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

FORM 10-Q

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

For the quarterly period ended September 30, 2018

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: 001-38541

Magenta Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**81-0724163**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
100 Technology Square Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	**(Zip Code)**

(857) 242-0170
(Registrant's telephone number, including area code)

50 Hampshire Street
Cambridge, Massachusetts 02139
(Former address)

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

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

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

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

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

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

As of October 31, 2018 there were 33,151,539 shares of Common Stock, $0.001 par value per share, outstanding.

Magenta Therapeutics, Inc.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Magenta Therapeutics, Inc.

Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 159,674	$ 51,402
Restricted cash	165	165
Prepaid expenses and other current assets	3,025	936
Total current assets	162,864	52,503
Restricted cash	1,780	—
Property and equipment, net	8,149	1,956
Other assets	—	4
Total assets	$ 172,793	$ 54,463
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,897	$ 167
Accrued expenses and other current liabilities	7,032	3,975
Total current liabilities	11,929	4,142
Long-term liabilities	1,080	—
Total liabilities	13,009	4,142
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock (Series A and B), $0.001 par value; no shares and 49,178,527 shares authorized as of September 30, 2018 and December 31, 2017, respectively; no shares and 49,178,527 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	92,439
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized as of September 30, 2018; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares and 70,000,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively; 34,327,554 shares and 4,458,547 shares issued and 33,102,167 shares and 2,351,247 shares outstanding as of September 30, 2018 and December 31, 2017, respectively	33	2
Additional paid-in capital	245,798	3,091
Accumulated deficit	(86,047)	(45,211)
Total stockholders' equity (deficit)	159,784	(42,118)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 172,793	$ 54,463

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

Magenta Therapeutics, Inc.

Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	11,418	5,210	28,950	22,348
General and administrative	5,284	1,805	13,083	5,209
Total operating expenses	16,702	7,015	42,033	27,557
Loss from operations	(16,702)	(7,015)	(42,033)	(27,557)
Interest and other income, net	687	102	1,197	102
Net loss and comprehensive loss	(16,015)	(6,913)	(40,836)	(27,455)
Accretion of redeemable convertible preferred stock to redemption value	—	(6)	(88)	(213)
Cumulative dividends on redeemable convertible preferred stock	—	—	—	(437)
Reversal of cumulative dividends on redeemable convertible preferred stock	—	—	—	634
Net loss attributable to common stockholders	$ (16,015)	$ (6,919)	$ (40,924)	$ (27,471)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (3.44)	$ (3.05)	$ (15.90)
Weighted average common shares outstanding, basic and diluted	32,997,346	2,009,880	13,396,856	1,727,622

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

Magenta Therapeutics, Inc.

Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (40,836)	$ (27,455)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,152	1,486
Depreciation and amortization expense	516	247
License fees paid in preferred stock	—	9,275
Loss on disposal of property and equipment	67	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,085)	(321)
Accounts payable	2,104	1,167
Accrued expenses and other current liabilities	1,740	1,578
Other assets	—	(8)
Other long-term liabilities	1,080	—
Net cash used in operating activities	(29,262)	(14,031)
Cash flows from investing activities:		
Purchases of property and equipment	(3,321)	(1,882)
Proceeds from sale of property and equipment	12	—
Change in restricted cash	(1,780)	(135)
Net cash used in investing activities	(5,089)	(2,017)
Cash flows from financing activities:		
Proceeds from initial public offering, net of underwriting discounts and commissions	93,000	—
Proceeds from issuance of redeemable convertible preferred stock	52,300	71,695
Payments of initial public offering costs	(2,618)	—
Payments of redeemable convertible preferred stock issuance costs	(88)	(213)
Proceeds from issuance of restricted stock	—	4
Proceeds from exercise of common stock options	29	—
Net cash provided by financing activities	142,623	71,486
Net increase in cash and cash equivalents	108,272	55,438
Cash and cash equivalents at beginning of period	51,402	4,513
Cash and cash equivalents at end of period	$ 159,674	$ 59,951
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of redeemable convertible preferred stock to common stock	$ 144,739	$ —
Purchase of property and equipment included in accounts payable or accrued expenses	$ 3,467	$ —
Offering costs included in accounts payable or accrued expenses	$ 476	$ —
Accretion of redeemable convertible preferred stock to redemption value	$ 88	$ 213
Cumulative dividends on Series A redeemable convertible preferred stock	$ —	$ 437
Reversal of cumulative dividends on Series A redeemable convertible preferred stock	$ —	$ (634)

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

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

1. Nature of the Business and Basis of Presentation

Magenta Therapeutics, Inc. (the "Company") is a clinical-stage biopharmaceutical company developing novel medicines to bring the curative power of bone marrow transplant to more patients. The Company was incorporated under the laws of the State of Delaware in June 2015 as HSCTCo Therapeutics, Inc. In February 2016, the Company changed its name to Magenta Therapeutics, Inc.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On June 25, 2018, the Company completed its initial public offering ("IPO") pursuant to which it issued and sold 6,666,667 shares of common stock at a public offering price of $15.00 per share, resulting in net proceeds of $89.9 million, after deducting underwriting discounts and commissions and other offering expenses. Upon the closing of the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into shares of common stock.

Prior to its IPO, the Company had funded its operations primarily with proceeds from the sales of redeemable convertible preferred stock and issuance of convertible notes. The Company has incurred recurring losses since inception, including net losses of $40.8 million for the nine months ended September 30, 2018 and $35.5 million for the year ended December 31, 2017. As of September 30, 2018, the Company had an accumulated deficit of $86.0 million. The Company expects to continue to generate operating losses for the foreseeable future. As of the issuance date of the financial statements, the Company expects that its cash and cash equivalents of $159.7 million as of September 30, 2018 will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of these financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to fund its operations.

The Company expects its expenses to increase substantially in connection with ongoing activities, particularly as the Company advances its preclinical activities and clinical trials for its product candidates in development. Accordingly, the Company will need to obtain substantial additional funding in connection with continuing operations. If the Company is unable to raise capital when needed, or on attractive terms, it could be forced to delay, reduce or eliminate its research or drug development programs or any future commercialization efforts. 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 financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual for research and development expenses, the valuation of stock-based awards and prior to the IPO, the valuation of common shares. 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 could differ from those estimates.

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

Unaudited Interim Financial Information

The balance sheet at December 31, 2017 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The Company believes, however, that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Registration Statement on Form S-1 (File No. 333-225178) on file with SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2018 and results of operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017 have been made. The results of operations for the nine months ended September 30, 2018 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2018.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity as a reduction of additional paid-in capital generated as a result of the offering.

Fair Value Measurements

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

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

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

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

The Company accounts for uncertainty in income taxes recognized in its financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with shareholders. There was no difference between net loss and comprehensive loss for each of the periods presented in the accompanying financial statements.

Net Loss per Share

In June 2018, upon the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock automatically converted into 23,375,405 shares of the Company's common stock. Prior to this conversion, the Company followed the two-class method when computing net income (loss) per share as the Company had issued shares that met the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including outstanding stock options and unvested restricted common stock. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common stock.

The Company's outstanding redeemable convertible preferred stock contractually entitled the holders of such shares to participate in distributions but contractually did not require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards granted by the Company entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The Company reported a net loss attributable to common stockholders for the three and nine months ended September 30, 2018 and 2017.

Classification and Accretion of Redeemable Convertible Preferred Stock

Prior to the conversion of the redeemable convertible preferred stock to common stock in connection with the IPO, the Company had classified redeemable convertible preferred stock outside of stockholders' equity (deficit) because the shares contained certain redemption features that were not solely within the control of the Company. The Company immediately accreted the carrying value of its redeemable convertible preferred stock to redemption value at the end of each reporting period as if the end of the reporting period were the redemption date.

