing shall not limit Landlord's obligations under this Lease to maintain the roof. Tenant shall use and maintain the Roof Terrace so as not to cause any damage to the Building (including the parking garage) or the Complex or any interference with the use, operation or maintenance of the Building or any mechanical, electrical or other building systems of the Building.

If, at any time during the Term, Tenant ceases to satisfy the Roof Terrace Threshold, Tenant's right to exclusive use of the Roof Terrace shall terminate and Landlord may require Tenant to repair any damage to the Building (including the roof) caused by the installation or removal of such Roof Terrace and/or Terrace FF&E, provided however, Tenant shall not be required to remove the Roof Terrace improvements at the expiration or earlier termination of the Term, but Tenant shall remove all Terrace FF&E. In the event that any governmental agency having jurisdiction over the Building imposes any rooftop or common space taxes or other taxes or fees on Landlord or the Building in connection with the use or operation of the Roof Terrace and/or the Terrace FF&E, Tenant shall pay to Landlord the amount of any such tax or fee imposed in connection with Tenant's use or operation of the Roof Terrace and/or the Terrace FF&E.

1.2 Tenant shall not, and shall not direct, suffer or permit any of its agents, contractors, employees, licensees or invitees (collectively, the "Tenant Entities") to at any time handle, use, manufacture, store or dispose of in or about the Premises or the Building any (collectively "Hazardous Materials") flammables, explosives, radioactive materials, hazardous wastes or materials, toxic wastes or materials, or other similar substances, petroleum products or derivatives or any substance subject to regulation by or under any federal, state and local laws and ordinances relating to the protection of the environment or the keeping, use or disposition of environmentally hazardous materials, substances, or wastes, presently in effect or hereafter adopted, all amendments to any of them, and all rules and regulations issued pursuant to any of such laws or ordinances (collectively "Environmental Laws"), nor shall Tenant suffer or permit any Hazardous Materials to be used in any manner by Tenant Entities not fully in compliance with all Environmental Laws, in the Premises or the Building and appurtenant land or allow the environment to become contaminated by Tenant Entities with any Hazardous Materials. Notwithstanding the foregoing, Tenant and Tenant Entities may handle, store, use or dispose of products containing small quantities of Hazardous Materials (such as aerosol cans containing insecticides, toner for copiers, paints, paint remover and the like) to the extent customary and necessary for the use of the Premises for general office purposes; provided that Tenant shall always handle, store, use, and dispose of any such Hazardous Materials in a safe and lawful manner and never allow such Hazardous Materials to contaminate the Premises, Building and appurtenant land or the environment. Tenant shall protect, defend, indemnify and hold each and all of the Landlord Entities (as defined in Article 30) harmless from and against any and all loss, claims, liability or costs (including court costs and reasonable attorney's fees) incurred by reason of any failure of Tenant to fully comply with all applicable Environmental Laws, or the presence, handling, use or disposition in or from the Premises of any Hazardous Materials by Tenant or any

Tenant Entity (even though permissible under all applicable Environmental Laws or the provisions of this Lease), or by reason of any actual or asserted failure of Tenant to keep, observe, or perform any provision of this Section 1.2, provided, however, in no event shall Tenant be responsible for any loss or liability attributable to the presence of any Hazardous Materials at the Premises, the Building or Lot which existed prior to the Commencement Date. Landlord has no knowledge of the presence of Hazardous Materials at the Premises, the Building or the Lot that is required to be removed or remediated under applicable Legal Requirements.

1.3 The Tenant shall have, as appurtenant to the Premises, rights to use in common with others entitled thereto:

1.3.1 the common facilities included in the Building or the Lot, including common walkways, driveways, lobbies, hallways, ramps, stairways, loading docks, the bicycle storage area, and passenger and freight elevators;

1.3.2 subject to Article 39, the parking facility (including the visitor's parking area and parking spaces reserved for the disabled), at locations which may from time to time be designated by Landlord. Use of the parking facility shall be subject to the right of the Landlord to restrict parking during snowplowing operations, and during repair, maintenance and restriping work affecting the parking area, provided Tenant's use thereof is not adversely affected in a disproportionate manner to other Building tenants;

1.3.3 the pipes, ducts, conduits, wires and appurtenant equipment serving the Premises; and

1.3.4 if the Premises include less than the entire rentable area of any floor, the common toilets in the central core area of such floor.

Such rights shall always be subject to the Rules and Regulations set forth in Exhibit D as the same may be reasonably amended by the Landlord from time to time in a non-discriminatory manner, and such other reasonable rules and regulations from time to time established by Landlord by suitable notice, and to the right of Landlord to designate and change from time to time areas and facilities so to be used, provided such designations and changes do not deprive Tenant of the substantive benefits of such areas and facilities. In the event of a conflict or inconsistency between the terms and conditions of this Lease, and the Rules and Regulations, the terms of this Lease shall control. Tenant shall have free access to the Premises on business days during Building Business Hours and access at all other times subject to reasonable security restrictions from time to time in effect, and subject always to restrictions based on emergency conditions.

Not included in the Premises are the ceiling, the floor and all perimeter walls of the space identified in Exhibit A, except the inner surfaces thereof and the perimeter doors and windows. Notwithstanding that a portion of the Premises are shown to comprise the entire 14th floor of the Building, the Premises do not include any elevators, common stairwells, shafts, ducts and conduits passing through the Premises and building systems not exclusively serving the Premises, and Landlord shall retain responsibility for the repair and maintenance of the same throughout the term of this Lease. Tenant agrees that Landlord shall have the right to place in the Premises (but in such manner as not unreasonably to interfere with Tenant's use of the Premises) utility lines, telecommunication lines, shafts, pipes and the like, for the use and benefit of Landlord and other tenants in the Building, and to replace and maintain and repair such lines, pipes and the like, in, over and upon the Premises. Such utility lines, pipes and the like, shall not be deemed part of the Premises under this Lease.

1.4 Tenant and the Tenant Entities will be entitled to the non-exclusive use of the common areas of the Building as they exist from time to time during the Term, including the parking facilities, subject to Landlord's rules and regulations regarding such use. However, in no event will Tenant or the Tenant Entities park more vehicles in the parking facilities than Tenant's Proportionate Share of the total parking spaces available for common use. The foregoing shall not be deemed to provide Tenant with an exclusive right to any parking spaces or any guaranty of the availability of any particular parking spaces or any specific number of parking spaces. If the Building is being operated in accordance with Green Building Standards, Landlord may, in its sole discretion elect to establish

preferred parking programs for hybrid and alternative fuel vehicles so long as there is no reduction in Tenant's parking rights under this Lease.

1.5 Landlord shall install for Tenant, at Landlord's sole cost and expense, Building standard signage on the lobby directory and on the fourteenth (14th) floor common lobby and the tenth (10th) floor common lobby at no charge. Tenant may install, at Tenant's expense, one (1) building standard identification sign on the glass doors in the 13th floor separate elevator area serving the Premises.

2. TERM**.**

2.1 The Term of this Lease shall commence (i) with respect to the 14th Floor Premises, on the date (the "**14th Floor Delivery Date**") that Landlord shall tender possession of the 14th Floor Premises to Tenant in the "**14th Floor Delivery Condition**" (as defined below) and (ii) with respect to the 10th Floor Premises, on the date (the "**10th Floor Delivery Date**") that Landlord shall tender possession of the 10th Floor Premises to Tenant vacant, broom clean and free of all property and debris, except for the existing furniture in the 10th Floor Premises substantially as identified in the inventory list and plan attached hereto as **Exhibit E** (the "**10th Floor Furniture**") and otherwise in their "AS-IS" condition (the "**10th Floor Delivery Condition**") and shall terminate with respect to both Premises Components on the Termination Date, unless sooner terminated by the provisions of this Lease. In no event shall Landlord deliver possession of the 14th Floor Premises (i) prior to September 15, 2020, or (ii) during any period when a Construction Moratorium (as hereinafter defined) is in effect for the Building. Landlord shall perform the work ("**Landlord's 14th Floor Work**") specifically described in Exhibit B to this Lease on or before the Scheduled Delivery Date. The four (4) month period between the 14th Floor Delivery Date and the 14th Floor Commencement Date shall be hereinafter referred to as the "**Tenant 14th Floor Construction Period**." Tenant's possession of the 14th Floor Premises during the Tenant 14th Floor Construction Period shall be subject to all of the terms and conditions of this Lease, including without limitation the insurance, indemnity and casualty provisions of this Lease, except that Tenant shall not be required to pay Monthly Installments of Rent or additional rent under Section 4 of this Lease for the 14th Floor Premises during the Tenant 14th Floor Construction Period.

Landlord shall deliver possession of the 14th Floor Premises to Tenant vacant, broom-clean, free of all occupants and their possessions and furniture and with Landlord's 14th Floor Work substantially complete (the "**14th Floor Delivery Condition**").

Except to the extent required to be installed by Tenant as part of the Tenant's Work in accordance with Exhibit B attached hereto, the base building systems serving the Premises (including but not limited to HVAC, electrical, life safety, and plumbing) will be in good working condition suitable for office use on the applicable delivery date for such Premises Component. In the event Landlord is unable to deliver possession of the 14th Floor Premises in the 14th Floor Delivery Condition by the Scheduled Delivery Date due to the holding over or retention of possession by any tenant or occupant, and such failure continues in excess of thirty (30) days, Landlord shall promptly institute and diligently pursue to completion a summary process action against such tenant or occupant. In the event that Landlord has not delivered the 14th Floor Premises in the 14th Floor Delivery Condition by the date that is sixty (60) days after the Scheduled Delivery Date for the 14th Floor Premises, subject to delays resulting from Force Majeure Events and Tenant Delays, Tenant shall receive a credit of one day of Monthly Installment of Rent due (for the 14th Floor Premises only) hereunder for each day after such date that Landlord does not deliver the 14th Floor Premises in the 14th Floor Delivery Condition (the "**14th Floor Rent Credit**"). Such 14th Floor Rent Credit shall be applied commencing after the Abatement Period for the 14th Floor Premises. In addition, in the event Landlord has not delivered the 14th Floor Premises in the 14th Floor Delivery Condition by the date that is one hundred twenty (120) days after the Scheduled Delivery Date for the 14th Floor Premises, subject to delays resulting from Force Majeure Events and Tenant Delays, Tenant shall have the right to terminate this Lease by delivering thirty (30) days' prior written notice to Landlord, provided and on the express condition that Tenant repays to Landlord 100% of any of the 10th Floor TI Allowance that was disbursed to Tenant prior to the date of such termination, and upon exercise of such right and repayment of the 10th Floor TI Allowance, the rights and obligations of the parties hereto shall terminate, except Landlord shall be obligated to immediately return to Tenant the portion of the Security Deposit and all other sums paid hereunder. Notwithstanding the foregoing, if Landlord shall deliver the 14th Floor Premises to Tenant in the 14th Floor Delivery Condition within the 30-day period after

Landlord's receipt of Tenant's termination notice, such notice shall be of no further force or effect, and this Lease shall not so terminate.

Tenant agrees that Landlord's failure to substantially complete Landlord's 14th Floor Work by the Scheduled Delivery Date shall not affect the other obligations of Tenant under this Lease, except that the actual 14th Floor Delivery Date shall be postponed until the date that Landlord substantially completes Landlord's 14th Floor Work and delivers the 14th Floor Premises in the 14th Floor Delivery Condition, subject in all events to Tenant's termination rights and rent abatement rights set forth in this Section 2.1.

The three (3) month period between the 10th Floor Commencement Date and the 10th Floor Rent Commencement Date shall be hereinafter referred to as the "Tenant 10th Floor Construction Period." Tenant's possession of the 10th Floor Premises during the Tenant 10th Floor Construction Period shall be subject to all of the terms and conditions of this Lease, including without limitation the insurance, indemnity and casualty provisions of this Lease, except that Tenant shall not be required to pay Monthly Installments of Rent or additional rent under Section 4 of this Lease for the 10th Floor Premises during the Tenant 10th Floor Construction Period. Notwithstanding the foregoing, Tenant shall in no event be entitled to any credit or abatement of Rent, nor shall Tenant have any right to terminate this Lease if Landlord shall fail to deliver the 10th Floor Premises, provided, however, if Landlord has not delivered the 10th Floor Premises in the 10th Floor Delivery Condition by the date that is ninety (90) days after the Scheduled Delivery Date for the 10th Floor Premises, subject to Tenant Delays but expressly not subject to postponement on account of Force Majeure Events, Tenant shall have the right to terminate this Lease by delivering thirty (30) days' prior written notice to Landlord, provided and on the express condition that Tenant repays to Landlord 100% of any of the 14th Floor TI Allowance that was disbursed to Tenant prior to the date of such termination, and upon exercise of such right and repayment of the 14th Floor TI Allowance, the rights and obligations of the parties hereto shall terminate, except Landlord shall be obligated to immediately return to Tenant the portion of the Security Deposit and all other sums paid hereunder. Notwithstanding the foregoing, if Landlord shall deliver the 10th Floor Premises to Tenant in the 10th Floor Delivery Condition within the 30-day period after Landlord's receipt of Tenant's termination notice for the 10th Floor Premises, such notice shall be of no further force or effect, and this Lease shall not so terminate.

2.2 Tenant shall, at Landlord's request, execute and deliver a memorandum agreement provided by Landlord in the form of Exhibit C attached hereto, setting forth the actual Delivery Date, Commencement Date, Rent Commencement Date, and Termination Date (as applicable for each of the 10th Floor Premises and 14th Floor Premises). Should Tenant fail to do so within thirty (30) days after Landlord's request or to provide notice to Landlord that Tenant dispute the dates set forth in the proposed agreement, the information set forth in such memorandum provided by Landlord shall be conclusively presumed to be agreed and correct.

2.3 For the purposes of this Lease, a "Landlord Delay" shall mean any actual delay in the completion or commencement of the Tenant's Work caused by any negligence of Landlord or its agents, employees, or contractors or any failure by Landlord to act when Landlord has a duty so to act under the law or under the express terms of this Lease.

2.4 If Landlord or Tenant is in any way delayed or prevented from performing any obligation (except, with respect to Tenant, its obligations to pay rent and other sums due under this Lease, any obligation set forth in Exhibit B, any obligation with respect to insurance pursuant to Article XIII, any obligation to give notice with respect to extensions, expansions or otherwise, and any holdover) due to fire, act of God, governmental act or failure to act, pandemic, epidemic, governmental restrictions or orders, strike, labor dispute, inability to procure materials, or any cause beyond Landlord's or Tenant's (as applicable) reasonable control (whether similar or dissimilar to the foregoing events) (each a "**Force Majeure Event**"), then the time for performance of such obligation shall be excused for the period of such delay or prevention and extended for a period equal to the period of such delay or prevention. Except as otherwise provided in Section 3.2 of this Lease, no Force Majeure Event shall delay or excuse the timely payment of all items of rent by Tenant. Financial disability or hardship shall never constitute a Force Majeure Event.

2.5 Landlord and Tenant acknowledge that in response to the COVID-19 pandemic, the City of Cambridge issued an order on March 18, 2020 (which order was extended on April 2, 2020), and amended on May 20, 2020), limiting all non-essential construction projects until June 15, 2020 (such order, as the same may be further amended, together with any existing or subsequent federal, state or local governmental order that suspends non-essential construction projects in the City of Cambridge, a "Construction Moratorium"). While Landlord anticipates that the Construction Moratorium will no longer be in effect on the Scheduled Delivery Date, Landlord agrees that neither the applicable delivery date for any Premises Component nor the Applicable Commencement Date for any Premises Component will occur while any Construction Moratorium is in effect affecting such Premises Component that prohibits Tenant from commencing or continuing the Tenant's Work for the applicable Premises Component. In addition, if after the Applicable Delivery Date for a Premises Component or the Applicable Commencement Date for such Premises Component, a new Construction Moratorium is imposed during the Tenant construction period for such Premises Component that prevents Tenant from commencing or continuing the performance of Tenant's Work (including, for such purposes, the inability to apply for or obtain a building permit or a final inspection and governmental sign off for Tenant's Work) in such Premises Component which causes an actual delay in the performance of Tenant's Work to such Premises Component, then the Applicable Commencement Date for such Premises Component will be postponed on a day for day basis for each day that the Construction Moratorium is in effect following the later date to occur of (i) the applicable delivery date for such Premises Component, and (ii) the date the Tenant's Plans for such Premises Component have been approved by Landlord (an "Excused Construction Delay"). For the avoidance of doubt, the Applicable Commencement Date (and the Applicable Rent Commencement Date) will not be postponed for any period of time that a Construction Moratorium is in effect and which elapses prior to the time that Tenant has submitted and obtained Landlord's approval of the Tenant's Plans for the applicable Premises Component.