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

Recently Adopted Accounting Pronouncements

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-09, *Compensation—Stock Compensation* (Topic 718): Scope of Modification Accounting ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. For public and non-public entities, the standard was effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company's adoption of ASU 2017-09 on January 1, 2018 did not have an impact on the Company's financial position, results of operations or cash flows.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 will require lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. Leases will be classified as either operating or finance, and classification will be based on criteria similar to current lease accounting, but without explicit bright lines. For public entities, the guidance is effective for annual reporting periods beginning after December 15, 2018 and for interim periods within those fiscal years. For non-public entities and emerging growth companies that choose to take advantage of the extended transition period, the guidance is effective for annual reporting periods beginning after December 15, 2019. Early adoption is permitted for all entities. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), which added an optional transition method under which financial statements may be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. For public entities, the standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. For non-public entities and emerging growth companies that choose to take advantage of the extended transition period, the standard is effective for annual periods beginning after December 15, 2018. Early adoption is permitted for all entities. The Company is currently evaluating the impact that the adoption of ASU 2016-15 will have on its financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230)* ("ASU 2016-18"), which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. For public entities, ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. For non-public entities and emerging growth companies that choose to take advantage of the extended transition period, the standard is effective for fiscal years beginning after December 15, 2018. Early adoption is permitted for all entities. The Company is currently evaluating the impact that the adoption of ASU 2016-18 will have on its financial statements.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public entities, ASU 2017-11 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For non-public entities and emerging growth companies that choose to take advantage of the extended transition period, ASU 2017-11 is effective for annual periods beginning after December 15, 2019. Early adoption is permitted for all entities. The Company does not expect the adoption of ASU 2017-11 will have a material impact on its financial statements.

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. For public entities, ASU 2018-07 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For non-public entities and emerging growth companies that choose to take advantage of the extended transition period, ASU 2018-07 is effective for annual periods beginning after December 15, 2019. Early adoption is permitted for all entities but no earlier than the Company's adoption of ASU 2014-09. The Company is currently evaluating the impact that the adoption of ASU 2018-07 will have on its financial statements.

3. Fair Value of Financial Assets

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

	Fair Value Measurements at September 30, 2018 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 159,687	$ —	$ —	$ 159,687
Total	$ 159,687	$ —	$ —	$ 159,687

	Fair Value Measurements at December 31, 2017 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 51,147	$ —	$ —	$ 51,147
Total	$ 51,147	$ —	$ —	$ 51,147

During the nine months ended September 30, 2018, there were no transfers between Level 1, Level 2 and Level 3.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued external research and development expenses	$ 2,907	$ 1,531
Accrued payroll and related expenses	1,909	1,330
Accrued leasehold improvements	1,232	—
Accrued professional fees	563	963
Accrued other	421	151
	$ 7,032	$ 3,975

5. Redeemable Convertible Preferred Stock

In June 2018, the Company effected a one-for-2.58398 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's redeemable convertible preferred stock ("Preferred Stock"). Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

In April 2018, the Company entered into a Series C preferred stock purchase agreement, pursuant to which the Company sold 11,223,102 shares of Series C redeemable convertible preferred stock (the "Series C Preferred Stock") at a price of $4.66 per share for total gross proceeds of $52.3 million. In connection with the Series C Preferred Stock purchase agreement, the Company's certificate of incorporation was amended and restated to authorize the Company to issue 11,226,000 shares of Series C Preferred Stock and to increase the number of common stock authorized from 70,000,000 to 85,000,000 shares. In addition, the redemption date of the Preferred Stock was changed from any time on or after April 21, 2022, to the fifth anniversary of the Series C Original Issue Date, or April 2, 2023.

As of December 31, 2017, the Preferred Stock consisted of the following (in thousands, except share amounts):

	December 31, 2017				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	35,663,974	35,663,974	$39,939	$ 35,664	13,801,936
Series B Preferred Stock	13,514,553	13,514,553	52,500	52,500	5,230,130
	49,178,527	49,178,527	$92,439	$ 88,164	19,032,066

Upon the closing of the IPO in June 2018, the Company's Preferred Stock automatically converted into 23,375,405 shares of common stock.

6. Equity

On June 25, 2018, the Company completed its IPO, pursuant to which it issued and sold 6,666,667 shares of common stock at a public offering price of $15.00 per share, resulting in net proceeds of $89.9 million after deducting underwriting discounts and commissions and other offering expenses.

As of September 30, 2018, the Company's amended and restated certificate of incorporation authorizes the Company to issue 150,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share.

7. Stock-Based Awards

2016 Stock Option and Grant Plan

In April 2018, the Company's 2016 Stock Option and Grant Plan (the "2016 Plan") was amended to increase the number of shares reserved for issuance under the 2016 Plan by 1,884,850 shares to 5,900,917 shares. Upon effectiveness of the Company's 2018 Stock Option and Incentive Plan, (the "2018 Plan") in June 2018, the remaining 1,142,136 shares available under the 2016 Plan became available for issuance under the 2018 Plan and no future issuance will be made under the 2016 Plan. Additionally, shares of common stock underlying any awards under the 2016 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) will be available for future awards under the 2018 Plan.

2018 Stock Option and Incentive Plan

The 2018 Plan was approved in May 2018 and became effective on June 19, 2018. The 2018 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. The Company initially reserved 1,765,162 shares of common stock plus the 1,142,136 shares of common stock remaining available for issuance under the 2016 Plan for the issuance of awards under the 2018 Plan. As of September 30, 2018, 2,645,476 shares remained available for future grants under the 2018 Plan.

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

The 2018 Plan provides that the number of shares reserved and available for issuance under the 2018 Plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee. This number is subject to adjustment in the event of a stock split, stock dividend or other change in capitalization.

Grant of Stock Options

During the nine months ended September 30, 2018, the Company granted options to certain employees, directors and consultants for the purchase of 3,033,636 shares of common stock with a weighted average grant date fair value of $6.57 per share.

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development expenses	$ 2,022	$ 417	$ 4,612	$ 1,070
General and administrative expenses	1,654	148	3,540	416
	$ 3,676	$ 565	$ 8,152	$ 1,486

As of September 30, 2018, total unrecognized compensation cost related to unvested share-based awards was $22.8 million, which is expected to be recognized over a weighted average period of 2.4 years. As of September 30, 2018, there were 398,777 unvested shares of restricted stock and 187,686 options held by non-employees.

8. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	$ (16,015)	$ (6,913)	$ (40,836)	$ (27,455)
Accretion of redeemable convertible preferred stock to redemption value	—	(6)	(88)	(213)
Cumulative dividends on redeemable convertible preferred stock	—	—	—	(437)
Reversal of cumulative dividends on redeemable convertible preferred stock	—	—	—	634
Net loss attributable to common stockholders	$ (16,015)	$ (6,919)	$ (40,924)	$ (27,471)
Denominator:				
Weighted average common shares outstanding—basic and diluted	32,997,346	2,009,880	13,396,856	1,727,622
Net loss per share attributable to common stockholders—basic and diluted	$ (0.49)	$ (3.44)	$ (3.05)	$ (15.90)

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

Common Stock Equivalents

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

	As of September 30,	
	2018	2017
Stock options to purchase common stock	3,558,282	522,822
Unvested restricted common stock	1,225,387	2,928,548
Redeemable convertible preferred stock (as converted to common stock)	—	19,032,066
	4,783,669	22,483,436

9. Commitments and Contingencies

Leases

In May 2018, the Company entered into a sublease for up to approximately 69,000 square feet of office and laboratory space in Cambridge, Massachusetts. The sublease is subject and subordinate to a prime lease between the sublandlord and the prime landlord. The term of the sublease commenced in June 2018 and expires in February 2028. The sublandlord has the right to terminate the sublease after five years. The Company is also obligated to pay real estate taxes and other costs related to the premises, including costs of operations and management of the new leased premises. In connection with the sublease, the sublandlord agreed to fund up to $0.7 million in tenant improvements to the leased facility. The Company is required to maintain a cash balance of $1.8 million to secure a letter of credit associated with the sublease. This amount was classified as noncurrent restricted cash in the balance sheet at September 30, 2018.