3. RENT.

3.1 Commencing on the Applicable Commencement Date for each Premises Component and subject to the Abatement Period, Tenant agrees to pay to Landlord the Annual Rent in effect from time to time by paying the Monthly Installment of Rent then in effect on or before the first day of each full calendar month during the Term. The Monthly Installment of Rent in effect at any time shall be one-twelfth (1/12) of the Annual Rent in effect at such time. Rent for any period during the Term which is less than a full month shall be a prorated portion of the Monthly Installment of Rent based upon the number of days in such month. Subject to the Abatement Period, said Rent shall be paid to Landlord, without deduction or offset (except as otherwise expressly provided in this Lease) and without notice or demand, at the Rent Payment Address, as set forth on the Reference Pages, or to such other person or at such other place as Landlord may from time to time designate in writing. If there have been more than two (2) monetary Event of Defaults under this Lease in any 24-month period, Landlord may require by notice to Tenant that all subsequent rent payments be made by an automatic payment from Tenant's bank account to Landlord's account, without cost to Landlord. Tenant must implement such automatic payment system prior to the next scheduled rent payment or within ten (10) days after Landlord's notice, whichever is later. Unless specified in this Lease to the contrary, all amounts and sums payable by Tenant to Landlord pursuant to this Lease shall be deemed additional rent.

3.2 Tenant recognizes that late payment of any rent or other sum due under this Lease will result in administrative expense to Landlord, the extent of which additional expense is extremely difficult and economically impractical to ascertain. Tenant therefore agrees that if rent or any other sum is not paid when due and payable pursuant to this Lease, a late charge shall be imposed in an amount equal to the greater of: (a) Fifty Dollars ($50.00), or (b) five percent (5%) of the unpaid rent or other payment, provided, however, Tenant shall not incur any late charge for the first late payment in any twelve (12) month period. The amount of the late charge to be paid by Tenant shall be reassessed and added to Tenant's obligation for each successive month until paid. The provisions of this Section 3.2 in no way relieve Tenant of the obligation to pay rent or other payments on or before the date on which they are due, nor do the terms of this Section 3.2 in any way affect Landlord's remedies pursuant to Article 19 of this Lease in the event said rent or other payment is unpaid after date due.

3.3 Tenant hereby acknowledges and agrees that the obligations of Tenant hereunder shall be separate and independent covenants and agreements, that rent shall continue to be payable in all events (unless this Lease

expressly provides to the contrary) and that the obligations of Tenant hereunder shall continue unaffected, unless the requirement to pay or perform the same shall have been terminated pursuant to an express provision of this Lease. Landlord and Tenant each acknowledges and agrees that the independent nature of the obligations of Tenant hereunder represents fair, reasonable, and accepted commercial practice with respect to the type of property subject to this Lease. Such acknowledgements by Tenant are a material inducement to Landlord entering into this Lease.

4. RENT ADJUSTMENTS**.**

4.1 For the purpose of this Article 4, the following terms are defined as follows:

4.1.1 **Lease Year:** Each calendar year falling partly or wholly within the Term.

4.1.2 **Expenses:** All costs of operation, maintenance, repair, replacement and management of the Building (including the amount of any credits which Landlord may grant to particular tenants of the Building in lieu of providing any standard services or paying any standard costs described in this Section 4.1.2 for similar tenants), as determined in accordance with generally accepted accounting principles, including the following costs by way of illustration, but not limitation: Insurance Costs, costs to maintain certification for Green Building Standards (excluding capital expenditure retrofitting or replacement costs to conform with certification requirements); water and sewer charges; utility costs, including, but not limited to, the cost of heat, light, power, steam, gas and energy for the Building; waste disposal; recycling costs; the cost of cleaning, disinfecting and janitorial services; the cost of security and alarm services (including any central station signaling system); costs of cleaning, repairing, replacing and maintaining the common areas, including parking and landscaping, window cleaning costs; labor costs; costs and expenses of managing the Building including management and/or administrative fees; air conditioning maintenance costs; elevator maintenance fees and supplies; material costs; equipment costs including the cost of maintenance, repair and service agreements and rental and leasing costs; purchase costs of equipment; current rental and leasing costs of items which would be capital items if purchased; tool costs; licenses, permits and inspection fees; wages and salaries; employee benefits and payroll taxes; accounting and legal fees; any sales, use or service taxes incurred in connection therewith. Expenses shall include Insurance Costs. In addition, Landlord shall be entitled to recover, as additional rent in Expenses, Tenant's Proportionate Share of: (i) an allocable portion of the cost of capital improvement items which are reasonably calculated to reduce operating expenses; (ii) the cost of maintenance and repair of the fire sprinklers and suppression systems and other life safety systems; and (iii) other capital expenses which are required under any Legal Requirements which were not applicable to the Building on the Commencement Date; but the costs described in this sentence shall be amortized over the reasonable life of such expenditures in accordance with such reasonable life and amortization schedules as shall be determined by Landlord in accordance with generally accepted accounting principles, with interest on the unamortized amount at one percent (1%) in excess of the Wall Street Journal prime lending rate announced from time to time. Expenses shall not include Taxes, Excluded Costs, depreciation or amortization of the Building or equipment in the Building except as provided herein, loan principal payments, costs of alterations of tenants' premises, leasing commissions, interest expenses on long-term borrowings or advertising costs. Notwithstanding any provision to the contrary in this Lease, "**Excluded Costs**" shall be defined as (i) any mortgage charges (including interest, principal, points and fees, and ground rent); (ii) costs in connection with leasing space in the Building, including advertising, brokerage commissions; lease concessions, rental abatements and construction allowances granted to specific tenants; (iii) salaries of executives and owners or other employees not directly employed in the management/operation of the Building; (iv) the cost of work done by Landlord for or on behalf of a particular tenant which is separately chargeable to such tenant; (v) the costs of any contributions made by Landlord to any tenant of the Building in connection with the build-out of its premises; (vi) franchise or income taxes imposed on Landlord; (vii) costs paid directly by individual tenants to suppliers, including tenant electricity, telephone and other utility costs if Tenant is separately metered or check metered including, without limitation, any Tenant Electricity as defined below; (viii) increases in premiums for insurance when such increase is caused solely by the use of the Building by any other tenant of the Building; (ix) omitted; (x) costs relating to maintaining Landlord's existence as a corporation, partnership or other entity; (xi) advertising and other fees and costs incurred in procuring tenants; (xii) the cost of any items for which Landlord is reimbursed by insurance, condemnation awards, refund, rebate or otherwise, and any expenses for repairs or maintenance to the extent covered by warranties, guaranties and service contracts; (xiii) costs incurred in connection with any disputes between Landlord and its employees, between

Landlord and Building management, or between Landlord and other tenants or occupants; (xiv) costs incurred in connection with the sale, financing or refinancing of the Building; (xv) fines, interest and penalties incurred due to the late payment of Taxes or Expenses or Insurance Costs; (xvi) costs of any expansions of the Building; (xvii) amounts (exclusive of the management fee) paid to subsidiaries or affiliates of Landlord for goods and/or services rendered to the Building to the extent such amounts exceed the competitive costs for delivery of such services were they not provided by such related parties; (xviii) payments for rented equipment, the cost of which equipment would constitute a capital expenditure if the equipment were purchased, to the extent that such payments exceed the amount which could have been included in Expenses had Landlord purchased such equipment rather than leasing such equipment; (xix) charitable or political contributions; (xx) replacement or contingency reserves or any bad debt loss, rent loss or reserves for bad debts or rent loss; (xxi) costs associated with retail leases at the Building, if any, to the extent such cost would exceed that of an office tenant; (xxii) the cost of testing, remediation or removal, transportation or storage of Hazardous Materials in the Building or on the Lot required by Environmental Laws provided, however, the foregoing shall not prohibit the inclusion of expenses to test, remove or remediate materials (whether existing at the Building as of the date of this Lease or subsequently introduced to the Building) which are not as of the date of this Lease (or as of the date of the introduction) deemed to be Hazardous Materials under applicable Legal Requirements but which are subsequently deemed to be Hazardous Materials under applicable Legal Requirements, (xxiii) capital expenditures except as permitted above, or (xxiv) costs to make improvements, alterations, additions or replacements to the Building which are required in order to render the same in compliance with Legal Requirements in effect as of the Commencement Date.

4.1.3 **Taxes:** Real estate taxes and any other taxes, charges and assessments which are levied with respect to the Building or the Lot, or with respect to any improvements, fixtures and equipment or other property of Landlord, real or personal, located in the Building and used in connection with the operation of the Building and said Lot, any payments to any ground lessor in reimbursement of tax payments made by such lessor; and all fees, expenses and costs incurred by Landlord in investigating, protesting, contesting or in any way seeking to reduce or avoid increase in any assessments, levies or the tax rate pertaining to any Taxes to be paid by Landlord in any Lease Year. Taxes shall be determined without regard to any "green building" credit and shall not include any corporate franchise, or estate, inheritance or net income tax, or transfer tax imposed upon any transfer by Landlord of its interest in this Lease or the Building or any taxes to be paid by Tenant pursuant to Article 28.

4.1.4 **Insurance Costs:** Any and all insurance charges of or relating to all insurance policies and endorsements deemed by Landlord to be reasonably necessary or desirable and relating in any manner to the protection, preservation, or operation of the Building or any part thereof, except for the insurance required under Section 11.4 hereof, so long as such insurance is consistent with insurance maintained by owners of similar office buildings (including size and location).

4.2 If in any Lease Year following the Applicable Rent Commencement Date for each Premises Component, (i) Expenses incurred shall exceed Expenses incurred in the Base Year (Expenses) and/or (ii) Taxes incurred by Landlord in any Lease Year shall exceed the amount of such Taxes which became due and payable in the Base Year (Taxes), Tenant shall pay, as additional rent for such Lease Year, Tenant's Proportionate Share of each such excess amount.

4.3 The annual determination of Expenses and Taxes shall be made by Landlord and Landlord shall deliver a statement to Tenant containing such determination within 180 days after the end of each calendar year, which shall be in reasonable detail and shall be binding upon Landlord and Tenant, subject to the provisions of this Section 4.3. During the Term, Tenant may review, at Tenant's sole cost and expense (except as provided below), the books and records supporting such determination in an office of Landlord, or Landlord's agent, during normal business hours, upon giving Landlord five (5) days advance written notice within one hundred twenty (120) days after receipt of such determination, but in no event more often than once in any one (1) year period, subject to execution of a confidentiality agreement reasonably acceptable to Landlord, and provided that if Tenant utilizes an independent accountant or agent to perform such review it shall be one of national standing which is reasonably acceptable to Landlord, and who is not compensated on a contingency basis and is also subject to such confidentiality agreement. Tenant shall pay the cost of such review/audit, provided, however, that if Landlord and Tenant agree that Expenses and Taxes were overstated by more than five percent (5%), Landlord shall reimburse

Tenant for its reasonable out-of-pocket costs incurred in connection with such review/audit (not to exceed $3,000.00). If Tenant fails to object to Landlord's determination of Expenses within such one hundred twenty (120) day period, or if any such objection fails to state with specificity the reason for the objection, Tenant shall be deemed to have approved such determination and shall have no further right to object to or contest such determination. In the event that during all or any portion of any Lease Year or Base Year, the Building is not fully rented and occupied Landlord shall make an appropriate adjustment in occupancy-related Expenses/Taxes for such year for the purpose of avoiding distortion of the amount of such Expenses to be attributed to Tenant by reason of variation in total occupancy of the Building, by employing consistent and sound accounting and management principles to determine Expenses/Taxes that would have been paid or incurred by Landlord had the Building been ninety-five percent (95%) rented and occupied, and the amount so determined shall be deemed to have been Expenses/Taxes for such Lease Year or the Base Year, as applicable.

4.4 Prior to the actual determination thereof for a Lease Year, Landlord may from time to time estimate Tenant's liability for Expenses and/or Taxes under Section 4.1, Article 6 and Article 28 for the Lease Year or portion thereof. Landlord will give Tenant written notification of the amount of such estimate and Tenant agrees that it will pay, by increase of its Monthly Installments of Rent due in such Lease Year, additional rent in the amount of such estimate. Any such increased rate of Monthly Installments of Rent pursuant to this Section 4.4 shall remain in effect until further written notification to Tenant pursuant hereto.

4.5 When the above mentioned actual determination of Tenant's liability for Expenses and/or Taxes is made for any Lease Year and when Tenant is so notified in writing, then:

4.5.1 If the total additional rent Tenant actually paid pursuant to Section 4.3 on account of Expenses and/or Taxes for the Lease Year is less than Tenant's liability for Expenses and/or Taxes, then Tenant shall pay such deficiency to Landlord as additional rent in one lump sum within thirty (30) days of receipt of Landlord's bill therefor; and

4.5.2 If the total additional rent Tenant actually paid pursuant to Section 4.3 on account of Expenses and/or Taxes for the Lease Year is more than Tenant's liability for Expenses and/or Taxes, then Landlord shall credit the difference against the then next due payments to be made by Tenant under this Article 4, or, if the Lease has terminated, refund the difference in cash. Tenant shall not be entitled to a credit by reason of actual Expenses and/or Taxes in any Lease Year being less than Expenses and/or Taxes in the Base Year (Expenses and/or Taxes).

4.6 If the Applicable Commencement Date is other than January 1 or if the Termination Date is other than December 31, Tenant's liability for Expenses and Taxes for the Lease Year in which said Date occurs shall be prorated based upon a three hundred sixty-five (365) day year.

5. SECURITY DEPOSIT**.**

5.1 Tenant shall deposit the Security Deposit with Landlord upon the execution of this Lease. Said sum shall be held by Landlord as security for the faithful performance by Tenant of all the terms, covenants and conditions of this Lease to be kept and performed by Tenant and not as an advance rental deposit or as a measure of Landlord's damage in case of Tenant's default. If Tenant defaults with respect to any provision of this Lease after notice and the expiration of applicable cure periods (provided that no such notice and cure will apply if Landlord is prevented by law from delivering such notice to Tenant), Landlord may use any part of the Security Deposit for the payment of any rent or any other sum in default, or for the payment of any amount which Landlord may spend or become obligated to spend by reason of Tenant's default, or to compensate Landlord for any other loss or damage which Landlord may suffer by reason of Tenant's default. If any portion is so used, Tenant shall within ten (10) days after written demand therefor, deposit with Landlord an amount sufficient to restore the Security Deposit to its original amount (or provide a new Letter of Credit) and Tenant's failure to do so shall be a material breach of this Lease. Except to such extent, if any, as shall be required by law, Landlord shall not be required to keep the Security Deposit separate from its general funds, and Tenant shall not be entitled to interest on such deposit. Landlord having made any deductions from the Security Deposit as Landlord is entitled under the terms of this Lease, the Security

Deposit or any balance thereof shall be returned to Tenant at such time after termination of this Lease when Landlord shall have determined that all of Tenant's obligations under this Lease have been fulfilled.

5.2 The required Security Deposit shall be in the form of an Irrevocable Standby Letter of Credit in favor of Landlord (the "letter of credit") in the amount set forth on the Reference Pages. Under any circumstance under which Landlord is entitled the use of all or a part of the Security Deposit, then, Landlord, in addition to all other rights and remedies provided under the Lease, shall have the right to draw down all or a portion of the full balance of the letter of credit and retain the proceeds. The following terms and conditions shall govern the letter of credit:

5.2.1 Upon expiration of the Term, the letter of credit shall be returned to Tenant when Tenant is entitled to return of its Security Deposit.

5.2.2 The letter of credit shall be in favor of Landlord, shall be issued by a commercial bank reasonably acceptable to Landlord, shall comply with all of the terms and conditions of this Section 5.2 and shall otherwise be in form reasonably acceptable to Landlord. Without limiting the generality of the foregoing, (i) the letter of credit must provide for all notices to the beneficiary to be sent simultaneously to up to two (2) addressees specified in the letter of credit, and (ii) there shall be no requirement of signature guaranty for draws, assignments or other documentary action to be taken by the beneficiary. If, at any time while the letter of credit is outstanding, (i) the issuing bank is declared insolvent or taken into receivership by the Federal Deposit Insurance Corporation or any other governmental agency, or is closed for any reason, or (ii) Landlord reasonably believes that the issuing bank may be or become insolvent or otherwise unable to meet its obligations, then, not later than thirty (30) days after written notice from Landlord, Tenant shall cause the existing letter of credit to be replaced by a new letter of credit issued by another commercial bank reasonably acceptable to Landlord, with such new letter of credit to comply with all of the terms and conditions of this Section 5.2. If Tenant fails to deliver an acceptable replacement letter of credit within such 30 day period, Landlord shall have the right to present the existing letter of credit to the issuing bank for payment, and the entire sum so obtained shall be paid to Landlord, to be held by Landlord until Tenant would otherwise be entitled to the return of the letter of credit, and to be retained by Landlord if a default occurs.

5.2.3 The initial letter of credit shall have an expiration date not earlier than fifteen (15) months after the 14th Floor Commencement Date. A draft of the form of letter of credit must be submitted to Landlord for its approval prior to issuance.

5.2.4 The letter of credit or any replacement letter of credit shall be irrevocable for the term thereof and shall automatically renew on a year to year basis until a period ending not earlier than three (3) months after the Termination Date ("End Date") without any action whatsoever on the part of Landlord; provided that the issuing bank shall have the right not to renew the letter of credit by giving written notice to Landlord not less than sixty (60) days prior to the expiration of the then current term of the letter of credit that it does not intend to renew the letter of credit. Tenant understands that the election by the issuing bank not to renew the letter of credit shall not, in any event, diminish the obligation of Tenant to maintain such an irrevocable letter of credit in favor of Landlord through such date.

5.2.5 Landlord, or its then managing agent, shall have the right from time to time to make one or more draws on the letter of credit at any time that Landlord has the right to use all or a part of the Security Deposit pursuant to Article 5 of this Lease, and the proceeds may be applied as permitted under said Article 5. The letter of credit must state that it can be presented for payment at the office of the issuer or an approved correspondent in the metropolitan area in which the Building is located. Funds may be drawn down on the letter of credit upon presentation to the issuing or corresponding bank of Landlord's (or Landlord's then managing agent's) certificate stating as follows:

> "Beneficiary is entitled to draw on this credit pursuant to that certain Lease dated for reference January , 2020 between RREEF AMERICA REIT II CORP. PPP, a Maryland corporation, as Landlord and BLACK DIAMOND THERAPEUTICS, INC., a Delaware corporation, as Tenant, as amended from time to time."

It is understood that if Landlord or its managing agent be a corporation, partnership or other entity, then such statement shall be signed by an officer (if a corporation), a general partner (if a partnership), or any authorized party (if another entity).

5.2.6 Tenant acknowledges and agrees (and the letter of credit shall so state) that the letter of credit shall be honored by the issuing bank without inquiry as to the truth of the statements set forth in such draw request and regardless of whether the Tenant disputes the content of such statement.

5.2.7 In the event of a transfer of Landlord's interest in the Premises, Landlord shall have the right to transfer the letter of credit to the transferee and Tenant shall take whatever action and pay any bank fees necessary to effectuate such transfer and thereupon the Landlord shall, without any further agreement between the parties, be released by Tenant from all liability therefor, and it is agreed that the provisions hereof shall apply to every transfer or assignment of said letter of credit to a new landlord.

5.2.8 Without limiting the generality of the foregoing, if the letter of credit expires earlier than the End Date, or the issuing bank notifies Landlord that it will not renew the letter of credit, Landlord shall accept a renewal thereof or substitute letter credit (such renewal or substitute letter of credit to be in effect not later than thirty (30) days prior to the expiration of the expiring letter of credit), irrevocable and automatically renewable as above provided to the End Date upon the same terms as the expiring letter of credit or upon such other terms as may be acceptable to Landlord. However, if (i) the letter of credit is not timely renewed, or (ii) a substitute letter of credit, complying with all of the terms and conditions of this Section is not timely received, then Landlord may present the expiring letter of credit to the issuing bank, and the entire sum so obtained shall be paid to Landlord, to be held by Landlord in accordance with Article 5 of the Lease. Notwithstanding the foregoing, Landlord shall be entitled to receive from Tenant a fee in an amount not to exceed $500.00 for attorneys' fees incurred in connection with the review of any proposed substitute letter of credit pursuant to this subparagraph.

5.3 Provided that no Event of Default then exists under this Lease and there has not been an Event of Default under this Lease at any time during the two (2) years preceding the Reduction Date, then on the expiration of the second (2nd) Rent Year for the 14th Floor Premises (the "**Reduction Date**"), Landlord shall permit the amount of the Letter of Credit to be reduced to (or a replacement Letter of Credit may be issued in the amount of) $778,892.00. If Tenant satisfies the condition precedent for the reduction of the Letter of Credit, such reduction will be accomplished by an amendment to the existing Letter of Credit reasonably acceptable to Landlord or by delivery of a new Letter of Credit in the reduced amount and otherwise complying with the requirements of this Article 5. In no event shall the Letter of Credit have automatic reduction provisions.

6. ALTERATIONS.

6.1 Except for those, if any, specifically provided for in Exhibit B to this Lease, Tenant shall not make or suffer to be made any alterations, additions, or improvements ("**Alterations**"), including, but not limited to, the attachment of any fixtures or equipment in, on, or to the Premises or any part thereof or the making of any improvements as required by Article 7, without the prior written consent of Landlord. When applying for such consent, Tenant shall, if requested by Landlord, furnish complete plans and specifications for such Alterations. Landlord's consent shall not be unreasonably withheld, conditioned or delayed with respect to Alterations which (i) are not structural in nature, (ii) are not visible from the exterior of the Building, and (iii) do not adversely affect or require modification of the Building's electrical, mechanical, plumbing, HVAC or other systems.

6.2 Notwithstanding the foregoing, Landlord's consent shall not be required with respect to non-structural Alterations which do not cost more than $10,000.00 in any one instance (and $50,000.00 in the aggregate per 12 month period) so long as the Alteration (i) does not adversely affect any of the Building's electrical, mechanical, plumbing, HVAC or other systems, (ii) is not visible from the exterior of the Building, and (iii) does not require the issuance of any permits, licenses, approvals or the like pursuant to any Legal Requirements (hereinafter, "**Permitted Alterations**") In the event Landlord consents to the making of any such Alteration, the same shall be made by using either Landlord's contractor or a contractor reasonably approved by Landlord, in either event at Tenant's sole cost and expense. If Tenant shall employ any contractor other than Landlord's contractor and such

other contractor or any subcontractor of such other contractor shall employ any non-union labor or supplier, Tenant shall be responsible for and hold Landlord harmless from any and all delays, damages and extra costs suffered by Landlord as a result of any dispute with any labor unions concerning the wage, hours, terms or conditions of the employment of any such labor. In any event, except in connection with Permitted Alterations, Landlord may charge Tenant a construction management fee not to exceed three percent (3%) of the cost of such work to cover its overhead as it relates to such proposed work, plus third-party costs actually incurred by Landlord in connection with the proposed work and the design thereof, with all such amounts being due thirty (30) days after Landlord's demand.

6.3 All Alterations proposed by Tenant shall be constructed in accordance with all Legal Requirements and with Landlord's Building construction standards (if any) from time to time to the extent applicable (which standards shall be made available to Tenant by Landlord's Building manager upon request). Tenant shall use Building standard materials where applicable, and Tenant shall, prior to construction, provide the additional insurance required under Article 11 in such case, and also all such assurances to Landlord as Landlord shall reasonably require to assure payment of the costs thereof, including but not limited to, notices of non-responsibility, waivers of lien, surety company performance bonds and funded construction escrows and to protect Landlord and the Building and appurtenant land against any loss from any mechanic's, materialmen's or other liens. Tenant shall pay in addition to any sums due pursuant to Article 4, any increase in real estate taxes solely attributable to any such Alteration for so long, during the Term, as such increase is ascertainable; at Landlord's election said sums shall be paid in the same way as sums due under Article 4.

7. REPAIR**.**

7.1 Landlord shall have no obligation to alter, remodel, improve, repair, decorate or paint the Premises, except as specified in Section 2.1 and Exhibit B if attached to this Lease and except that Landlord shall repair and maintain in good working condition the structural portions of the Building, including, without limitation, the roof, floor slabs, exterior window frames and glass, base Building systems serving tenants in general including, without limitation, the security, basic plumbing, air conditioning, ventilation, life safety generator, sewer, heating, sprinkler, fire safety, mechanical and electrical systems installed or furnished by Landlord or serving the common areas and facilities or the Building tenants generally. By taking possession of the Premises, Tenant accepts them as being in good order, condition and repair and in the condition in which Landlord is obligated to deliver them, except as set forth in the punch list to be delivered pursuant to Section 2.1; provided, however, the foregoing shall in no way diminish Landlord's ongoing repair and maintenance obligations under this Lease. It is hereby understood and agreed that no representations respecting the condition of the Premises or the Building have been made by Landlord to Tenant, except as specifically set forth in this Lease.

7.2 Tenant shall, at all times during the Term, keep the Premises in good condition and repair excepting damage by fire, or other casualty, and in compliance with all applicable Legal Requirements, all at Tenant's sole expense. Repair and maintenance work shall be undertaken in compliance with Landlord's Building construction standards (if any) from time to time to the extent applicable (which standards shall be made available to Tenant by Landlord's Building manager upon request).

7.3 Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after written notice (or actual notice, whoever is earlier) of the need of such repairs or maintenance is given to Landlord by Tenant.

7.4 Except as provided in Article 22 or as otherwise expressly provided in this Lease, there shall be no abatement of rent and no liability of Landlord by reason of any injury to or interference with Tenant's business arising from the making of any repairs, alterations or improvements in or to any portion of the Building or the Premises or to fixtures, appurtenances and equipment in the Building. Except to the extent, if any, prohibited by law, Tenant waives the right to make repairs at Landlord's expense under any law, statute or ordinance now or hereafter in effect.

8. LIENS**.** Tenant shall keep the Premises, the Building and appurtenant land and Tenant's leasehold interest in the Premises free from any liens arising out of any services, work or materials performed, furnished, or contracted

for by Tenant, or obligations incurred by Tenant. In the event that Tenant fails, within fifteen (15) days following the imposition of any such lien, to either cause the same to be released of record or provide Landlord with insurance against the same issued by a major title insurance company or such other protection against the same as Landlord shall accept (such failure to constitute an Event of Default), Landlord shall have the right to cause the same to be released by such means as it shall deem proper, including payment of the claim giving rise to such lien. All such sums paid by Landlord and all reasonable expenses incurred by it in connection therewith shall be payable to it by Tenant within ten (10) days of Landlord's demand .

9. ASSIGNMENT AND SUBLETTING**.**

9.1 Tenant shall not have the right to assign or pledge this Lease or to sublet the whole or any part of the Premises whether voluntarily or by operation of law, or permit the use or occupancy of the Premises by anyone other than Tenant, and shall not make, suffer or permit such assignment, subleasing or occupancy without the prior written consent of Landlord, such consent not to be unreasonably withheld, conditioned or delayed, and said restrictions shall be binding upon any and all assignees of the Lease and subtenants of the Premises. In the event Tenant desires to sublet, or permit such occupancy of, the Premises, or any portion thereof, or assign this Lease, Tenant shall give written notice thereof to Landlord at least thirty (30) days but no more than one hundred eighty (180) days prior to the proposed commencement date of such subletting or assignment, which notice shall set forth the name of the proposed subtenant or assignee, the relevant terms of any sublease or assignment and copies of financial reports and other relevant financial information of the proposed subtenant or assignee.

9.2 Notwithstanding any assignment or subletting, permitted or otherwise, Tenant shall at all times remain directly, primarily and fully responsible and liable for the payment of the rent specified in this Lease and for compliance with all of its other obligations under the terms, provisions and covenants of this Lease. Upon the occurrence of an Event of Default, if the Premises or any part of them are then assigned or sublet, Landlord, in addition to any other remedies provided in this Lease or provided by law, may, at its option, collect directly from such assignee or subtenant all rents due and becoming due to Tenant under such assignment or sublease and apply such rent against any sums due to Landlord from Tenant under this Lease, and no such collection shall be construed to constitute a novation or release of Tenant from the further performance of Tenant's obligations under this Lease.

9.3 In addition to Landlord's right to approve of any subtenant or assignee, Landlord shall have the option, in its sole discretion, in the event of any proposed subletting or assignment, to terminate this Lease, or in the case of a proposed subletting of less than the entire Premises, to recapture the portion of the Premises to be sublet, as of the date the subletting or assignment is to be effective. The option shall be exercised, if at all, by Landlord giving Tenant written notice given by Landlord to Tenant within thirty (30) days following Landlord's receipt of Tenant's written notice as required above. However, if Tenant notifies Landlord, within five (5) days after receipt of Landlord's termination notice, that Tenant is rescinding its proposed assignment or sublease, the termination notice shall be void and the Lease shall continue in full force and effect. If this Lease shall be terminated with respect to the entire Premises pursuant to this Section, the Term of this Lease shall end on the date stated in Tenant's notice as the effective date of the sublease or assignment as if that date had been originally fixed in this Lease for the expiration of the Term. If Landlord recaptures under this Section only a portion of the Premises, the rent to be paid from time to time during the unexpired Term shall abate proportionately based on the proportion by which the approximate square footage of the remaining portion of the Premises shall be less than that of the Premises as of the date immediately prior to such recapture. Tenant shall, at Tenant's own cost and expense, discharge in full any outstanding commission obligation which may be due and owing as a result of any proposed assignment or subletting, whether or not the Premises are recaptured pursuant to this Section 9.3 and rented by Landlord to the proposed tenant or any other tenant.

9.4 Except with respect to a Permitted Transfer, as defined below, in the event that Tenant sells, sublets, assigns or transfers this Lease, Tenant shall pay to Landlord as additional rent an amount equal to fifty percent (50%) of any Increased Rent (as defined below), less the Costs Component (as defined below), when and as such Increased Rent is received by Tenant. As used in this Section, "Increased Rent" shall mean the excess of (i) all rent and other consideration which Tenant is entitled to receive in exchange for any sale, sublease, assignment or other transfer of this Lease, over (ii) the rent otherwise payable by Tenant under this Lease at such time. For

purposes of the foregoing, any consideration received by Tenant in form other than cash shall be valued at its fair market value as determined by Landlord in good faith. The "Costs Component" is that amount which, if paid monthly, would fully amortize on a straight-line basis, over the entire period for which Tenant is to receive Increased Rent, the reasonable costs incurred by Tenant in connection with such sublease or assignment which shall be limited to leasing commissions, tenant improvement contributions, architectural and engineering fees, legal fees, and the unamortized costs of any initial improvements made by Tenant in excess of the Tenant Improvement Allowance.