The tenant improvement allowance and payment escalations specified in the lease agreement are accrued or deferred as appropriate such that rent expense per square foot is recognized on a straight-line basis over the terms of occupancy. The Company recorded rent expense of $1.8 million and $0.3 million during the three months ended September 30, 2018 and 2017, respectively, and $2.9 million and $0.8 million during the nine months ended September 30, 2018 and 2017, respectively.

In August 2018, in connection with the sublease agreement entered into in May 2018, the Company entered into an agreement for the build-out and customization of this space. Under the agreement, the Company is obligated to make payments of up to $6.8 million, of which $5.2 million has been incurred through September 30, 2018.

The Company had a sublease for office space in Cambridge, Massachusetts that expired in September 2018. The Company was required to maintain a cash balance of $0.2 million to secure a letter of credit associated with this sublease. This amount was classified as restricted cash in the balance sheet at September 30, 2018 and December 31, 2017.

As of September 30, 2018, the future minimum lease payments due under the noncancelable operating lease is as follows (in thousands):

Remainder of 2018 (3 months)	$ 1,335
2019	5,434
2020	5,597
2021	5,765
2022	5,938
Thereafter	33,632
	$57,701

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

Collaboration Agreement

In March 2018, the Company entered into a collaboration agreement with Heidelberg Pharma Research GmbH, ("HDPR") whereby the parties agreed to combine the Company's stem cell platform with proprietary antibodies across up to four exclusive targets with HDPR's proprietary Antibody Targeted Amanitin Conjugates platform. Under the agreement, the Company may pay upfront technology access fees, research exclusivity fees and payment for research support. Additionally, upon the exercise of certain license rights, the Company may be obligated to pay HDPR development, regulatory and commercial milestone payments of up to $83.5 million per target as well as royalties on net sales of products licensed under the agreement. During the three and nine months ended September 30, 2018, the Company recorded less than $0.1 million and $0.8 million, respectively, of research and development expense related to this agreement for upfront technology access fees, research exclusivity fees and research support. In October 2018, the Company exercised one of its options under the agreement for an exclusive development and commercialization license with respect to a target, which resulted in a low single digit million dollar payment to HDPR.

Intellectual Property Licenses

In November 2016, the Company entered into a license agreement with the President and Fellows of Harvard College ("Harvard") for an exclusive, worldwide, royalty-bearing license for certain technologies related to conditioning and mobilization. In consideration for these rights the Company paid Harvard an upfront fee of $0.1 million and reimbursed Harvard $0.3 million for costs incurred by Harvard related to the patented technology, which amounts were recorded as research and development expense during the year ended December 31, 2016. The Company also issued 385,063 shares of common stock in connection with the license agreement. The fair value of the shares of $0.3 million as of the issuance date was recorded as research and development expense during the year ended December 31, 2016. The Company is obligated to pay Harvard maintenance fees of less than $0.1 million annually through 2019 and $0.1 million annually thereafter and to reimburse qualified expenses related to the patents. The Company is also obligated to pay milestone payments of up to $7.4 million for the first two licensed products upon the achievement of certain development and regulatory milestones and to pay royalties on a product-by-product and country-by-country basis on net sales of products licensed under the agreement. As of September 30, 2018, no milestones related to this agreement have been met.

In April 2017, the Company entered into a license agreement with Novartis International Pharmaceutical Ltd. ("Novartis") to use and develop certain patent rights (the "Novartis License"). Under the Novartis License, the Company was granted an exclusive, worldwide, sublicensable license to research, develop and commercialize certain licensed products that contain Novartis compounds for the expansion of cord blood derived non-gene-edited/-modified hematopoietic stem cells. In consideration for these rights, the Company issued 2,500,000 shares of Series A redeemable convertible preferred stock and 643,550 shares of Series B redeemable convertible preferred stock to Novartis. The total fair value of the shares of $9.3 million as of the issuance date was recorded as research and development expense during the year ended December 31, 2017. The Company is obligated to make payments of up to $177.0 million upon the achievement of specified clinical and regulatory milestones and up to $125.0 million upon the achievement of specified commercial milestones and to pay tiered royalties, on a product-by-product and country-by-country basis, up to a maximum of 20% on net sales of products licensed under the agreement. As of September 30, 2018, no milestones related to the Novartis License have been met.

The Company has agreements with third parties in the normal course of business, under which it can license certain developed technologies. If the Company exercises its rights to license the respective technologies it may be subject to additional fees and milestone payments. As of September 30, 2018, the Company has not exercised its rights to license such technologies.

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 senior management 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 claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its financial statements as of September 30, 2018 or December 31, 2017.

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

Legal Proceedings

The Company is not currently a party to 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 the costs related to its legal proceedings as they are incurred.

10. 401(k) Savings Plan

The Company has a 401(k) available for participating employees who meet certain eligibility requirements. Eligible employees may defer a portion of their salary as defined by the plan. Company contributions to the plan may be made at the discretion of the board of directors of the Company. To date, the Company has not made any contributions to the plan.

11. Income Taxes

The Company did not provide for any income taxes in the three and nine months ended September 30, 2018 and 2017. The Company had net deferred tax assets of $12.5 million at December 31, 2017. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at each of September 30, 2018 and December 31, 2017, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

The Company has not recorded any amounts for unrecognized tax benefits as of September 30, 2018 or December 31, 2017. As of September 30, 2018 and December 31, 2017, the Company had no accrued interest or tax penalties recorded. The Company's income tax return reporting periods since 2015 are open to income tax audit examination by the federal and state tax authorities.

12. Related Parties

Atlas Venture Life Science Advisors, LLC and Third Rock Ventures LLC

During the three and nine months ended September 2017, the Company received consulting, advisory and related services from Atlas Venture Life Science Advisors, LLC and Third Rock Ventures LLC, holders, together with their affiliates, of more than 5% of the Company's common stock outstanding. For the three months ended September 30, 2017, the Company recorded less than $0.1 million of general and administrative expenses for management and advisory services and other related services provided by these investors, of which $0.1 million was paid. For the nine months ended September 30, 2017, the Company recorded $0.1 million of general and administrative expenses for management and advisory services and other related services provided by these investors, and made payments of $0.2 million. There were no services provided during the nine months ended September 30, 2018. There were no amounts owed to these investors as of September 30, 2018 or December 31, 2017.

Be The Match BioTherapies, LLC

Effective March 2018, the President of Be The Match BioTherapies, LLC became a member of the Company's board of directors. The Company has a collaboration agreement with Be The Match BioTherapies, LLC and a research agreement with an affiliated organization, Center for International Blood and Marrow Transplant Research. For the three months ended September 30, 2018, the Company recorded $0.1 million to research and development expenses and less than $0.1 million to general and administrative expenses and made payments of $0.1 million related to these agreements. For the nine months ended September 30, 2018, the Company recorded $0.3 million to research and development expenses and $0.1 million to general and administrative expenses and made payments of $0.6 million related to these agreements. As of September 30, 2018, amounts on the balance sheet related to these agreements was less than $0.1 million included in accounts payable and other current liabilities and $0.1 million included in prepaid expenses.

Magenta Therapeutics, Inc.

Notes to Financial Statements
(Unaudited)

In April 2018, the Company sold 246,781 shares of Series C Preferred Stock to Be The Match Bio Therapies, LLC for $1.1 million (see Note 5).

13. Subsequent Event

In October 2018, with the landlord's consent, the Company entered into a two-year sub-sublease of 13,643 square feet of office space in Cambridge, Massachusetts beginning in October 2018 under which it will receive $2.3 million of payments over the sub-sublease term.

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

This Quarterly Report on Form 10-Q of Magenta Therapeutics, Inc. (the "Company") contains or incorporates statements that constitute forward-looking statements within the meaning of the federal securities laws. Any statements that do not relate to historical or current facts or matters are forward looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "could", "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects", "potential," "continue" or the negative of these terms or other comparable terminology. Forward-looking statements appear in a number of places in this Quarterly Report on Form 10-Q and include, but are not limited to, statements about:

- the timing and the success of clinical trials of MGTA-456 and any other product candidates;
- the outcomes of our preclinical studies, including under our C200 program;
- our ability to enroll patients in our clinical trials at the pace that we project;
- whether the results of our trials will be sufficient to support domestic or foreign regulatory approvals for MGTA-456 or any other product candidates we may develop;
- our ability to establish clinical programs moving forward in multiple indications by 2020, with a rapidly advancing portfolio and sustainable platform;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- our ability to obtain, including on an expedited basis, and maintain regulatory approval of MGTA-456 or any other product candidates we may develop;
- the level of expenses related to any of our product candidates or clinical development programs;
- our expectation that our existing capital resources will be sufficient to enable us to fund our planned development of MGTA-456 and any other product candidates we may identify and pursue;
- the benefits of the use of MGTA-456 or any other product candidate, if approved;
- our ability to successfully commercialize MGTA-456 or any other product candidates we may identify and pursue, if approved;
- our ability to successfully find collaborators for E478 or any of our current and future programs and product candidates;
- the rate and degree of market acceptance of MGTA-456 or any other product candidates we may identify and pursue;
- our ability to obtain orphan drug designation for any of our product candidates we may identify;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture MGTA-456 or any other product candidate in conformity with the Food and Drug Administration's requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- our ability to successfully build a specialty sales force and commercial infrastructure;
- our ability to compete with companies currently producing or engaged in the clinical development of treatments for the disease indications that we pursue and treatment modalities that we develop;
- our reliance on third parties to conduct our clinical trials;
- our reliance on third-party contract manufacturers to manufacture and supply our product candidates for us;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain intellectual property protection for MGTA-456 or any other product candidates we may identify and pursue;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act, or the JOBS Act;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You are urged to carefully review the disclosures we make concerning these risks and other factors that may affect our business and operating results under "Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q, as well as our other reports filed with the Securities and Exchange Commission (the "SEC"), which disclosures are incorporated herein by reference. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document. The Company does not intend, and undertakes no obligation, to update any forward-looking information to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events, unless required by law to do so.

Overview

We are a clinical-stage biotechnology company developing novel medicines to bring the curative power of bone marrow transplant to more patients. Transplant is a well-established and often curative medical procedure, and emerging data on stem cell gene therapy, which is bone marrow transplant using gene-modified stem cells, suggest the potential for meaningful benefit with this newer form of transplant. Bone marrow transplant and stem cell gene therapies use the same widely-adopted, decades-old transplant process. As it exists today, bone marrow transplant is a large market opportunity, and improvements to the current approaches could extend bone marrow transplant to more patients. The ability to treat patients with a bone marrow transplant is limited by the challenge of obtaining sufficient cells to perform the procedure, the inherent morbidity and mortality of current methods used to prepare patients for transplant, and complications following transplant.

At Magenta, we believe we are uniquely positioned to overcome these challenges and to lead a new era in transplant medicine. Our portfolio of product candidates includes biologics, small molecules and a cell therapy designed to address deficiencies in existing approaches and extend the curative power of bone marrow transplant to more patients across many diseases. Currently, only a fraction of eligible patients with these diseases receive a transplant because the risks and challenges outweigh the potential for a cure. These include diseases where bone marrow transplant is a standard of care (e.g., blood cancers such as acute myelogenous leukemia, myelodysplastic syndromes, multiple myeloma, and non-Hodgkin lymphoma), diseases where transplant is performed but limited in use (e.g., hemoglobinopathies such as sickle cell disease and beta-thalassemia), and autoimmune diseases. Emerging clinical data suggest that bone marrow transplant may represent a breakthrough approach with curative potential for patients with severe autoimmune diseases. For example, recent results from multiple clinical trials show that patients with autoimmune diseases, including multiple sclerosis and scleroderma, can be cured with a transplant. However, based on our epidemiology analyses, currently only approximately 1 to 2% of eligible patients with multiple sclerosis or scleroderma in the United States and Europe receive a bone marrow transplant.

To address the major unmet medical needs in the existing bone marrow transplant process, we are developing a stem cell biology discovery platform and building a comprehensive portfolio of novel therapeutics. Our programs will improve stem cell dose (expansion), stem cell collection (mobilization), patient preparation for transplant (conditioning) and potential post-transplant complications, to address key limitations of the bone marrow transplant process to allow more patients to benefit. Within our expansion program, MGTA-456, our most advanced clinical product candidate, is a cell therapy that has achieved clinical proof of concept in 36 patients with blood cancers and is now being studied in patients with fatal inherited metabolic diseases. MGTA-456 is produced by significantly expanding the number of stem cells in cord blood units, and has the potential to allow patients to have a better chance for a successful stem cell transplant. Within our mobilization program, MGTA-145 is focused on enabling physicians to more easily harvest a greater number of blood stem cells, known as hematopoietic stem cells or HSCs, from patients and donors to improve patient outcomes. Our targeted transplant conditioning programs, which prepare the patient for transplant, are designed to selectively remove stem and/or immune cells from a patient prior to transplant, and to be far less toxic than the decades-old radiation and chemotherapy-based approaches which are still the only available options. Our post-transplant complications program is designed to target the donor immune cells within the patient that cause Graft vs. Host Disease, or GvHD, which can be a fatal complication of transplant.

We intend to become a fully integrated discovery, development and commercial company in the field of transplant medicine. We believe that our product portfolio will offer significant commercial synergies. We are developing our products so that they can each be used individually or in combination with each other. As a result, our portfolio could be utilized in a manner tailored to the patient's disease, such that a patient may receive more than one Magenta therapy as part of their individual transplant journey.

Since our inception in 2015, we have focused substantially all of our efforts and financial resources on organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, and undertaking preclinical studies, and in the case of MGTA-456, clinical trials. We do not have any products approved for sale and have not generated any revenue from product sales.

On June 25, 2018, we completed an initial public offering, or IPO, of our common stock, pursuant to which we issued and sold 6,666,667 shares of common stock at a public offering price of $15.00 per share, resulting in net proceeds of $89.9 million after deducting underwriting discounts and commissions and other offering expenses. Prior to the IPO, we funded our operations primarily with proceeds from the sales of redeemable convertible preferred stock and issuance of convertible notes.

Since our inception, we have incurred significant operating losses. 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 product candidates. Our net loss was $40.8 million for the nine months ended September 30, 2018 and $35.5 million for the year ended December 31, 2017. As of September 30, 2018, we had an accumulated deficit of $86.0 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we:

- continue enrollment in our Phase II clinical trial of MGTA-456;
- prepare for and initiate our preclinical studies and clinical trials of our product candidates;
- develop any other future product candidates we may choose to pursue;
- continue research and development and drug discovery and initiate additional clinical trials;
- seek marketing approval for any of our product candidates that successfully complete clinical development, if any;
- maintain compliance with applicable regulatory requirements;
- develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our product candidates and commercialization of any of our product candidates for which we obtain marketing approval, if any;
- maintain, expand, protect and enforce our intellectual property portfolio;
- develop and expand our sales, marketing and distribution capabilities for our product candidates for which we obtain marketing approval, if any; and
- expand our operational, financial and management systems and increase personnel, including to support our clinical development and commercialization efforts and our operations as a public company.