9.5 Notwithstanding any other provision hereof, it shall be considered reasonable for Landlord to withhold its consent to any assignment of this Lease or sublease of any portion of the Premises if at the time of either Tenant's notice of the proposed assignment or sublease or the proposed commencement date thereof, there shall exist any uncured Event of Default of Tenant or matter which will become an Event of Default of Tenant with passage of time unless cured (unless Tenant cures within the applicable time period), or if the proposed assignee or sublessee is an entity: (a) with which Landlord is already in negotiation at the Building; (b) is already an occupant of the Building unless Landlord is unable to provide the amount of space required by such occupant; (c) is a governmental agency; (d) is not consistent with the reputational quality of tenants in the Building as determined in Landlord's reasonable discretion; (e) with which the payment for the sublease or assignment is determined in whole or in part based upon its net income or profits; or (f) would subject the Premises to a use which would: (i) involve increased personnel or wear upon the Building; (ii) violate any exclusive right granted to another tenant of the Building; (iii) require any addition to or modification of the Premises or the Building in order to comply with building code or other governmental requirements; or, (iv) involve a violation of Section 1.2; or (v) shall, in Landlord's reasonable opinion, cause the Building or any part thereof to be in material non-compliance with Landlord's sustainability practices and/or the "green building" certification or rating obtained, or in the process of being obtained by Landlord for the Building. Tenant expressly agrees that for the purposes of any statutory or other requirement of reasonableness on the part of Landlord, Landlord's refusal to consent to any assignment or sublease for any of the reasons described in this Section 9.5, shall be conclusively deemed to be reasonable.

9.6 Upon any request to assign or sublet, Tenant will pay to Landlord the Assignment/Subletting Fee plus, on demand, a sum equal to all of Landlord's costs, including reasonable attorney's fees, incurred in investigating and considering any proposed or purported assignment or pledge of this Lease or sublease of any of the Premises, regardless of whether Landlord shall consent to, refuse consent, or determine that Landlord's consent is not required for, such assignment, pledge or sublease. Any purported sale, assignment, mortgage, transfer of this Lease or subletting which does not comply with the provisions of this Article 9 shall be void.

9.7 If Tenant is a corporation, limited liability company, partnership or trust, any transfer or transfers of or change or changes within any twelve (12) month period in the number of the outstanding voting shares of the corporation or limited liability company, the general partnership interests in the partnership or the identity of the persons or entities controlling the activities of such partnership or trust resulting in the persons or entities owning or controlling a majority of such shares, partnership interests or activities of such partnership or trust at the beginning of such period no longer having such ownership or control shall be regarded as equivalent to an assignment of this Lease to the persons or entities acquiring such ownership or control and shall be subject to all the provisions of this Article 9 to the same extent and for all intents and purposes as though such an assignment. Notwithstanding the foregoing, this Section 9.7 shall not apply to any such transfer, transfers, change or changes in control where made in connection with a public offering of equity or debt and/or the subsequent hypothecation, conversion or exchange of interests on a recognized public exchange.

9.8 Notwithstanding anything herein to the contrary, Tenant may, without the requirement of obtaining Landlord's consent and without constituting an assignment or sublease hereunder, assign this Lease or sublease any portion of the Premises to any entity which controls, is controlled by or under common control with Tenant (an "Affiliate") or assign this Lease to any entity with or into which Tenant may merge or consolidate or to which Tenant may sell all or substantially all of its assets or equity interests (each, a "Transfer"), provided that all of the following conditions are satisfied: (a) there must not be an uncured Event of Default at the time of the Transfer; (b) the successor entity (or Tenant if Tenant is the surviving entity) shall have a net worth following the Transfer that is equal to or better than the net worth of Tenant during the 12 months immediately prior to the Transfer; and (c)

Tenant must give Landlord written notice at least ten (10) business days before such Transfer; provided, however, that if the Transfer is subject to a nondisclosure or confidentiality agreement, then Tenant will notify Landlord within five (5) business days following the Transfer. A Transfer that satisfies all of such conditions is a "Permitted Transfer." Tenant's notice to Landlord shall include information and documentation reasonably evidencing that the Transfer qualifies as a Permitted Transfer hereunder and that each of the above conditions has been satisfied. If requested by Landlord, Tenant's successor shall sign and deliver to Landlord a commercially reasonable form of assumption agreement. In the event that, at any time after a Permitted Transfer, the Affiliate to which the Permitted Transfer is made ceases to qualify as an Affiliate of the original Tenant, such event shall be deemed a Transfer that is subject to all of the provisions of Section 9. Any right of Landlord to terminate this Lease or recapture the Premises, as set forth in Section 9.3, or receive any amounts set forth in Section 9.5 hereunder shall not apply to a Permitted Transfer.

10. INDEMNIFICATION**.** None of the Landlord Entities shall be liable and Tenant hereby waives all claims against them for any damage to any property or any injury to any person in or about the Premises or the Building by or from any cause whatsoever (including without limiting the foregoing, rain or water leakage of any character from the roof, windows, walls, basement, pipes, plumbing works or appliances, the Building not being in good condition or repair, gas, fire, oil, electricity or theft), except, with respect to personal injury only, to the extent caused by or arising from the negligence or willful misconduct of Landlord or its agents, employees or contractors. Tenant shall protect, indemnify and hold the Landlord Entities harmless from and against any and all loss, claims, liability or costs (including court costs and reasonable attorney's fees) incurred by reason of (a) any damage to any property (including but not limited to property of any Landlord Entity) or any injury (including but not limited to death) to any person occurring in, on or about the Premises or the Building to the extent that such injury or damage shall be caused by or arise from any act, negligence, fault, or negligent omission by or of Tenant or any Tenant Entity to meet any standards imposed by any duty with respect to the injury or damage; (b) the conduct or management of any work or thing whatsoever done by the Tenant in or about the Premises or from transactions of the Tenant concerning the Premises; (c) Tenant's failure to comply with any and all Legal Requirements applicable to the condition or use of the Premises or its occupancy where Tenant is required to comply with such Legal Requirements under this Lease; or (d) any breach or default on the part of Tenant in the performance of any covenant or agreement on the part of the Tenant to be performed pursuant to this Lease. The provisions of this Article shall survive the termination of this Lease with respect to any claims or liability accruing prior to such termination.

Subject to Section 12 and Section 40 and except to the extent caused by or arising from the negligence or willful misconduct of Tenant or any Tenant Entity, Landlord agrees to indemnify and hold Tenant harmless from and against any and all loss, claims or costs incurred by or claimed against Tenant to the extent such injury or damage shall be caused by the negligence or willful misconduct of Landlord, its employees, agents or contractors.

11. INSURANCE**.**

11.1 Tenant shall keep in force throughout the Term: (a) a Commercial General Liability insurance policy or policies to protect the Landlord Entities against any liability to the public or to any invitee of Tenant or a Landlord Entity incidental to the use of or resulting from any accident occurring in or upon the Premises with a limit of not less than $1,000,000.00 per occurrence and not less than $2,000,000.00 in the annual aggregate, or such larger amount as Landlord may prudently require from time to time, covering bodily injury and property damage liability and $1,000,000 products/completed operations aggregate; (b) Business Auto Liability covering owned, non-owned and hired vehicles with a limit of not less than $1,000,000 per accident; (c) Worker's Compensation Insurance with limits as required by statute and Employers Liability with limits of $500,000 each accident, $500,000 disease policy limit, $500,000 disease--each employee; (d) All Risk or Special Form coverage protecting Tenant against loss of or damage to Tenant's alterations, additions, improvements, carpeting, floor coverings, panelings, decorations, fixtures, inventory and other business personal property situated in or about the Premises to the full replacement value of the property so insured; and, (e) Business Interruption Insurance with limit of liability representing loss of at least approximately six (6) months of income.

11.2 The aforesaid policies shall (a) be provided at Tenant's expense; (b) name the Landlord as additional insureds (General Liability) and loss payee (Property—Special Form); (c) be issued by an insurance

company with a minimum Best's rating of "A-:VII" during the Term; and (d) provide that said insurance shall not be canceled unless thirty (30) days prior written notice (ten days for non-payment of premium) shall have been given to Landlord; a certificate of Liability insurance on ACORD Form 25 and a certificate of Property insurance on ACORD Form 27 shall be delivered to Landlord by Tenant upon the earlier to occur of the 10th Floor Commencement Date and the 14th Floor Commencement Date and at least thirty (30) days prior to each renewal of said insurance.

11.3 Whenever Tenant shall undertake any Alterations in, to or about the Premises ("Work") the aforesaid insurance protection must extend to and include injuries to persons and damage to property arising in connection with such Alterations, without limitation including liability under any applicable structural work act, and such other insurance as Landlord shall require; and the policies of or certificates evidencing such insurance must be delivered to Landlord prior to the commencement of any such Work.

11.4 Landlord agrees to maintain in full force and effect, at all times during the Term of this Lease, (i) property damage insurance covering the Building and Landlord's property in amounts of coverage as is required by any institutional mortgagee of the Building or, if there is no institutional mortgagee of the Building, then in amounts of coverage as may from time to time be carried by reasonably prudent owners of comparable buildings in Cambridge, Massachusetts; and (ii) commercial general liability insurance with respect to the Building in an amount not less than amounts required to be carried by Tenant under this Lease for such liability coverage. Landlord may satisfy such insurance requirements by including the Property in a so called "blanket" insurance policy.

12. WAIVER OF SUBROGATION**.** Tenant and Landlord hereby mutually waive their respective rights of recovery against each other (and on behalf of their respective property insurers) for any property loss insured (or required to be insured pursuant to this Lease) by fire, extended coverage, All Risks or other insurance now or hereafter existing for the benefit of the respective party but only to the extent of the net insurance proceeds payable under such policies (or, with respect to any insurance required to be carried by Tenant or Landlord hereunder, to the extent the net insurance proceeds would have been payable under such policies but for such party's failure to carry such insurance). Each party shall obtain any special endorsements required by their insurer to evidence compliance with the aforementioned waiver.

13. SERVICES AND UTILITIES**.**

13.1 Subject to the other provisions of this Lease, Landlord agrees to furnish to the Premises, the following services and utilities subject to the rules and regulations of the Building prescribed from time to time: (a) water suitable for normal office use of the Premises and common areas of the Building; (b) heat, ventilating and air conditioning required in Landlord's commercially reasonable judgment for the use and occupation of the Premises during Building Business Hours; (c) nightly janitorial service on generally recognized business days; (d) passenger elevator service by non-attended automatic elevators; (e) card access controlled system serving the Building ; and (f) equipment to bring to the Premises electricity for lighting, convenience outlets and other normal office use. Subject to scheduling per Landlord's rules and requirements, Tenant will have the right to access and use of the loading docks and freight elevators on a 24-hour, 7 days per week basis. To the extent that Tenant is not billed directly by a public utility or another third-party sub-metering company, Tenant shall pay, within five (5) days of Landlord's demand, for all electricity used by Tenant in the Premises. The electricity charge shall be at the rates charged for such services by the local public utility. In the absence of Landlord's gross negligence or willful misconduct, Landlord shall not be liable for, and Tenant shall not be entitled to, any abatement or reduction of rental by reason of Landlord's failure to furnish any of the foregoing, unless such failure shall persist for more than seven (7) consecutive days after written notice of such failure is given to Landlord by Tenant (and provided further that Landlord shall not be liable when such failure is caused by accident, breakage, repairs, labor disputes of any character, the acts or omissions of Tenant or Tenant Parties, energy usage restrictions or by any other cause, similar or dissimilar, beyond the reasonable control of Landlord), in which case fixed Annual Rent and Tenant's Proportionate Share of Expenses and Taxes shall abate from and after the eighth (8th) consecutive day following such notice from Tenant, until the service or utility interruption has been corrected. Landlord shall use reasonable efforts to remedy any interruption in the furnishing of services and utilities.

There are Quad Logic meters available in the Building which currently serve the Premises and which separately submeter Tenant's electric usage. Tenant will be billed for its electrical usage without mark-up by Energenix or another third party submetering services company selected by Landlord and within ten (10) business days following the date of the invoice. Any submetering configuration that may be rendered necessary due to Tenant's alterations to the Premises shall be performed by Tenant at Tenant's expense. If at any time during the Term the electrical submeter for the Premises is not operational, then Landlord shall promptly cause the repair of such submeter and may charge Tenant for Tenant's estimated electricity usage in the Premises (based on historical usage) at Landlord's then standard electrical rate (which is currently $2.00 per RSF per year) until such repairs are complete. Landlord shall not be liable in any way to Tenant for any failure or defect in the supply or character of electrical energy furnished to the Premises by reason of any requirement, act or omission of the public utility serving the Building with electricity unless due to the act or omission of Landlord. Tenant's use of electrical energy in the Premises shall not at any time exceed the capacity of any of the electrical conductors and equipment in or otherwise serving the Premises. In order to insure that such capacity is not exceeded and to avert possible adverse effect upon the Building electrical services, Tenant shall give notice to Landlord and obtain Landlord's prior written consent whenever Tenant shall connect to the Building electrical distribution system any major fixtures, appliances or equipment, except for standard office equipment, such as computers, copiers, printers, and server equipment. Any additional feeders or risers to supply Tenant's electrical requirements in addition to those originally installed and all other equipment proper and necessary in connection with such feeders or risers, shall be installed by Landlord upon Tenant's request, at the sole cost and expense of Tenant, provided that such additional feeders and risers are permissible under applicable laws and insurance regulations and the installation of such feeders or risers will not cause permanent damage or injury to the Building or cause or create a dangerous condition or unreasonably interfere with other tenants of the Building. Tenant agrees that it will not make any significant alteration or material addition to the electrical equipment and/or appliances in the Premises without the prior written consent of Landlord in each instance first obtained, which consent will not be unreasonably withheld or delayed, and will promptly advise Landlord of any alteration or addition to such electrical equipment and/or appliances. Tenant, at Tenant's expense, shall purchase, install and replace all light fixtures, bulbs, tubes, lamps, lenses, globes, ballasts and switches used in the Premises.

13.2 Should Tenant require any additional work or service, as described above, including services furnished outside ordinary business hours specified above, Landlord may, on terms to be agreed, upon reasonable advance notice by Tenant, furnish such additional service and Tenant agrees to pay Landlord such charges as may be agreed upon, including any tax imposed thereon, but in no event at a charge less than Landlord's actual cost plus overhead for such additional service and, where appropriate, a reasonable allowance for depreciation of any systems being used to provide such service. The current charge for after-hours HVAC service is specified on the Reference Pages, which rate is subject to increase as hereinafter provided.

13.3 Wherever heat-generating machines or equipment are used by Tenant in the Premises which affect the temperature otherwise maintained by the air conditioning system or Tenant allows occupancy of the Premises by more persons than the heating and air conditioning system is designed to accommodate, in either event whether with or without Landlord's approval, Landlord reserves the right to install supplementary heating and/or air conditioning units in or for the benefit of the Premises and the cost thereof, including the cost of installation and the cost of operations and maintenance, shall be paid by Tenant to Landlord within thirty (30) days of Landlord's demand. . In addition ,if applicable, Landlord may install and shall have access to the Premises to monitor a separate meter (or submeter) to determine the actual use of any utility in the Premises or any shared common area and may make available and share actual whole-project energy and water usage data as necessary to maintain the Building's "green building" certification, if any. If Tenant is billed directly by a public utility, then, upon request, Tenant shall provide monthly utility usage to Landlord in electronic or paper format or provide permission for Landlord to request information regarding Tenant's utility usage directly from the utility company.

13.4 Tenant will not, without the written consent of Landlord, use any apparatus or device in the Premises, including but not limited to, electronic data processing machines and machines using current in excess of 2000 watts and/or 20 amps or 120 volts, which will in any way increase the amount of electricity or water usually furnished or supplied for use of the Premises for normal office use, nor connect with electric current, except through existing electrical outlets in the Premises, or water pipes, any apparatus or device for the purposes of using electrical

current or water. If Tenant shall require water or electric current in excess of that usually furnished or supplied for use of the Premises as normal office use, Tenant shall procure the prior written consent of Landlord for the use thereof, which Landlord may refuse, and if Landlord does consent, Landlord may cause a water meter or electric current meter to be installed so as to measure the amount of such excess water and electric current. The cost of any such meters shall be paid for by Tenant. Tenant agrees to pay to Landlord within five (5) days of Landlord's demand , the cost of all such excess water and electric current consumed (as shown by said meters, if any, or, if none, as reasonably estimated by Landlord) at the rates charged for such services by the local public utility or agency, as the case may be, furnishing the same, plus any additional expense incurred in keeping account of the water and electric current so consumed.