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

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

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

As of September 30, 2018, we had cash and cash equivalents of $159.7 million. We believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through at least the first quarter of 2020. See “—Liquidity and Capital Resources.”

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and 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, we may generate revenue in the future from product sales. If we enter into license or collaboration agreements for any of our product candidates or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Operating Expenses

Research and Development Expenses

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, which include:

- employee-related expenses, including salaries and related costs, and stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with contract research organizations, or CROs;
- the cost of consultants and contract manufacturing organizations, or CMOs, that manufacture drug products for use in our preclinical studies and clinical trials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and supplies; and
- payments made under third-party licensing agreements.

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

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to consultants, central laboratories, contractors, CMOs and CROs in connection with our preclinical and clinical development activities. We do not allocate employee costs, costs associated with our platform technology or facility expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

The table below summarizes our research and development expenses incurred by development program:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)			
Conditioning	$ 2,053	$1,947	$ 6,843	$ 5,019
Mobilization	1,183	365	2,599	1,023
Expansion	1,189	520	3,467	10,162
GvHD	264	—	883	—
Unallocated expenses	6,729	2,378	15,158	6,144
Total research and development expenses	$11,418	$5,210	$28,950	$22,348

The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties, including the following:

- successful completion of preclinical studies and clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- raising additional funds necessary to complete clinical development of and commercialize our product candidates;
- obtaining and maintaining patent, trade secret and other intellectual property 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;
- developing and implementing marketing and reimbursement strategies;
- 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 therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- protecting and enforcing our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of the products following approval.

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

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. We expect research and development costs to increase significantly for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, and stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, 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. We also anticipate that we will incur 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.

Interest and Other Income, Net

Interest and other income, net, consists of interest income and insignificant amounts of miscellaneous income and expense unrelated to our core operations.

Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2017, we had federal and state net operating loss carryforwards of $18.7 million and $19.3 million, respectively, which begin to expire in 2035. As of December 31, 2017, we also had federal and state research and development tax credit carryforwards of $1.0 million and $0.4 million, respectively, which begin to expire in 2035 and 2030, respectively.

On December 22, 2017, the Tax Cuts and Jobs Act, or TCJA, was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from 35% to 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The tax rate change resulted in (i) a reduction in the gross amount of our deferred tax assets as of December 31, 2017, without an impact on the net amount of our deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that of our critical accounting policies described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, with the SEC on June 21, 2018, the following involve the most judgment and complexity:

- accrued research and development expenses;
- determination of fair value of common and preferred stock;
- common and preferred stock issued for licenses; and
- stock-based compensation.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	11,418	5,210	6,208
General and administrative	5,284	1,805	3,479
Total operating expenses	16,702	7,015	9,687
Loss from operations	(16,702)	(7,015)	(9,687)
Interest and other income, net	687	102	585
Net loss	$(16,015)	$(6,913)	$(9,102)

Research and Development Expenses

	Three Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Direct research and development expenses by program:			
Conditioning	$ 2,053	$1,947	$ 106
Mobilization	1,183	365	818
Expansion	1,189	520	669
GvHD	264	—	264
Unallocated expenses:			
Personnel related (including stock-based compensation)	2,978	1,172	1,806
Consultant fees	1,341	645	696
Facility related and other	2,410	561	1,849
Total research and development expenses	$11,418	$5,210	$6,208

The increase in expense related to our mobilization program was due to an increase in preclinical costs for toxicology studies and manufacturing to support our Investigational New Drug, or IND, enabling studies. The increase in expense related to our expansion program was due to an increase in clinical trial and manufacturing costs incurred for our MGTA-456 Phase II study for inherited metabolic diseases, which we initiated in December 2017, and preparation for planned additional clinical trials in indications beyond inherited metabolic diseases. The increase in spending related to our Graft vs. Host Disease, or GvHD, program was due to costs related to our drug discovery efforts, primarily target validation and lead identification.

The increase in personnel-related costs included in unallocated expenses was due to an increase in headcount and stock-based compensation in our research and development function. Personnel-related costs for the three months ended September 30, 2018 and 2017 included stock-based compensation expense of $0.9 million and $0.1 million, respectively. The increase in consultant fees was primarily due to an increase in stock-based compensation of $0.7 million, from $0.4 million for the three months ended September 30, 2017 to $1.1 million for the three months ended September 30, 2018. The increase in facility related and other costs was primarily due to higher facility costs related to our new sublease agreement for our Cambridge, Massachusetts facility, which we entered into in May 2018.

General and Administrative Expenses

	Three Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 2,960	$ 832	$2,128
Professional and consultant fees	1,113	670	443
Facility related and other	1,211	303	908
Total general and administrative expenses	$ 5,284	$ 1,805	$3,479

The increase in personnel-related costs was primarily a result of an increase in stock-based compensation and headcount. Personnel-related costs for the three months ended September 30, 2018 and 2017 included stock-based compensation expense of $1.6 million and $0.1 million, respectively. The increase in professional and consultant fees was primarily due to an increase in patent costs and other fees associated with operating as a public company. The increase in facility related and other costs was primarily due to higher facility costs related to our new sublease agreement for our Cambridge, Massachusetts facility, which we entered into in May 2018 as well as director and officer insurance costs.

Interest and Other Income, Net

The increase in interest and other income, net was primarily due to an increase in interest income resulting from our net proceeds from our IPO in June 2018.

Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	28,950	22,348	6,602
General and administrative	13,083	5,209	7,874
Total operating expenses	42,033	27,557	14,476
Loss from operations	(42,033)	(27,557)	(14,476)
Interest and other income, net	1,197	102	1,095
Net loss	$(40,836)	$(27,455)	$(13,381)

Research and Development Expenses

	Nine Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Direct research and development expenses by program:			
Conditioning	$ 6,843	$ 5,019	$ 1,824
Mobilization	2,599	1,023	1,576
Expansion	3,467	10,162	(6,695)
GvHD	883	—	883
Unallocated expenses:			
Personnel related (including stock-based compensation)	7,463	2,932	4,531
Consultant fees	3,170	1,514	1,656
Facility related and other	4,525	1,698	2,827
Total research and development expenses	$28,950	$22,348	$ 6,602

Expenses related to our conditioning program increased primarily as a result of costs incurred in connection with our collaboration agreement with Heidelberg Pharma Research GmbH for an upfront technology access fee, research exclusivity fees and payments for research support related to our drug discovery efforts, primarily lead optimization. Conditioning program costs also increased due to our proof of mechanism and ongoing lead optimization in non-human primate studies. The increase in expense related to our mobilization program was due to an increase in preclinical costs for toxicology studies and manufacturing to support our IND enabling studies. Expenses related to our expansion program decreased primarily as a result of the prior year cost of in-licensing technology of $9.3 million for the rights to MGTA-456 under a license agreement with Novartis. This decrease was partially offset by increased clinical trial and manufacturing costs in the nine months ended September 30, 2018 incurred for our MGTA-456 Phase II study for inherited metabolic diseases, which we initiated in December 2017, and preparation for planned additional clinical trials in indications beyond inherited metabolic diseases. The increase in spending related to our GvHD program was due to costs related to our drug discovery efforts, primarily target validation.

The increase in personnel-related costs included in unallocated expenses was due to an increase in headcount and stock-based compensation expense in our research and development function. Personnel-related costs for the nine months ended September 30, 2018 and 2017 included stock-based compensation expense of $1.9 million and $0.2 million, respectively. The increase in consultant fees was primarily due to an increase in stock-based compensation of $1.8 million, from $0.9 million for the nine months ended September 30, 2017 to $2.7 million for the nine months ended September 30, 2018. The increase in facility related and other costs was primarily due to higher facility costs related to our new sublease agreement for our Cambridge, Massachusetts facility, which we entered into in May 2018.

General and Administrative Expenses

	Nine Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 7,277	$2,153	$5,124
Professional and consultant fees	3,388	2,204	1,184
Facility related and other	2,418	852	1,566
Total general and administrative expenses	$13,083	$5,209	$7,874

The increase in personnel-related costs was primarily a result of an increase in stock-based compensation expense and an increase in headcount. Personnel-related costs for the nine months ended September 30, 2018 and 2017 included stock-based compensation expense of $3.4 million and $0.4 million, respectively. The increase in professional and consultant fees was primarily due to an increase in patent costs and other fees associated with operating as a public company. The increase in facility related and other costs was primarily due to higher facility costs related to our new sublease agreement for our Cambridge, Massachusetts facility, which we entered into in May 2018, as well as director and officer insurance costs and an increase in information technology-related expenses.

Interest and Other Income, Net

The increase in interest and other income, net was primarily due to an increase in interest income resulting from our net proceeds from our IPO in June 2018 and our sale of series C redeemable convertible preferred stock in April 2018.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. To date, we have funded our operations primarily with proceeds from the sales of redeemable convertible preferred stock and issuance of convertible notes. On June 25, 2018, we completed the IPO of our common stock, pursuant to which we issued and sold 6,666,667 shares of common stock at a public offering price of $15.00 per share, resulting in net proceeds of $89.9 million after deducting underwriting discounts and commissions and other offering expenses. As of September 30, 2018, we had cash and cash equivalents of $159.7 million.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Cash used in operating activities	$ (29,262)	$ (14,031)
Cash used in investing activities	(5,089)	(2,017)
Cash provided by financing activities	142,623	71,486
Net increase in cash and cash equivalents	$ 108,272	$ 55,438

Operating Activities

During the nine months ended September 30, 2018, operating activities used $29.3 million of cash, primarily resulting from our net loss of $40.8 million, partially offset by non-cash charges of $8.7 million and cash provided by changes in our operating assets and liabilities of $2.8 million. Net cash provided by changes in our operating assets and liabilities for the nine months ended September 30, 2018 consisted primarily of a $3.8 million increase in accounts payable and accrued expenses and other current liabilities, and a $1.1 million increase in long-term liabilities, all partially offset by an increase of $2.1 million in prepaid expenses and other current assets.

During the nine months ended September 30, 2017, operating activities used $14.0 million of cash, primarily resulting from our net loss of $27.5 million, partially offset by non-cash charges of $11.0 million and cash provided by changes in our operating assets and liabilities of $2.4 million. Net cash provided by changes in our operating assets and liabilities for the nine months ended September 30, 2017 consisted primarily of a $2.7 million increase in accounts payable and accrued expenses and other current liabilities, partially offset by an increase of $0.3 million in prepaid expenses and other current assets.

Changes in accounts payable, accrued expenses and other current liabilities and prepaid expenses in both periods were generally due to growth in our business and the timing of vendor invoicing and payments. The increase in long-term liabilities was related to deferred rent for our new sublease agreement for our Cambridge, Massachusetts facility, which we entered into in May 2018.

Investing Activities

During the nine months ended September 30, 2018 and 2017, we used $3.3 million and $1.9 million, respectively, to purchase property and equipment. During the nine months ended September 30, 2018 and 2017, we increased our restricted cash by $1.8 million and $0.1 million, respectively, to secure letters of credit related to our sublease agreements.

Financing Activities

During the nine months ended September 30, 2018, net cash provided by financing activities was $142.6 million, consisting primarily of proceeds from our IPO, net of underwriting discounts and commissions, of $93.0 million and net proceeds of $52.2 million from the sale of series C redeemable convertible preferred stock, both partially offset by $2.6 million of payments of IPO costs.

During the nine months ended September 30, 2017, net cash provided by financing activities was $71.5 million, consisting primarily of $6.3 million of the remaining proceeds received in January 2017 from the sale of Series A redeemable convertible preferred stock that we recorded as other receivable as of December 31, 2016, $15.4 million of proceeds from the sale of additional shares of Series A redeemable convertible preferred stock and $49.8 million of net proceeds received from the sale of Series B redeemable convertible preferred stock.

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 for our product candidates in development. In addition, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of current and future preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to conclude;
- the outcome, timing and cost of meeting and maintaining compliance with regulatory requirements established by the U.S. Food and Drug Administration, the European Medical Agency and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the effect of existing or new competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

As of September 30, 2018, we had cash and cash equivalents of $159.7 million. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through at least the first quarter of 2020. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical 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 those listed above.

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

Contractual Obligations and Commitments

The following summarizes our principal contractual obligations and commitments as of September 30, 2018 and the effects such obligations are expected to have on our liquidity and cash flow in future periods. Our principal contractual obligations and commitments as of December 31, 2017 are described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, with the SEC on June 21, 2018.

	Payments Due By Period				
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	More Than 5 Years
			(in thousands)		
Operating lease commitments(1)	$57,701	$ 1,335	$ 11,031	$ 11,703	$ 33,632
Contractual obligations(2)	1,641	1,641	—	—	—
Total	$59,342	$ 2,976	$ 11,031	$ 11,703	$ 33,632

(1) In May 2018, we entered into a sublease for up to approximately 69,000 square feet of office and laboratory space in Cambridge, Massachusetts. The term of the lease commenced in June 2018 and expires in February 2028. Over the lease term, we are obligated to pay $59.2 million in rental payments. Such remaining payments are reflected in the table above.

(2) In August 2018, in connection with the sublease agreement entered into in May 2018 for office and laboratory space in Cambridge, Massachusetts, we entered into an agreement for the build-out and customization of this space. Under the agreement, we are obligated to make payments of up to $6.8 million of which $5.2 million has been incurred through September 30, 2018. The remaining payments are reflected in the table above.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the preceding table as the amount and timing of such payments are not known.

We have also entered into license and collaboration agreements with third parties, which are in the normal course of business. We have not included future payments under these agreements in the table of contractual obligations above since obligations under these agreements are contingent upon future events such as our achievement of specified development, regulatory, and commercial milestones, or royalties on net product sales. As of September 30, 2018, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

Off-Balance Sheet Arrangements

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

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risks.

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are in the form of a money market fund, which is primarily invested in short-term U.S. Treasury obligations. However, because of the short-term nature of the investments in our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2018 and 2017.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial Officer (our Treasurer, Vice President, Finance), has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2018 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 be involved in lawsuits, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters which may arise in the ordinary course of business. While the outcome of such proceedings cannot be predicted with certainty, as of September 30, 2018, we were not party to any legal proceedings that we would expect to have a material adverse impact on our financial position, results of operations or cash flow.

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 on Form 10-Q 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 facing the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impact our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical-stage biotechnology company developing novel medicines to bring the curative power of bone marrow transplant to more patients, and have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. 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. As a result, we are not profitable and have incurred losses in each period since our inception in June 2015. For the nine months ended September 30, 2018 and the years ended December 31, 2017 and 2016, we reported a net loss of $40.8 million, $35.5 million and $9.4 million, respectively. As of September 30, 2018, we had an accumulated deficit of $86.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

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 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 will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any product candidates for which we receive regulatory approval, including potentially building our own commercial organization to address the United States, the European Union and certain other markets. As of September 30, 2018, we had approximately $159.7 million in cash and cash equivalents. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to conclude;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medical Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;

- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We cannot be certain that additional funding will be available on acceptable terms, or at all. 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 one or more of our product candidates or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our 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, our stockholder's ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect our stockholder's rights. 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.