13.5 Tenant will not, without the written consent of Landlord, contract with a utility provider to service the Premises with any utility, including, but not limited to, telecommunications, electricity, water, sewer or gas, which is not previously providing such service to other tenants in the Building. Subject to Landlord's reasonable rules and regulations and the provisions of Articles 6 and 26, Tenant shall be entitled to the use of wiring ("Communications Wiring") from the existing telecommunications nexus in the Building to the Premises, sufficient for normal general office use of the Premises. Tenant shall not install any additional Communications Wiring, nor remove any Communications Wiring, without in each instance obtaining the prior written consent of Landlord, which consent may be withheld in Landlord's sole and absolute discretion. Landlord's shall in no event be liable for disruption in any service obtained by Tenant pursuant to this paragraph.

13.6 Tenant covenants and agrees to (a) comply with applicable law regarding the collection, sorting, separation, and recycling of garbage, waste products, trash and other refuse at the Building (collectively, "trash") and (b) to sort and separate its trash into separate recycling containers as required by law, or pursuant to Landlord's recycling policy for the Building. Landlord reserves the right to refuse to collect or accept from Tenant any trash that is not separated and sorted as required by law or pursuant to Landlord's recycling policy, and to require Tenant to arrange for such collection at Tenant's cost, utilizing a contractor reasonably satisfactory to Landlord. Tenant shall pay all costs, expenses, fines, penalties or damages that may be imposed on Landlord or Tenant by reason of Tenant's failure to comply with the provisions of this paragraph.

14. HOLDING OVER**.** Tenant shall pay Landlord for each day Tenant retains possession of the Premises or part of them after termination of this Lease by lapse of time or otherwise at the rate ("Holdover Rate") which shall be equal to the greater of (a) Two Hundred Percent (200%) of the amount of the Annual Rent for the last period prior to the date of such termination plus all Rent Adjustments under Article 4; or (b) the then market rental value of the Premises as determined by Landlord assuming a new lease of the Premises of the then usual duration and other terms, in either case, prorated on a daily basis, and also, if such holdover continues for more than thirty (30) days, pay all damages sustained by Landlord by reason of such retention. In any event, no provision of this Article 14 shall be deemed to waive Landlord's right of reentry or any other right under this Lease or at law.

15. SUBORDINATION**.** Without the necessity of any additional document being executed by Tenant for the purpose of effecting a subordination, this Lease shall be subject and subordinate at all times to ground or underlying leases and to the lien of any mortgages or deeds of trust now or hereafter placed on, against or affecting the Building, Landlord's interest or estate in the Building, or any ground or underlying lease; provided, however, that if the lessor, mortgagee, trustee, or holder ("**Mortgagee**") of any such mortgage or deed of trust elects to have Tenant's interest in this Lease be superior to any such instrument, then, by notice to Tenant, this Lease shall be deemed superior, whether this Lease was executed before or after said instrument. Notwithstanding the foregoing, Tenant covenants and agrees to execute and deliver within ten (10) days of Landlord's request such further commercially reasonable instruments evidencing such subordination or superiority of this Lease as may be required by Landlord. Landlord represents and warrants that there are no ground or underlying leases or mortgages affecting the Building, Landlord's interest or estate in the Building. Upon written request from Tenant, Landlord agrees to exercise commercially reasonable efforts to obtain from any future Mortgagee a subordination, non—disturbance and attornment agreement in favor of Tenant in the then customary form of such Mortgagee.

16. RULES AND REGULATIONS**.** Tenant shall faithfully observe and comply with all the rules and regulations as set forth in Exhibit D to this Lease and all reasonable and non-discriminatory modifications of and

additions to them from time to time put into effect by Landlord of which Tenant received notice. Landlord shall not be responsible to Tenant for the non-performance by any other tenant or occupant of the Building of any such rules and regulations.

17. REENTRY BY LANDLORD.

17.1 Landlord reserves and shall at all times have the right to re-enter the Premises at reasonable times upon reasonable prior verbal notice (except in the case of an emergency or notice of an unsafe condition in which case no prior notice will be required) to inspect the same, to supply janitor service and any other service to be provided by Landlord to Tenant under this Lease, to show said Premises to prospective purchasers, mortgagees or tenants, and to alter, improve or repair the Premises and any portion of the Building, without abatement of rent, and may for that purpose erect, use and maintain scaffolding, pipes, conduits and other necessary structures and open any wall, ceiling or floor in and through the Building and Premises where reasonably required by the character of the work to be performed, provided entrance to the Building or the Premises shall not be blocked thereby, and further provided that the business of Tenant shall not be interfered with unreasonably. Landlord shall have the right at any time to change the arrangement and/or locations of entrances, or passageways, doors and doorways, and corridors, windows, elevators, stairs, toilets or other public parts of the Building and to change the name, number or designation by which the Building is commonly known. In the event that Landlord damages any portion of any wall or wall covering, ceiling, or floor or floor covering within the Premises, Landlord shall repair or replace the damaged portion to match the original as nearly as commercially reasonable but shall not be required to repair or replace more than the portion actually damaged. Tenant hereby waives any claim for damages for any injury or inconvenience to or interference with Tenant's business, any loss of occupancy or quiet enjoyment of the Premises, and any other loss occasioned by any action of Landlord authorized by this Article 17. Notwithstanding the foregoing, Landlord shall use commercially reasonable efforts to minimize interference with Tenant's conduct of business and access to the Premises and common area restrooms in connection with any such entries into the Premises or other activities permitted under this Section 17.1, provided, however, the foregoing shall not require to perform work outside of normal business hours

17.2 For each of the aforesaid purposes, Landlord shall at all times have and retain a key with which to unlock all of the doors in the Premises, excluding Tenant's vaults and safes or special security areas (designated in advance), and Landlord shall have the right to use any and all means which Landlord may deem proper to open said doors in an emergency to obtain entry to any portion of the Premises. As to any portion to which access cannot be had by means of a key or keys in Landlord's possession, in the event of an emergency, Landlord is authorized to gain access by such means as Landlord shall reasonably elect and the cost of repairing any damage occurring in doing so shall be borne by Tenant and paid to Landlord within thirty (30) days of Landlord's demand.

18. DEFAULT.

18.1 Except as otherwise provided in Article 20, the following events shall be deemed to be an "Event of Default" under this Lease:

18.1.1 Tenant shall fail to pay when due any sum of money becoming due to be paid to Landlord under this Lease, whether such sum be any installment of the rent reserved by this Lease, any other amount treated as additional rent under this Lease, or any other payment or reimbursement to Landlord required by this Lease, whether or not treated as additional rent under this Lease, and such failure shall continue for a period of five (5) days after written notice that such payment was not made when due, but if any such notice shall be given, for the twelve (12) month period commencing with the date of such notice, the failure to pay within five (5) business days after due any additional sum of money becoming due to be paid to Landlord under this Lease during such period shall be an Event of Default, without notice.

18.1.2 Tenant shall fail to comply with any term, provision or covenant of this Lease which is not provided for in another Section of this Article and shall not cure such failure within thirty (30) days after written notice of such failure to Tenant provided, however, that such failure shall not be an event of default if such failure could not reasonably be cured during such thirty (30) day period, Tenant has commenced the cure within such thirty

(30) day period and thereafter is diligently pursuing such cure to completion, but the total aggregate cure period shall not exceed ninety (90) days.

18.1.3 Tenant shall fail to vacate the Premises immediately upon termination of this Lease, by lapse of time or otherwise, or upon termination of Tenant's right to possession only.

18.1.4 Tenant shall become insolvent, admit in writing its inability to pay its debts generally as they become due, file a petition in bankruptcy or a petition to take advantage of any insolvency statute, make an assignment for the benefit of creditors, make a transfer in fraud of creditors, apply for or consent to the appointment of a receiver of itself or of the whole or any substantial part of its property, or file a petition or answer seeking reorganization or arrangement under the federal bankruptcy laws, as now in effect or hereafter amended, or any other applicable law or statute of the United States or any state thereof.

18.1.5 A court of competent jurisdiction shall enter an order, judgment or decree adjudicating Tenant bankrupt, or appointing a receiver of Tenant, or of the whole or any substantial part of its property, without the consent of Tenant, or approving a petition filed against Tenant seeking reorganization or arrangement of Tenant under the bankruptcy laws of the United States, as now in effect or hereafter amended, or any state thereof, and such order, judgment or decree shall not be vacated or set aside or stayed within sixty (60) days from the date of entry thereof.

19. REMEDIES.

19.1 Except as otherwise provided in Article 20, upon the occurrence of any of the Events of Default described or referred to in Article 18, Landlord shall have the option to pursue any one or more of the following remedies without any notice or demand whatsoever, concurrently or consecutively and not alternatively:

19.1.1 Landlord may, at its election, terminate this Lease or terminate Tenant's right to possession only, without terminating the Lease.

19.1.2 Upon any termination of this Lease, whether by lapse of time or otherwise, or upon any termination of Tenant's right to possession without termination of the Lease, Tenant shall surrender possession and vacate the Premises immediately, and deliver possession thereof to Landlord, and Tenant hereby grants to Landlord full and free license to enter into and upon the Premises in such event and to lawfully repossess Landlord of the Premises as of Landlord's former estate and to expel or remove Tenant and any others who may be occupying or be within the Premises and to remove Tenant's signs and other evidence of tenancy and all other property of Tenant therefrom without being deemed in any manner guilty of trespass, eviction or forcible entry or detainer, and without incurring any liability for any damage resulting therefrom, Tenant waiving any right to claim damages for such re-entry and expulsion, and without relinquishing Landlord's right to rent or any other right given to Landlord under this Lease or by operation of law.

19.1.3 Upon any termination of this Lease, whether by lapse of time or otherwise, Landlord shall be entitled to recover as damages, all rent, including any amounts treated as additional rent under this Lease, and other sums due and payable by Tenant on the date of termination, plus as liquidated damages and not as a penalty, an amount equal to the sum of: (a) an amount equal to the then present value of the rent reserved in this Lease for the residue of the stated Term of this Lease including any amounts treated as additional rent under this Lease and all other sums provided in this Lease to be paid by Tenant, minus the fair rental value of the Premises for such residue; (b) the value of the time and expense necessary to obtain a replacement tenant or tenants, and the estimated expenses described in Section 19.1.4 relating to recovery of the Premises, preparation for reletting and for reletting itself; and (c) the cost of performing any other covenants which would have otherwise been performed by Tenant.

19.1.4 Upon any termination of Tenant's right to possession only without termination of the Lease:

19.1.4.1 Neither such termination of Tenant's right to possession nor Landlord's taking and holding possession thereof as provided in Section 19.1.2 shall terminate the Lease or release Tenant, in whole or in part, from any obligation, including Tenant's obligation to pay the rent, including any amounts treated as additional rent, under this Lease for the full Term, and if Landlord so elects Tenant shall continue to pay to Landlord the entire amount of the rent as and when it becomes due, including any amounts treated as additional rent under this Lease, for the remainder of the Term plus any other sums provided in this Lease to be paid by Tenant for the remainder of the Term.

19.1.4.2 Landlord shall use commercially reasonable efforts to relet the Premises or portions thereof to the extent required by applicable law. Landlord and Tenant agree that nevertheless Landlord shall at most be required to use only the same efforts Landlord then uses to lease premises in the Building generally and that in any case that Landlord shall not be required to give any preference or priority to the showing or leasing of the Premises or portions thereof over any other space that Landlord may be leasing or have available and may place a suitable prospective tenant in any such other space regardless of when such other space becomes available and that Landlord shall have the right to relet the Premises for a greater or lesser term than that remaining under this Lease, the right to relet only a portion of the Premises, or a portion of the Premises or the entire Premises as a part of a larger area, and the right to change the character or use of the Premises. In connection with or in preparation for any reletting, Landlord may, but shall not be required to, make repairs, alterations and additions in or to the Premises and redecorate the same to the extent Landlord deems reasonably necessary or desirable, and Tenant shall pay the cost thereof, together with Landlord's expenses of reletting, including, without limitation, any commission incurred by Landlord, within thirty (30) days of Landlord's demand. Landlord shall not be required to observe any instruction given by Tenant about any reletting or accept any tenant offered by Tenant unless such offered tenant has a credit-worthiness acceptable to Landlord and leases the entire Premises upon terms and conditions including a rate of rent (after giving effect to all expenditures by Landlord for tenant improvements, broker's commissions and other leasing costs) all no less favorable to Landlord than as called for in this Lease, nor shall Landlord be required to make or permit any assignment or sublease for more than the current term or which Landlord would not be required to permit under the provisions of Article 9.

19.1.4.3 Until such time as Landlord shall elect to terminate the Lease and shall thereupon be entitled to recover the amounts specified in such case in Section 19.1.3, Tenant shall pay to Landlord upon demand the full amount of all rent, including any amounts treated as additional rent under this Lease and other sums reserved in this Lease for the remaining Term, together with the costs of repairs, alterations, additions, redecorating and Landlord's expenses of reletting and the collection of the rent accruing therefrom (including reasonable attorney's fees and broker's commissions), as the same shall then be due or become due from time to time, less only such consideration as Landlord may have received from any reletting of the Premises; and Tenant agrees that Landlord may file suits from time to time to recover any sums falling due under this Article 19 as they become due. Any proceeds of reletting by Landlord in excess of the amount then owed by Tenant to Landlord from time to time shall be credited against Tenant's future obligations under this Lease but shall not otherwise be refunded to Tenant or inure to Tenant's benefit.

19.2 Upon the occurrence of an Event of Default, Landlord may (but shall not be obligated to) cure such default at Tenant's sole expense. Without limiting the generality of the foregoing, Landlord may, at Landlord's option, enter into and upon the Premises if Landlord determines in its sole but reasonable discretion that Tenant is not acting within a commercially reasonable time to maintain, repair or replace anything for which Tenant is responsible under this Lease or to otherwise effect compliance with its obligations under this Lease and correct the same, without being deemed in any manner guilty of trespass, eviction or forcible entry and detainer and without incurring any liability for any damage or interruption of Tenant's business resulting therefrom and Tenant agrees to reimburse Landlord within thirty (30) days of Landlord's demand as additional rent, for any expenses which Landlord may incur in thus effecting compliance with Tenant's obligations under this Lease, plus interest from the date of expenditure by Landlord at the Wall Street Journal prime rate.

19.3 Tenant understands and agrees that in entering into this Lease, Landlord is relying upon receipt of all the Annual Rent and Monthly Installments of Rent to become due with respect to all the Premises originally leased hereunder over the full Initial Term of this Lease for amortization, including interest at the Amortization Rate.