Our company has a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We are an early-stage company. We were founded and commenced operations in June 2015. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, and undertaking preclinical studies, and in the case of MGTA-456, clinical trials. Aside from MGTA-456, all of our research programs and product candidates are still in the preclinical or research stage of development, and their risk of failure is high. We have not yet demonstrated an ability to initiate or successfully complete any clinical trials (other than for MGTA-456), including large-scale, pivotal clinical trials; obtain marketing approvals; manufacture a commercial-scale medicine, or arrange for a third party to do so on our behalf; or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop a new medicine from the time it is discovered to when it is available for treating patients. 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 new business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize product candidates we may identify for development. We may not generate revenues from product sales for the next several years, if ever. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators', ability to successfully:

- identify product candidates and complete research and preclinical and clinical development of any product candidates we may identify;
- seek and obtain regulatory and marketing approvals for any of our product candidates for which we complete clinical trials;
- launch and commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualify for adequate coverage and reimbursement by government and third-party payors for any of our product candidates for which we obtain regulatory and marketing approval;
- develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any of our product candidates for which we obtain regulatory and marketing approval;
- obtain market acceptance of any product candidates we may develop as viable treatment options;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;
- negotiate favorable terms in any collaboration, licensing, or other arrangements into which we may enter and perform our obligations in such collaborations;
- maintain, protect, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
- avoid and defend against third-party interference or infringement claims; and
- attract, hire, and retain qualified personnel.

Even if one or more of the product candidates we may develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. This Quarterly Report on Form 10-Q does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

We have limited director and officer insurance and commercial insurance policies. Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage, and insurers may not respond as we intend to cover insurable events that may occur. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

Risks Related to Product Development and Regulatory Approval

We are very early in our development efforts. All but one of our product candidates, MGTA-456, are still in preclinical development. If we are unable to advance our product candidates to 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 all but one of our product candidates, MGTA-456, are still in preclinical development. We have only recently completed initial preclinical studies for MGTA-145. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product and we may never be able to develop or commercialize a marketable product.

Each of our programs and product candidates will require additional preclinical and clinical development; regulatory approval in multiple jurisdictions; obtaining manufacturing supply, capacity and expertise; building of a commercial organization; substantial investment and significant marketing efforts before we generate any revenue from product sales. Our product candidates must be authorized for marketing by the FDA, or certain other foreign regulatory agencies, such as the EMA, 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 and successful enrollment and completion of clinical trials, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable, under the FDA's cGCPs, and the FDA's current Good Laboratory Practices, or cGLPs;
- effective Investigational New Drug applications, or INDs, or Clinical Trial Authorisations, or CTAs, that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- positive results from our future clinical programs that support a finding of safety and effectiveness and an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishment of arrangements with third-party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities;
- successful development of our internal manufacturing processes or transfer to larger-scale facilities operated by either a contract manufacturing organization, or CMO, or by us;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates;
- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- establishment and maintenance of healthcare coverage and adequate reimbursement;
- enforcement and defense of intellectual property rights and claims; and
- maintenance of a continued acceptable safety profile of our product candidates following approval.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize 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.

Our planned clinical trials or those of our collaborators may reveal significant adverse events not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. 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. 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. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. For example, we have observed a limited number of serious

adverse effects in our Phase II clinical trial of MGTA-456 in blood cancers that were considered to be related to the investigational treatment, and there is no guarantee that we will not see more serious adverse effects in the future. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trial, patients may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities, or an institutional review board, or IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Clinical development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

With the exception of MGTA-456, our other product candidates are still in the preclinical development stage, and their risk of failure is high. It is impossible to predict when or if any of our programs will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of any of our future product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. The outcome of preclinical studies 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 products.

Successful completion of clinical trials is a prerequisite to submitting a new drug application, or NDA, or a biologics license application, or BLA, to the FDA, a Marketing Authorization Application, or MAA, to the EMA and similar approval filings to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

We may experience delays in completing our preclinical studies and initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators, IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of any 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 these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of preclinical studies and clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other bone marrow transplant and cell-based therapies that raise safety or efficacy concerns about our product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by 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 using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, in December 2015, prior to our license of MGTA-456 from Novartis International Pharmaceutical Ltd., or Novartis, the FDA imposed a partial clinical hold on the cryopreserved part of the protocol covered by the IND application for MGTA-456 until Novartis demonstrated comparability between the fresh and cryopreserved product. This partial clinical hold was later removed by the FDA in June 2016 after Novartis presented satisfactory comparability data between the fresh and cryopreserved product. We cannot guarantee that we will not be subject to further holds by the FDA or other regulatory authorities in the future. 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. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our preclinical or future clinical development programs may harm our business, financial condition and prospects significantly.

We have no experience as a company in obtaining regulatory approval for a drug.

As a company, we have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all future new drug applications, or NDAs, or BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any current or future product candidates. If the FDA does not approve any future NDAs or BLAs, it may require that we conduct additional costly clinical, preclinical or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA or BLA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing MGTA-456 or any other product candidate, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any product candidates we may develop, we may need to abandon or limit our further clinical development of those product candidates.

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

Bone marrow transplant is a high-risk procedure with curative potential that may result in complications or adverse events for patients in our clinical trials or for patients that use any of our product candidates, if approved.

Bone marrow transplant can cure patients across multiple diseases, but its use carries with it risks of toxicity, serious adverse events and death. Because many of our therapies are used to prepare or treat patients undergoing bone marrow transplant, patients in our clinical trials or patients that use any of our product candidates may be subject to many of the risks that are currently inherent to the bone marrow transplant process. In particular, bone marrow transplant involves certain known potential post-procedure complications that may manifest several weeks or months after a transplant and which may be more common in certain patient populations. For example, up to 20% of patients with inherited metabolic diseases treated with transplant experience primary engraftment failure, resulting in severe complications, including death. The first patient dosed in our ongoing Phase II clinical trial of MGTA-456 in patients with inherited metabolic diseases successfully engrafted, and subsequently developed autoimmune cytopenia, a known potential complication of bone marrow transplant in this patient population, which includes severe side effects and the possibility of death. This has been deemed by the principal investigator overseeing the Phase II study and the chair of our data safety monitoring committee to be unrelated to the use of MGTA-456 specifically but instead is deemed to be related to complications common to transplant. If these or other serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were the result of bone marrow transplant or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates. All serious adverse events or unexpected side effects are continually monitored per the clinical study's approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by our product candidates, we would follow the study protocol's requirements, which call for our data safety monitoring committee to review all available clinical data in making a recommendation regarding the study's continuation.

If we are not able to identify a safe and effective dose for any of our ADCs, we may need to delay, abandon or limit our development of any potential product candidates.

ADCs utilize toxins to kill cells, and we may not be able to identify a safe and effective dose for some of our potential product candidates. ADCs, including those that have received marketing approval, have dose-dependent safety findings that can include liver toxicity, depending on the target of the ADC and the drug used in the conjugate. In addition, ADCs may have other adverse side effects including fatalities. In our initial proof of mechanism non-human primate study, designed to test a probe CD117-ADC designed to deplete hematopoietic stem cells, or HSCs, we observed some instances of transient elevation of liver enzymes that were dose- and toxin-dependent. Out of the twelve non-human primates treated with the probe CD117-ADC in the initial study, one treated with the highest dose was euthanized subsequent to receiving scheduled pain medication before a planned bone marrow aspirate. In addition, one non-human primate in each of the two highest dose groups in the initial study showed the anticipated signs of bone marrow failure resulting from HSC depletion and were euthanized prior to the end of the study. We have initiated a second dose-escalation study in non-human primates with a CD117-ADC probe compound engineered to have a shorter half-life and a lower number of drugs per antibody. In the first phase of this second study, one of the three non-human primates tested at the highest of the three dose levels showed elevated liver enzymes and was subsequently euthanized. Although these ongoing studies may potentially validate the non-human primate as a suitable model for efficacy and tolerability, if we are not able to ultimately show that an optimized CD117-ADC can deplete HSCs at a safe and effective dose, we may need to delay, abandon or limit these development efforts.