For purposes hereof, the "Concession Amount" shall be defined as the aggregate of all amounts forgone or expended by Landlord as free rent under this Lease, under Exhibit B hereof for construction allowances (excluding therefrom any amounts expended by Landlord for Initial Alterations (if any), as defined in Exhibit B), and for brokers' commissions payable by reason of this Lease. Accordingly, Tenant agrees that if this Lease or Tenant's right to possession of the Premises leased hereunder shall be terminated as of any date ("Default Termination Date") prior to the expiration of the full Initial Term hereof by reason of a default of Tenant, there shall be due and owing to Landlord as of the day prior to the Default Termination Date, as rent in addition to all other amounts owed by Tenant as of such date, the amount ("Unamortized Amount") of the Concession Amount determined as set forth below; provided, however, that in the event that such amounts are recovered by Landlord pursuant to any other provision of this Article 19, Landlord agrees that it shall not attempt to recover such amounts pursuant to this Section 19.3. For the purposes hereof, the Unamortized Amount shall be determined in the same manner as the remaining principal balance of a mortgage with interest at the Amortization Rate payable in level payments over the same length of time as from the effectuation of the Concession concerned to the end of the full Initial Term of this Lease would be determined. The foregoing provisions shall also apply to and upon any reduction of space in the Premises, as though such reduction were a termination for Tenant's default, except that (i) the Unamortized Amount shall be reduced by any amounts paid by Tenant to Landlord to effectuate such reduction and (ii) the manner of application shall be that the Unamortized Amount shall first be determined as though for a full termination as of the Effective Date of the elimination of the portion, but then the amount so determined shall be multiplied by the fraction of which the numerator is the rentable square footage of the eliminated portion and the denominator is the rentable square footage of the Premises originally leased hereunder; and the amount thus obtained shall be the Unamortized Amount.

19.4 Notwithstanding anything to the contrary contained in this Lease, with respect to any legal proceedings or actions, if either party places the enforcement of this Lease or any part thereof in the hands of an attorney, or files suit upon the same, in any case, as a result of a breach by the other party of its covenants under this Lease, or if Landlord places the recovery of possession of the Premises in the hands of an attorney, the prevailing party in any such proceeding or action shall be entitled to recover its reasonable out-of-pocket attorneys' fees and disbursements, and court costs. As used herein, the term "prevailing party" shall mean the party who substantially prevails in the matter at issue including a party who dismisses an action for recovery hereunder in exchange for payment of sums allegedly due, performance of covenants allegedly breached or consideration substantially equal to the relief sought in the action. **TENANT EXPRESSLY WAIVES ANY RIGHT TO: (A) TRIAL BY JURY; AND (B) SERVICE OF ANY NOTICE REQUIRED BY ANY PRESENT OR FUTURE LAW OR ORDINANCE APPLICABLE TO LANDLORDS OR TENANTS BUT NOT REQUIRED BY THE TERMS OF THIS LEASE.**

19.5 Pursuit of any of the foregoing remedies shall not preclude pursuit of any of the other remedies provided in this Lease or any other remedies provided by law (all such remedies being cumulative), nor shall pursuit of any remedy provided in this Lease constitute a forfeiture or waiver of any rent due to Landlord under this Lease or of any damages accruing to Landlord by reason of the violation of any of the terms, provisions and covenants contained in this Lease.

19.6 No act or thing done by Landlord or its agents during the Term shall be deemed a termination of this Lease or an acceptance of the surrender of the Premises, and no agreement to terminate this Lease or accept a surrender of said Premises shall be valid, unless in writing signed by Landlord. No waiver by Landlord of any violation or breach of any of the terms, provisions and covenants contained in this Lease shall be deemed or construed to constitute a waiver of any other violation or breach of any of the terms, provisions and covenants contained in this Lease. Landlord's acceptance of the payment of rental or other payments after the occurrence of an Event of Default shall not be construed as a waiver of such Event of Default, unless Landlord so notifies Tenant in writing. Forbearance by either party in enforcing one or more of the remedies provided in this Lease upon an Event of Default shall not be deemed or construed to constitute a waiver of such Event of Default or of such party's right to enforce any such remedies with respect to such Event of Default or any subsequent Event of Default.

19.7 Intentionally Omitted.

19.8 Any and all property which may be removed from the Premises by Landlord pursuant to the authority of this Lease or of law, to which Tenant is or may be entitled, may be handled, removed and/or stored, as the case may be, by or at the direction of Landlord but at the risk, cost and expense of Tenant, and Landlord shall in no event be responsible for the value, preservation or safekeeping thereof. Tenant shall pay to Landlord, upon demand, any and all expenses incurred in such removal and all storage charges against such property so long as the same shall be in Landlord's possession or under Landlord's control. Any such property of Tenant not retaken by Tenant from storage within thirty (30) days after removal from the Premises shall, at Landlord's option, be deemed conveyed by Tenant to Landlord under this Lease as by a bill of sale without further payment or credit by Landlord to Tenant.

20. TENANT'S BANKRUPTCY OR INSOLVENCY.

20.1 If at any time and for so long as Tenant shall be subjected to the provisions of the United States Bankruptcy Code or other law of the United States or any state thereof for the protection of debtors as in effect at such time (each a "Debtor's Law"):

20.1.1 Tenant, Tenant as debtor-in-possession, and any trustee or receiver of Tenant's assets (each a "Tenant's Representative") shall have no greater right to assume or assign this Lease or any interest in this Lease, or to sublease any of the Premises than accorded to Tenant in Article 9, except to the extent Landlord shall be required to permit such assumption, assignment or sublease by the provisions of such Debtor's Law. Without limitation of the generality of the foregoing, any right of any Tenant's Representative to assume or assign this Lease or to sublease any of the Premises shall be subject to the conditions that:

20.1.1.1 Such Debtor's Law shall provide to Tenant's Representative a right of assumption of this Lease which Tenant's Representative shall have timely exercised and Tenant's Representative shall have fully cured any default of Tenant under this Lease.

20.1.1.2 Tenant's Representative or the proposed assignee, as the case shall be, shall have deposited with Landlord as security for the timely payment of rent an amount equal to the larger of: (a) three (3) months' rent and other monetary charges accruing under this Lease; and (b) any sum specified in Article 5; and shall have provided Landlord with adequate other assurance of the future performance of the obligations of the Tenant under this Lease. Without limitation, such assurances shall include, at least, in the case of assumption of this Lease, demonstration to the satisfaction of the Landlord that Tenant's Representative has and will continue to have sufficient unencumbered assets after the payment of all secured obligations and administrative expenses to assure Landlord that Tenant's Representative will have sufficient funds to fulfill the obligations of Tenant under this Lease; and, in the case of assignment, submission of current financial statements of the proposed assignee, audited by an independent certified public accountant reasonably acceptable to Landlord and showing a net worth and working capital in amounts determined by Landlord to be sufficient to assure the future performance by such assignee of all of the Tenant's obligations under this Lease.

20.1.1.3 The assumption or any contemplated assignment of this Lease or subleasing any part of the Premises, as shall be the case, will not breach any provision in any other lease, mortgage, financing agreement or other agreement by which Landlord is bound.

20.1.1.4 Landlord shall have, or would have had absent the Debtor's Law, no right under Article 9 to refuse consent to the proposed assignment or sublease by reason of the identity or nature of the proposed assignee or sublessee or the proposed use of the Premises concerned.

21. QUIET ENJOYMENT. Landlord represents and warrants that it has full right and authority to enter into this Lease and that Tenant, while paying the rental and performing its other covenants and agreements contained in this Lease, shall peaceably and quietly have, hold and enjoy the Premises for the Term without hindrance or molestation from Landlord subject to the terms and provisions of this Lease. Landlord shall not be liable for any interference or disturbance by other tenants or third persons, nor shall Tenant be released from any of the obligations of this Lease because of such interference or disturbance.

22. CASUALTY

22.1 In the event the Premises or the Building are damaged by fire or other cause and in Landlord's reasonable estimation such damage can be materially restored within one hundred eighty (180) days following the date of the damage, Landlord shall forthwith repair the same and this Lease shall remain in full force and effect, except that Tenant shall be entitled to a proportionate abatement in rent from the date of such damage. Such abatement of rent shall be made pro rata in accordance with the extent to which the damage and the making of such repairs shall interfere with the use and occupancy by Tenant of the Premises from time to time. Within forty-five (45) days from the date of such damage, Landlord shall notify Tenant, in writing, of Landlord's reasonable estimation of the length of time within which material restoration can be made. For purposes of this Lease, the Building or Premises shall be deemed "materially restored" if they are in such condition as would not prevent or materially interfere with Tenant's use of the Premises for the purpose for which it was being used immediately before such damage.

22.2 If such repairs cannot, in Landlord's reasonable estimation, be made within one hundred eighty (180) days following the commencement of restoration, Landlord and Tenant shall each have the option of giving the other, at any time within thirty (30) days after Landlord's notice of estimated restoration time, notice terminating this Lease as of the date of such damage. In the event of the giving of such notice, this Lease shall expire and all interest of the Tenant in the Premises shall terminate as of the date of such damage as if such date had been originally fixed in this Lease for the expiration of the Term. In the event that neither Landlord nor Tenant exercises its option to terminate this Lease, then Landlord shall repair or restore such damage, this Lease continuing in full force and effect, and the rent hereunder shall be proportionately abated as provided in Section 22.1.

22.3 Landlord shall not be required to repair or replace any damage or loss by or from fire or other cause to any panelings, decorations, partitions, railings, ceilings, floor coverings, office fixtures or any other property or improvements installed on the Premises by, or belonging to, Tenant. Any insurance which may be carried by Landlord or Tenant against loss or damage to the Building or Premises shall be for the sole benefit of the party carrying such insurance and under its sole control.

22.4 In the event that Landlord should fail to complete such repairs and material restoration within sixty (60) days after the date estimated by Landlord therefor as extended by this Section 22.4, Tenant may at its option and as its sole remedy terminate this Lease by delivering written notice to Landlord, within fifteen (15) days after the expiration of said period of time, whereupon the Lease shall end on the date of such notice or such later date fixed in such notice as if the date of such notice was the date originally fixed in this Lease for the expiration of the Term; provided, however, that if construction is delayed because of changes, deletions or additions in construction requested by Tenant, strikes, lockouts, casualties, Acts of God, war, material or labor shortages, government regulation or control or other causes beyond the reasonable control of Landlord, the period for restoration, repair or rebuilding shall be extended for the amount of time Landlord is so delayed but in no event to exceed an additional ninety (90) days.

22.5 Notwithstanding anything to the contrary contained in this Article: (a) Landlord shall not have any obligation whatsoever to repair, reconstruct, or restore the Premises when the damages resulting from any casualty covered by the provisions of this Article 22 occur during the last twelve (12) months of the Term or any extension thereof, or for which sufficient insurance proceeds to fully cover the repair and restoration are not received by Landlord (and such insufficiency is not due to Landlord's failure to carry the insurance required hereunder), but if Landlord determines not to repair such damages Landlord shall notify Tenant within a reasonable time (but in all events no more than ninety (90) days after the fire or casualty) and if such damages shall render any material portion of the Premises untenantable Tenant shall have the right to terminate this Lease by notice to Landlord within fifteen (15) days after receipt of Landlord's notice; and (b) in the event the holder of any indebtedness secured by a mortgage or deed of trust covering the Premises or Building requires that any insurance proceeds be applied to such indebtedness, then Landlord shall have the right to terminate this Lease by delivering written notice of termination to Tenant within fifteen (15) days after such requirement is made by any such holder, whereupon this Lease shall end on the date of such damage as if the date of such damage were the date originally fixed in this Lease for the expiration of the Term.

22.6 In the event of any damage or destruction to the Building or Premises by any peril covered by the provisions of this Article 22, it shall be Tenant's responsibility to properly secure the Premises and upon notice from Landlord to remove forthwith, at its sole cost and expense, such portion of all of the property belonging to Tenant or its licensees from such portion or all of the Building or Premises as Landlord shall request.

23. EMINENT DOMAIN**.** If all or any substantial part of the Premises shall be taken or appropriated by any public or quasi-public authority under the power of eminent domain, or conveyance in lieu of such appropriation, either party to this Lease shall have the right, at its option, of giving the other, at any time within thirty (30) days after such taking, notice terminating this Lease, except that Tenant may only terminate this Lease by reason of taking or appropriation, if such taking or appropriation shall be so substantial as to materially interfere with Tenant's use and occupancy of the Premises. If neither party to this Lease shall so elect to terminate this Lease, the rental thereafter to be paid shall be adjusted on a fair and equitable basis under the circumstances. In addition to the rights of Landlord above, if any substantial part of the Building shall be taken or appropriated by any public or quasi-public authority under the power of eminent domain or conveyance in lieu thereof, and regardless of whether the Premises or any part thereof are so taken or appropriated, Landlord shall have the right, at its sole option, to terminate this Lease. Landlord shall be entitled to any and all income, rent, award, or any interest whatsoever in or upon any such sum, which may be paid or made in connection with any such public or quasi-public use or purpose, and Tenant hereby assigns to Landlord any interest it may have in or claim to all or any part of such sums, other than any separate award which may be made with respect to Tenant's trade fixtures and moving expenses; Tenant shall make no claim for the value of any unexpired Term.

24. SALE BY LANDLORD**.** In event of a sale or conveyance by Landlord of the Building, the same shall operate to release Landlord from any future liability upon any of the covenants or conditions, expressed or implied, contained in this Lease in favor of Tenant, and in such event Tenant agrees to look solely to the responsibility of the successor in interest of Landlord in and to this Lease. Except as set forth in this Article 24, this Lease shall not be affected by any such sale and Tenant agrees to attorn to the purchaser or assignee. If any security has been given by Tenant to secure the faithful performance of any of the covenants of this Lease, Landlord shall transfer or deliver said security, as such, to Landlord's successor in interest and thereupon Landlord shall be discharged from any further liability with regard to said security.

25. ESTOPPEL CERTIFICATES**.** Within ten (10) business days following any written request which Landlord may make from time to time, Tenant shall execute and deliver to Landlord or mortgagee or prospective mortgagee a sworn statement certifying: (a) the date of commencement of this Lease; (b) the fact that this Lease is unmodified and in full force and effect (or, if there have been modifications to this Lease, that this Lease is in full force and effect, as modified, and stating the date and nature of such modifications); (c) the date to which the rent and other sums payable under this Lease have been paid; (d) the fact that, to the best of Tenant's knowledge, there are no current defaults under this Lease by either Landlord or Tenant except as specified in Tenant's statement; and (e) to the best of Tenant's knowledge, such other factual matters as may be requested by Landlord. Landlord and Tenant intend that any statement delivered pursuant to this Article 25 may be relied upon by any mortgagee, beneficiary or purchaser, and Tenant shall be liable for all loss, cost or expense resulting from the failure of any sale or funding of any loan caused by any material misstatement contained in such estoppel certificate.

26. SURRENDER OF PREMISES**.**

26.1 Tenant shall arrange to meet Landlord for two (2) joint inspections of the Premises, the first to occur at least thirty (30) days (but no more than sixty (60) days) before the last day of the Term, and the second to occur not later than forty-eight (48) hours after Tenant has vacated the Premises. In the event of Tenant's failure to arrange such joint inspections and/or participate in either such inspection, Landlord's inspection at or after Tenant's vacating the Premises shall be conclusively deemed correct for purposes of determining Tenant's responsibility for repairs and restoration.

26.2 Alterations, additions, and improvements in, on, or to the Premises made or installed by or for Tenant, including the initial Tenant Work, including, without limitation, carpeting, shall be and remain the property of Tenant during the Term. Upon the expiration or sooner termination of the Term, all Alterations (excluding

Tenant's equipment, trade fixtures and other personal property) shall become a part of the realty and shall belong to Landlord without compensation, and title shall pass to Landlord under this Lease as by a bill of sale. At the end of the Term or any renewal of the Term or other sooner termination of this Lease, Tenant will peaceably deliver up to Landlord possession of the Premises, together with all Alterations by whomsoever made, in the same conditions received or first installed, broom clean and free of all debris, excepting only ordinary wear and tear and damage by fire or other casualty. Notwithstanding the foregoing, if Landlord elects by notice given to Tenant at the time Landlord consents to any Alteration, Tenant shall, at Tenant's sole cost, remove any Alterations, including carpeting, so designated by Landlord's notice, and repair any damage caused by such removal; provided, however, in no event may Landlord require that Tenant remove any Alterations unless Landlord reasonably determines such Alterations are not standard office improvements (as opposed to "specialty" Alterations in the nature of internal stairways or raised floors) or will require material additional expense to demolish and/or remove at the end of the Term. Tenant must, at Tenant's sole cost, remove upon termination of this Lease, any and all of Tenant's furniture, furnishings, equipment, movable partitions of less than full height from floor to ceiling and other trade fixtures and personal property, as well as all data/telecommunications cabling and wiring installed by or on behalf of Tenant, whether inside walls, under any raised floor or above any ceiling (collectively, "**Personalty**"). Personalty not so removed shall be deemed abandoned by the Tenant and title to the same shall thereupon pass to Landlord under this Lease as by a bill of sale, but Tenant shall remain responsible for the cost of removal and disposal of such Personalty, as well as any damage caused by such removal.

26.3 All obligations of Tenant under this Lease not fully performed as of the expiration or earlier termination of the Term shall survive the expiration or earlier termination of the Term. Any otherwise unused Security Deposit shall be credited against the amount payable by Tenant under this Lease.

27. NOTICES**.** Any notice or document required or permitted to be delivered under this Lease shall be addressed to the intended recipient, by fully prepaid registered or certified United States Mail return receipt requested, or by reputable independent contract delivery service furnishing a written record of attempted or actual delivery, and shall be deemed to be delivered when tendered for delivery to the addressee at its address set forth on the Reference Pages, or at such other address as it has then last specified by written notice delivered in accordance with this Article 27. Any such notice or document may also be personally delivered if a receipt is signed by and received from, the individual, if any, named in Tenant's Notice Address.

28. TAXES PAYABLE BY TENANT**.** In addition to rent and other charges to be paid by Tenant under this Lease, Tenant shall reimburse to Landlord, upon demand, any and all taxes payable by Landlord (other than net income taxes) whether or not now customary or within the contemplation of the parties to this Lease: (a) upon, allocable to, or measured by or on the gross or net rent payable under this Lease, including without limitation any gross income tax or excise tax levied by the State, any political subdivision thereof, or the Federal Government with respect to the receipt of such rent; (b) upon or with respect to the possession, leasing, operation, management, maintenance, alteration, repair, use or occupancy of the Premises or any portion thereof, including any sales, use or service tax imposed as a result thereof; (c) upon or measured by the Tenant's gross receipts or payroll or the value of Tenant's equipment, furniture, fixtures and other personal property of Tenant or leasehold improvements, alterations or additions located in the Premises; or (d) upon this transaction or any document to which Tenant is a party creating or transferring any interest of Tenant in this Lease or the Premises. In addition to the foregoing, Tenant agrees to pay, before delinquency, any and all taxes levied or assessed against Tenant and which become payable during the term hereof upon Tenant's equipment, furniture, fixtures and other personal property of Tenant located in the Premises.

29. INTENTIONALLY DELETED.

30. DEFINED TERMS AND HEADINGS**.** The Article headings shown in this Lease are for convenience of reference and shall in no way define, increase, limit or describe the scope or intent of any provision of this Lease. Any indemnification or insurance of Landlord shall apply to and inure to the benefit of all the following "Landlord Entities", being Landlord, Landlord's investment manager, and the trustees, boards of directors, officers, general partners, beneficiaries, stockholders, employees and agents of each of them. Any option granted to Landlord shall also include or be exercisable by Landlord's trustee, beneficiary, agents and employees, as the case may be. In any

case where this Lease is signed by more than one person, the obligations under this Lease shall be joint and several. The terms “Tenant” and “Landlord” or any pronoun used in place thereof shall indicate and include the masculine or feminine, the singular or plural number, firms or corporations, and their and each of their respective successors, executors, administrators and permitted assigns, according to the context hereof. The term “rentable area” shall mean the rentable area of the Premises or the Building as calculated by the Landlord on the basis of the plans and specifications of the Building including a proportionate share of any common areas. Tenant hereby accepts and agrees to be bound by the figures for the rentable square footage of the Premises and Tenant’s Proportionate Share shown on the Reference Pages; however, Landlord may adjust either or both figures if there is manifest error, addition or subtraction to the Building or any business park or complex of which the Building is a part, remeasurement or other circumstance reasonably justifying adjustment. The term “Building” refers to the structure in which the Premises are located and the common areas (parking lots, sidewalks, landscaping, etc.) appurtenant thereto. If the Building is part of a larger complex of structures, the term “Building” may include the entire complex, where appropriate (such as shared Expenses, Insurance Costs or Taxes) and subject to Landlord’s reasonable discretion.

31. TENANT’S AUTHORITY**.** If Tenant signs as a corporation, partnership, trust or other legal entity, Tenant represents and warrants that each of the persons executing this Lease on behalf of Tenant has been and is qualified to do business in the state in which the Building is located, that the entity has full right and authority to enter into this Lease, and that all persons signing on behalf of the entity were authorized to do so by appropriate actions. If requested by Landlord, Tenant agrees to deliver to Landlord, simultaneously with the delivery of this Lease, a corporate resolution and proof of due authorization by partners, evidencing the due authorization of Tenant to enter into this Lease.

Tenant hereby represents and warrants that neither Tenant, nor any persons or entities holding any legal or beneficial interest whatsoever in Tenant, are (i) the target of any sanctions program that is established by Executive Order of the President or published by the Office of Foreign Assets Control, U.S. Department of the Treasury (“OFAC”); (ii) designated by the President or OFAC pursuant to the Trading with the Enemy Act, 50 U.S.C. App. § 5, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-06, the Patriot Act, Public Law 107-56, Executive Order 13224 (September 23, 2001) or any Executive Order of the President issued pursuant to such statutes; or (iii) named on the following list that is published by OFAC: “List of Specially Designated Nationals and Blocked Persons.” If the foregoing representation is untrue at any time during the Term, an Event of Default will be deemed to have occurred, without the necessity of notice to Tenant.

32. FINANCIAL STATEMENTS AND CREDIT REPORTS**.** At Landlord’s request (not more than once per year unless in connection with a sale or financing transaction), Tenant shall deliver to Landlord a copy, certified by an officer of Tenant as being a true and correct copy, of Tenant’s most recent audited financial statement, or, if unaudited, certified by Tenant’s chief financial officer as being true, complete and correct in all material respects. The foregoing shall not apply as long as Tenant is a publicly traded company. Tenant hereby authorizes Landlord to obtain one or more credit reports on Tenant at any time, and shall execute such further authorizations as Landlord may reasonably require in order to obtain a credit report.

33. COMMISSIONS**.** Each of the parties represents and warrants to the other that it has not dealt with any broker or finder in connection with this Lease, except as described on the Reference Pages. Landlord shall be responsible for all fees and commissions due to the broker described in the Reference Pages resulting from this Lease.

34. TIME AND APPLICABLE LAW**.** Time is of the essence of this Lease and all of its provisions. This Lease shall in all respects be governed by the laws of the state in which the Building is located. Whenever a period of time is prescribed for the taking of an action by Landlord or Tenant (other than payment obligations), the period of time for the performance of such action shall be extended by the number of days that the performance is actually delayed due to Force Majeure delays (as defined in Section 2.4).

35. SUCCESSORS AND ASSIGNS**.** Subject to the provisions of Article 9, the terms, covenants and conditions contained in this Lease shall be binding upon and inure to the benefit of the heirs, successors, executors, administrators and assigns of the parties to this Lease.

36. ENTIRE AGREEMENT**.** This Lease, together with its exhibits, contains all agreements of the parties to this Lease and supersedes any previous negotiations. There have been no representations made by the Landlord or Tenant or any of its representatives or understandings made between the parties other than those set forth in this Lease and its exhibits. This Lease may not be modified except by a written instrument duly executed by the parties to this Lease.

37. EXAMINATION NOT OPTION**.** Submission of this Lease shall not be deemed to be a reservation of the Premises. Landlord and Tenant shall not be bound by this Lease until the same has been executed and delivered by both parties, and until such delivery Landlord reserves the right to exhibit and lease the Premises to other prospective tenants. Notwithstanding anything contained in this Lease to the contrary, Landlord may withhold delivery of possession of the Premises from Tenant until such time as Tenant has paid to Landlord any security deposit required by Article 5, the first month's rent as set forth in Article 3 and any sum owed pursuant to this Lease. This Lease may be executed in two or more counterparts, which when taken together shall constitute one and the same instrument. The parties contemplate that they may be executing counterparts of this Lease transmitted by facsimile or PDF and agree and intend that a signature by facsimile or PDF shall bind the party so signing with the same effect as through the signature were an original signature. Any party delivering an executed counterpart of this Lease by email shall also deliver a manually executed original counterpart of this Lease, but the failure to deliver a manually executed original counterpart shall not affect the validity, enforceability or binding effect of this Lease.

38. RECORDATION**.** Tenant shall not record or register this Lease or a short form memorandum hereof without the prior written consent of Landlord, and then shall pay all charges and taxes incident such recording or registration.

39. PARKING.

39.1 During the initial Term of this Lease, Tenant agrees to lease from Landlord and Landlord agrees to lease to Tenant, the number and type of parking passes as set forth on the Reference Page of this Lease, provided that Tenant may request additional parking passes, subject to availability in Landlord's reasonable discretion to be leased by Landlord to Tenant in Landlord's sole discretion. This right to park in the Building's parking facilities (the "Parking Facility") shall be on an unreserved, nonexclusive, first come, first served basis, for passenger-size automobiles and is subject to the following terms and conditions:

39.1.1 Tenant shall pay to Landlord, or Landlord's designated parking operator, the Building's prevailing monthly parking charges, without deduction or offset, on the first day of each month during the Term of this Lease. The initial charges are specified on the Reference Page. Landlord will notify Tenant upon not less than thirty (30) days' notice of any increases in the monthly parking charges prior to billing Tenant any increases. No deductions from the monthly charge shall be made for days on which the Parking Facility is not used by Tenant unless such non-use is caused by Landlord's actions and continues for more than three (3) consecutive business days.

39.1.2 Tenant shall at all times abide by and shall cause each of Tenant's employees, agents, customers, visitors, invitees, licensees, contractors, assignees and subtenants (collectively, "Tenant's Parties") to abide by any rules and regulations ("Rules") for use of the Parking Facility that Landlord or Landlord's garage operator reasonably establishes from time to time, and otherwise agrees to use the Parking Facility in a safe and lawful manner. Landlord reserves the right to adopt, modify and enforce the Rules governing the use of the Parking Facility from time to time including any key-card, sticker or other identification or entrance system and hours of operation. Landlord may refuse to permit any person who violates such Rules to park in the Parking Facility, and any violation of the Rules shall subject the car to removal from the Parking Facility.

39.1.3 Unless specified to the contrary above, the parking spaces hereunder shall be provided on a non-designated "first-come, first-served" basis. Landlord reserves the right to assign specific spaces, and to reserve spaces for visitors, small cars, disabled persons or for other tenants or guests, and Tenant shall not park and shall not allow Tenant's Parties to park in any such assigned or reserved spaces. Tenant may validate visitor parking by such method as Landlord may approve, at the validation rate from time to time generally applicable to visitor parking. Tenant acknowledges that the Parking Facility may be closed entirely or in part in order to make repairs or perform maintenance services, or to alter, modify, re-stripe or renovate the Parking Facility, or if required by casualty, strike, condemnation, act of God, governmental law or requirement or other reason beyond the operator's reasonable control.

39.1.4 Tenant acknowledges that to the fullest extent permitted by law, Landlord shall have no liability for any damage to property or other items located in the parking areas of the Project (including without limitation, any loss or damage to tenant's automobile or the contents thereof due to theft, vandalism or accident), nor for any personal injuries or death arising out of the use of the Parking Facility by Tenant or any Tenant's Parties. The limitation on Landlord's liability under the preceding sentence shall not apply however to loss or damage arising directly from Landlord's gross negligence or willful misconduct. Without limiting the foregoing, if Landlord arranges for the parking areas to be operated by an independent contractor not affiliated with Landlord, Tenant acknowledges that Landlord shall have no liability for claims arising through acts or omissions of such independent contractor. Tenant hereby voluntarily releases, discharges, waives and relinquishes any and all actions or causes of action for personal injury or property damage occurring to Tenant or any of Tenant's Parties arising as a result of parking in the Parking Facility, or any activities incidental thereto, wherever or however the same may occur, and further agrees that Tenant will not prosecute any claim for personal injury or property damage against Landlord or any of its officers, agents, servants or employees for any said causes of action and in all events, Tenant agrees to look first to its insurance carrier for payment of any losses sustained in connection with any use of the Parking Facility. Tenant hereby waives on behalf of its insurance carriers all rights of subrogation against Landlord or Landlord's agents.

39.1.5 Tenant's right to park as described in this Article and this Lease is exclusive to Tenant and its employees and Permitted Transferees and any subtenant or assignee consented to by Landlord hereunder, but not to any other third party.

39.1.6 In the event any surcharge or regulatory fee is at any time imposed by any governmental authority with reference to parking, Tenant shall (commencing after two (2) weeks' notice to Tenant) pay, per parking pass, such surcharge or regulatory fee to Landlord in advance on the first day of each calendar month concurrently with the month installment of rent due under this Lease. Landlord will enforce any surcharge or fee in an equitable manner amongst the Building tenants.

39.2 If Tenant violates any of the terms and conditions of this Article, the operator of the Parking Facility shall have the right to remove from the Parking Facility any vehicles hereunder which shall have been involved or shall have been owned or driven by parties involved in causing such violation, without liability therefore whatsoever. In addition, Landlord shall have the right to cancel Tenant's right to use the Parking Facility pursuant to this Article upon ten (10) days' written notice, unless within such ten (10) day period, Tenant cures such default. Such cancellation right shall be cumulative and in addition to any other rights or remedies available to Landlord at law or equity, or provided under this Lease.

40. LIMITATION OF LANDLORD'S LIABILITY**.** Redress for any claim against Landlord under this Lease shall be limited to and enforceable only against and to the extent of Landlord's interest in the Building. The obligations of Landlord under this Lease are not intended to be and shall not be personally binding on, nor shall any resort be had to the private properties of, any of its or its investment manager's trustees, directors, officers, partners, beneficiaries, members, stockholders, employees, or agents. Except for Tenant's liability under Section 14 of this

Lease, in no case shall either party be liable to the other hereunder for any lost profits, damage to business, or any form of special, indirect or consequential damages.

41. EXTENSION OPTION. Tenant shall, provided the Lease is in full force and effect and there is no uncured Event of Default at the time of notification or commencement and there has not been any Event of Default in the two (2) years preceding the commencement of the Extension Term, have one (1) option to extend the Term of this Lease as to the entire Premises for a term of five (5) years (the "Extension Term"), on the same terms and conditions set forth in the Lease ("Tenant's Extension Option"), except as modified by the terms, covenants and conditions as set forth below:

41.1 If Tenant elects to exercise said option, then Tenant shall provide Landlord with written notice no earlier than the date which is fifteen (15) months prior to the expiration of the then current Term of the Lease but no later than the date which is nine (9) months prior to the expiration of the then current Term of this Lease. If Tenant fails to provide such notice, time being of the essence, Tenant shall have no further or additional right to extend or renew the term of the Lease.

41.2 The Annual Rent and Monthly Installment in effect at the expiration of the then current term of the Lease shall be modified for the Extension Term as hereinafter provided. The Annual Rent and Monthly Installment for the Extension Term shall be the then current fair market rental for comparable space in similar buildings in the East Cambridge submarket as of the date the applicable Extension Term is to commence, taking into account the specific provisions of the Lease which will remain constant and all then relevant factors. Landlord shall advise Tenant of Landlord's determination of the new Annual Rent and Monthly Installment for the Premises no later than thirty (30) days after receipt of Tenant's written request to exercise an Extension Term. Said request shall be made no earlier than thirty (30) days prior to the first date on which Tenant may exercise its option under this Paragraph. Said notification of the new Annual Rent may include a provision for its escalation to provide for a change in fair market rental between the time of notification and the commencement of the extension term. If, on or before the date which is 270 days prior to the commencement of the applicable Extension Term, Tenant has not agreed with Landlord's determination of the new Annual Rent after negotiating in good faith, either party may elect by notice (the "Arbitration Notice") to the other party to have the new Annual Rent arbitrated as described as follows.

41.2.1 If either party sends the Arbitration Notice, then such new Annual Rent shall be determined as follows: Landlord and Tenant shall each appoint (within twenty (20) days after the Arbitration Notice is received) a qualified MAI appraiser doing business in the area and, in turn, those two (2) independent MAI appraisers shall appoint a third (3rd) MAI appraiser and the majority shall decide the new Annual Rent for the Premises as of the commencement of the applicable Extension Term, which determination shall be consistent with the second sentence of Section 41.2 above and shall be binding on Landlord and Tenant. Landlord and Tenant shall equally share in the expense of this appraisal.

41.2.2 A qualified MAI appraiser shall be any person appointed by or on behalf of either party or appointed pursuant to the provisions hereof and: (i) shall be (A) a member of the American Institute of Real Estate Appraisers with not less than 10 years of experience in the appraisal of improved office and life sciences space in the greater Cambridge, Massachusetts metropolitan area, or (B) a licensed commercial real estate broker with not less than 15 years' experience representing landlords and/or tenants in the leasing of office and life sciences space in the greater Cambridge, Massachusetts metropolitan area; (ii) devoting substantially all of his or her time to professional appraisal or brokerage work, as applicable, at the time of appointment; and (iii) shall be in all respects impartial and disinterested.

41.3 The option to extend the Term for the Extension Term is not transferable; the parties hereto acknowledge and agree that they intend that the aforesaid option to extend the Term of this Lease shall be "personal" to the originally-named Tenant as set forth above and any assignee that is a

Permitted Transferee, and that in no event will any assignee or sublessee have any rights to exercise the aforesaid option to extend.

42. Offer Space Option. As used herein, "**Offer Space**" means any leasable area on the thirteenth (13th) floor of the Building as and when Landlord reasonably determines that the same will become available for lease to third parties and subject to the rights of any Superior Occupant (as hereinafter defined), provided, however, if any Offer Space is vacant as of the date of this Lease or is subject to a lease that expires in calendar year 2020, then such space will not be deemed "Offer Space" for purposes of this Article 42 until it has been leased by Landlord to a third party tenant.

(a) Subject to the terms of this Article 42 (including, without limitation, this Section 42(a), which limits Landlord's obligation to give an Offer Notice and Section 42(b), which limits Tenant's rights to exercise the Offer Space Option), Landlord shall not lease the Offer Space (or any portion thereof) to any third party without first offering the Offer Space (or such portion thereof) to Tenant as provided in this Article 42. Provided that (i) the Tenant under this Lease is the original named Tenant or a Permitted Transferee (the "Original Tenant"), (ii) this Lease shall not have been terminated, (iii) there is no uncured Event of Default at the time of Landlord's Offer Notice or as of the commencement date of the Lease for the Offer Space and there has not been any Event of Default in the two (2) years preceding the commencement date of the Lease for the Offer Space, and (iv) Tenant or a Permitted Transferee shall not have subleased more than twenty percent (20%) of the rentable square footage of the Premises] (the foregoing conditions, the "**ROFO Conditions**"), Landlord shall give such offer to Tenant in a notice (an "**Offer Notice**"), specifying (A) the location and rentable square feet of such Offer Space (or the applicable portion thereof), (B) the date or estimated date that such Offer Space (or the applicable portion thereof) has or shall become available (the "**Anticipated Inclusion Date**") and (C) Landlord's proposed fair market rent for the relevant Offer Space. Anything to the contrary contained herein notwithstanding, Tenant's right of first offer pursuant to this Article 42 is subordinate to the rights of any Superior Occupant and to Landlord's right to extend the term of any lease of, or enter into a new lease with any, occupants of any portion of the Offer Space, whether or not such occupant occupies such space as of the date of this Lease or pursuant to an agreement entered into after the date of this Lease, and whether or not pursuant to an option contained in such occupant's lease. The Term of the Lease for the Offer Space shall be co-terminous with the Term of this Lease for the Premises, provided, however, if the Anticipated Inclusion Date will occur during the last thirty-six (36) months of the Term, then: (a) if Tenant then has a right to extend the Term of this Lease pursuant to Section 41 which has not lapsed unexercised or been irrevocably waived, then Tenant shall have no right to lease such Offer Space unless Tenant irrevocably and unconditionally exercises Tenant's extension option prior to, or simultaneously with, the giving of Tenant's Acceptance Notice (notwithstanding any limitation as to the time of exercise set forth in Section 41); or (b) if Tenant has no further right to extend the Term (i.e., because Tenant's right to extend the Term of the Lease pursuant to Section 41 has been irrevocably waived by Tenant or has lapsed unexercised), then Landlord shall have no obligation to offer to Tenant and Tenant shall have no right to lease the Offer Space under this Section 41. Notwithstanding Tenant's exercise of its extension option in accordance with the foregoing clause (a), the fair market rental for the original Premises (as it may have been previously expanded) shall be determined at the same time and in the same manner such fair market rental would have been determined if Tenant had exercised the extension option within the time period for such exercise set forth in Section 41 of this Lease.

(b) Provided that the ROFO Conditions are satisfied, Tenant shall have the option (the "**Offer Space Option**"), exercisable by notice (an "**Acceptance Notice**") given to Landlord on or before the date that is ten (10) business days after the giving of the Offer Notice (time being of the essence with respect to the giving of an Acceptance Notice) to include the Offer Space set forth in the Offer Notice in the Premises, it being understood and agreed that in no event shall Tenant have the option to include in the Premises less than the entire Offer Space described in the Offer Notice.

(c) If Tenant timely delivers the Acceptance Notice, then, Landlord shall use commercially reasonable efforts to deliver vacant possession of the Offer Space to Tenant on the Anticipated Inclusion Date, provided, however, the Term of this Lease shall commence for such Offer Space and such Offer Space shall become part of the Premises upon all of the terms and conditions set forth in the Lease on the date on which Landlord, in fact, delivers such vacant possession to Tenant (the "Offer Space Inclusion Date"),, except that: (i) Annual Rent for such Offer Space shall be equal to the Fair Offer Rental for the applicable Offer Space, (ii) Tenant's Proportionate

Share with respect to such Offer Space shall be a fraction the numerator of which shall be the rentable square feet of such Offer Space and the denominator of which shall be the rentable square feet of the Building (it being agreed that such fraction shall be expressed as a percentage calculated to the nearest hundredth of a percent), (iii) Landlord shall not be required to perform any work, pay a Landlord's contribution or a work allowance or any other amount, or render any services to make the Building or such Offer Space ready for Tenant's use or occupancy, and Tenant shall accept such Offer Space in its "as is" condition on the Offer Space Inclusion Date, and (iv) the term of the lease of such Offer Space shall be coterminous with the Lease Term.

(d) "**Fair Offer Rental**" means the base or fixed annual rent that a willing lessee would pay and a willing lessor would accept for the Offer Space during the period it is to be leased, taking into account all then relevant factors.

(e) If Tenant timely exercises the Offer Space Option, at least one hundred twenty (120) days before the Anticipated Inclusion Date with respect to such Offer Space (unless at the time of the Acceptance Notice there are fewer than one hundred twenty (120) days before the Anticipated Inclusion Date with respect to such Offer Space, in which event, within thirty (30) days after Landlord's receipt of the Acceptance Notice), Landlord and Tenant shall commence such negotiations to attempt to agree upon the Fair Offer Rental. If Landlord and Tenant cannot reach agreement within twenty (20) Business Days after Landlord and Tenant commence such negotiations, Landlord and Tenant shall, within ten (10) Business Days thereafter, each select a reputable, qualified, independent, licensed real estate broker with at least fifteen (15) years' experience in office leasing in the Kendall Square area of Cambridge, Massachusetts and familiar with the rentals then being charged in the Building and in other comparable buildings (such brokers are referred to, respectively, as "**Landlord's OS Broker**" and "**Tenant's OS Broker**") who shall confer promptly after their selection by Landlord and Tenant and shall exercise good faith efforts to attempt to agree upon the Fair Offer Rental. If Landlord's OS Broker and Tenant's OS Broker cannot reach agreement within thirty (30) days, then, within twenty (20) days thereafter, they shall designate a third reputable, qualified, independent, licensed real estate broker with at least fifteen (15) years' experience in office leasing in the Kendall Square area of Cambridge, Massachusetts and familiar with the rentals then being charged in the Building and in other comparable buildings (such broker, the "Independent OS Broker"). Upon failure of Landlord's OS Broker and Tenant's OS Broker timely to agree upon the designation of the Independent OS Broker, then either Landlord or Tenant may request the President of American Arbitration Association office in Boston, Massachusetts to make such appointment. Within ten (10) days after such appointment, Landlord's OS Broker and Tenant's OS Broker shall each submit a letter to the Independent OS Broker setting forth such broker's estimate of the Fair Offer Rental and the rationale used in determining it (respectively, "Landlord's OS Broker's Letter") and "Tenant's OS Broker's Letter"). After receipt of both the Landlord's OS Broker's Letter and the Tenant's OS Broker's Letter, the Independent OS Broker shall send a copy of the Landlord's OS Broker's Letter to Tenant and a copy of the Tenant's OS Broker's Letter to Landlord. The Independent OS Broker shall consider such evidence as Landlord and/or Tenant may submit, conduct such investigations and hearings as he or she may deem appropriate and shall, within thirty (30) days after the date of his or her appointment, choose either the estimate set forth in Landlord's OS Broker's Letter or the estimate set forth in Tenant's OS Broker's Letter to be the Fair Offer Rental and such choice shall be binding upon Landlord and Tenant. Landlord and Tenant shall each pay the fees and expenses of its respective broker. The fees and expenses of the Independent OS Broker shall be shared equally by Landlord and Tenant. The brokers shall not have the power to add to, modify or change any of the provisions of the Lease. After a determination has been made of the Fair Offer Rental, the parties shall execute and deliver an instrument setting forth the Fair Offer Rental, but the failure to so execute and deliver any such instrument shall not affect the determination of Fair Offer Rental. Landlord and Tenant hereby (i) agree that any decision rendered in any dispute resolution held pursuant to this Section 42(e) shall be final and binding upon Landlord and Tenant, whether or not a judgment shall be entered in any court, and (ii) consent to the entry of any such order of judgment.

(f) If the dispute shall not have been resolved on or before the Offer Space Inclusion Date, then pending such resolution, Tenant shall pay, as Annual Rent for the Offer Space, the estimate set forth in Landlord's OS Broker's Letter. After the Annual Rent for the Offer Space has been determined as aforesaid, any amounts theretofore paid by Tenant to Landlord on account of Annual Rent in excess of the amount of Annual Rent as finally determined shall be credited by Landlord against the next ensuing Monthly Installment payable by Tenant to Landlord (unless such excess amount exceeds two (2) months' Annual Rent and there is no Event of Default in existence, in which case Landlord shall refund such excess to Tenant).

(g) If Landlord is unable to deliver possession of the Offer Space to Tenant for any reason on or before the Anticipated Inclusion Date, the Offer Space Inclusion Date shall be the date on which Landlord is able to so deliver possession and Landlord shall have no liability to Tenant therefor and the Lease shall not in any way be impaired, provided, however, if the Offer Space Inclusion Date does not occur within one hundred twenty (120) days following the Anticipated Inclusion Date, subject to delays resulting from Force Majeure Events and Tenant Delays, Tenant shall have the right to terminate this Lease as to the Offer Space only by delivering thirty (30) days' prior written notice to Landlord and upon exercise of such right, the rights and obligations of the parties hereto shall terminate as to the Offer Space only, except that if Landlord shall deliver the Offer Space to Tenant within the 30-day period after Landlord's receipt of Tenant's termination notice, such notice shall be of no further force or effect, and this Lease shall not so terminate with respect to the Offer Space.

(h) If Tenant fails to timely give an Acceptance Notice or declines Landlord's offer to lease any specific Offer Space, then (i) Landlord may enter into one or more leases of the specific Offer Space that is the subject of the Offer Notice with third parties on such terms and conditions as Landlord shall determine in its sole and absolute discretion (whether or not such terms are more or less favorable than those offered to Tenant), (ii) the Offer Space Option shall be null and void and of no further force and effect and Landlord shall have no further obligation to offer any of that Offer Space to Tenant (Tenant's Offer Space Option being a one-time right with respect to each such Offer Space), and (iii) Tenant shall have forever waived and relinquished its rights to such Offer Space to the extent previously offered under this Article 42.

(i) Promptly after the occurrence of an Offer Space Inclusion Date, Landlord and Tenant shall confirm the occurrence thereof and the inclusion of the Offer Space in the Premises by executing an instrument reasonably satisfactory to Landlord and Tenant; provided, however, that failure by Landlord or Tenant to execute such instrument shall not affect the inclusion of the Offer Space in the Premises in accordance with this Article 42.

(j) The rights granted to Tenant under this Article 42 are personal to the Original Tenant and any assignee that is a Permitted Transferee and may not be exercised by any assignee or subtenant of the Original Tenant. For purposes of the Lease, the term "**Superior Occupant**" for purposes of this Article 42 shall mean (i) the existing tenant from time to time of the applicable Offer Space (including, without limitation, the tenant of what would otherwise constitute Offer Space pursuant to leases entered into as part of the initial lease up of any currently vacant Offer Space or any Offer Space that is subject to a lease that expires in calendar year 2020), and (ii) any person or entity to whom Landlord may have granted prior to the date of this Lease any written option, right of first offer, right of second offer, right of first refusal, expansion right or other right to lease or occupy any Offer Space in the Building. Tenant expressly acknowledges and agrees that Landlord shall have the right to negotiate with and to lease any Offer Space at any time to the Superior Occupant(s) or extend or renew the lease or occupancy of any Superior Occupant(s) (whether or not such rights are expressly granted by a lease or other written instrument and whether or not such right to renew or continue its term of occupancy is subsequently memorialized in a lease or written instrument) before Landlord will have any obligation to offer the applicable Offer Space to Tenant pursuant to this Article 42. Landlord represents that, as of the date of this Lease, there are no Superior Occupants to any of the Offer Space of the type described in subclause (ii) of this subsection (j).

(k) The termination of the Lease during the Term shall also terminate and render void Tenant's Offer Space Option and election(s) under this Article 42, and nothing contained in this Article 42 shall prevent Landlord from exercising any right granted to or reserved by Landlord to terminate this Lease. Notwithstanding anything to the contrary contained in this Article 42, Landlord shall have the right, in its sole discretion, to waive any of the ROFO Conditions to Tenant's right to receive an Offer Notice and/or the effectiveness of Tenant's exercise of the Offer Space Option set forth in Sections 42(a) and (b) without thereby waiving any default by Tenant.

LANDLORD:
RREEF AMERICA REIT II CORP. PPP, a Maryland corporation

By: /s/ David F. Crane
Name: David F. Crane
Title: Vice President

By: /s/ Gerald F. Ianetta
Name: Gerald F. Ianetta
Title: Vice President

TENANT:
BLACK DIAMOND THERAPEUTICS, INC., a Delaware corporation

By: /s/ David M. Epstein
Name: David M. Epstein
Title: President & CEO

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, David M. Epstein, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2020 of Black Diamond Therapeutics, Inc.;

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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2020

By: /s/ David M. Epstein

David M. Epstein
President, Chief Executive Officer
and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) OR 15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Thomas Leggett, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2020 of Black Diamond Therapeutics, Inc.;

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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2020

By: /s/ Thomas Leggett

Thomas Leggett
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, David M. Epstein, the Chief Executive Officer, and Thomas Leggett, the Chief Financial Officer, of Black Diamond Therapeutics, Inc. (the "Company"), hereby certify, that, to their knowledge:

(1) the Quarterly Report on Form 10-Q for the period ended June 30, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 11, 2020 By: /s/ David M. Epstein

David M. Epstein
President, Chief Executive Officer
and Director
(Principal Executive Officer)

Date: August 11, 2020 By: /s/ Thomas Leggett

Thomas Leggett
Chief Financial Officer
(Principal Financial Officer)