Even if we obtain regulatory approval of any of our product candidates, the approved products may be subject to post-approval studies and will remain subject to ongoing regulatory requirements. If we fail to comply, or if concerns are identified in subsequent studies, our approval could be withdrawn and our product sales could be suspended.

If we are successful at obtaining regulatory approval for MGTA-456 or any of our other product candidates, regulatory agencies in the United States and other countries where a product will be sold may require extensive additional clinical trials or post-approval clinical trials that are expensive and time-consuming to conduct. In particular, therapeutic products administered for the treatment of certain inherited metabolic diseases, such as Hurler's syndrome and leukodystrophies, are likely to require extensive follow-up studies and close monitoring of patients after regulatory approval has been granted, for any signs of adverse effects that occur over a long period of time. These studies may be expensive and time-consuming to conduct and may reveal side effects or other harmful effects in patients that use our therapeutic products after they are on the market, which may result in the limitation or withdrawal of our drugs from the market. Alternatively, we may not be able to conduct such additional trials, which might force us to abandon our efforts to develop or commercialize certain product candidates. Even if post-approval studies are not requested or required, after our products are approved and on the market, there might be safety issues that emerge over time that require a change in product labeling or that require withdrawal of the product from the market, which would cause our revenue to decline.

Additionally, any products that we may successfully develop will be subject to ongoing regulatory requirements after they are approved. These requirements will govern the manufacturing, packaging, marketing, distribution, and use of our products. If we fail to comply with such regulatory requirements, approval for our products may be withdrawn, and product sales may be suspended. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and damage to our reputation.

Because we are developing product candidates for the treatment of diseases in which there is little clinical experience using new technologies, there is increased risk that the FDA, the EMA, or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

During the regulatory review process, we will need to identify success criteria and endpoints such that the FDA, the EMA, or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. As we are initially seeking to identify and develop product candidates to treat diseases in which there is little clinical experience using new technologies, there is heightened risk that the FDA, the EMA, or other regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results (reflecting a tangible benefit to patients). In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoints to a degree of statistical significance. This may be a particularly significant risk for many of the genetically defined diseases for which we plan to develop product candidates because many of these diseases have small patient populations, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Further, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the non-primary endpoints or other relevant data. The FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the European Union and other countries, such as the Committee for Advanced Therapies, or CAT, may make similar comments with respect to these endpoints and data. Any product candidates we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

A Breakthrough Therapy Designation or Regenerative Medicine Advanced 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 plan to seek a Breakthrough Therapy Designation or Regenerative Medicine Advanced Therapy Designation for our product candidates if the clinical data support such a designation for one or more 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. Biologics designated as breakthrough therapies by the FDA may also be eligible for 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 drugs 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.

Our current product candidates and any future product candidates may not be eligible for Orphan Drug status.

The United States and Europe may designate drugs for relatively small patient populations as orphan drugs. Orphan Drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but does make the product eligible for orphan drug exclusivity, reduced filing fees and specific tax credits. Generally, if a company receives the first marketing approval for a product with an Orphan Drug designation in the clinical indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that the FDA will not approve another application to market the same drug for the same indication, except in limited circumstances, for a period of seven years in the United States. This exclusivity, however, could block the approval of our proposed product candidates if a competitor obtains marketing approval before us. However, even if we obtain orphan drug exclusivity for any of our proposed product candidates, we may not be able to maintain it. For example, if a competitive product is shown to be clinically superior to our product candidates, any orphan drug exclusivity we have will not block the approval of such competitive product.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before 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 trials may instead opt to enroll in a 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 in such clinical trial site.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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

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

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if any product candidates we may develop meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a Risk Evaluation and Mitigation Strategy, or REMS. These regulatory authorities may require precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for any product candidates we may develop and materially adversely affect our business, financial condition, results of operations, and prospects.

A Fast Track 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 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. 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. Receipt of Fast Track Designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw any Fast Track Designation at any time. We may seek Fast Track Designation for MGTA-456 or any other product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates.

We may seek priority review designation for MGTA-456 or our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates, however, we cannot assume that MGTA-456 or our other product candidates will meet the criteria for that designation. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and such results do not guarantee approval of a product candidate by regulatory authorities.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for their product candidates. Even if we complete clinical development of MGTA-456, there can be no assurance that the FDA, EMA, or other regulatory authorities will approve MGTA-456 for marketing.

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 dosing regimen and other clinical trial procedures and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidate, and, correspondingly, our business and financial prospects would be negatively impacted.

Our product candidates for which we intend to seek approval may face competition from generic drugs or biosimilars sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a BLA. On March 6, 2015, the FDA approved the first biosimilar product under the BPCIA. However, the law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates are approved as a biological product under a BLA it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider any of our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Finally, there has been public discussion of potentially decreasing the period of exclusivity from the current 12 years. If such a change were to be enacted, our product candidates, if approved, could have a shorter period of exclusivity than anticipated.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, or the ACA, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. As implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Moreover, the Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

As an early stage small company that will be competing against numerous large, established companies that have substantially greater financial, technical, research manufacturing, marketing, distribution and other resources than us, we will be at a significant competitive disadvantage.

The pharmaceutical and biopharmaceutical industry is characterized by intense competition and rapid and significant technological changes and advancements. Many companies, research institutions and universities are doing research and development work in a number of areas similar to those that we focus on that could lead to the development of new products which could compete with and be superior to our product candidates.

Most of the companies with which we compete have substantially greater financial, technical, research, manufacturing, marketing, distribution and other resources than those of ours. A number of these companies may have or may develop technologies for developing products for treating various diseases, including certain inherited metabolic diseases such as Hurler's syndrome and leukodystrophies, that could prove to be superior to ours. We expect technological developments in the pharmaceutical and biopharmaceutical and related fields to occur at a rapid rate, and we believe competition will intensify as advances in these fields are made. Accordingly, we will be required to continue to devote substantial resources and efforts to research and development activities in order to potentially achieve and maintain a competitive position in this field. Products that we develop may become obsolete before we are able to market them or to recover all or any portion of our research and development expenses. We will be competing with respect to our products with companies that have significantly more experience and expertise in undertaking preclinical testing and human clinical trials with new or improved therapeutic products and obtaining regulatory approvals of such products. A number of these companies already market and may be in advanced phases of clinical testing of various drugs that will or may compete with our current product candidates or other future potential product candidates. Our competitors may develop or commercialize products more rapidly than we do or with significant advantages over any products we develop. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business.

In addition to larger pharmaceutical or biopharmaceutical companies that may develop different competing technologies or technologies within the transplant field, we will be competing with a number of smaller biotechnology companies that are focused on transplant technologies, which may include among others Gamida Cell Ltd., Nohla Therapeutics, Inc., and ExCellThera Inc. We are aware of Novartis' collaboration with Intellia Therapeutics, Inc. which includes efforts relating to expansion of HSCs that have been modified using CRISPR/Cas9 technology to express therapeutic proteins and delivered to patients for the treatment of potential treatment of blood disorders or primary immune deficiencies. Any programs and technology that develop as a result of this collaboration would likely compete directly with our E478 program.

Colleges, universities, governmental agencies and other public and private research organizations are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technologies that they have developed, some of which may be directly competitive with our programs and product candidates, including our lead product candidate, MGTA-456.

Risks Related to Manufacturing and Commercialization

We rely on third parties to conduct our preclinical and clinical trials and will rely on them to perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

Although we have recruited a team that has experience with clinical trials, as a company we have no experience in conducting clinical trials. Moreover, we do not have the ability to independently conduct preclinical studies and clinical trials, and we have relied upon, and plan to continue to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, or our CROs, to conduct preclinical studies and future clinical trials for our product candidates. We expect to rely heavily on these parties for execution of preclinical and future clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our preclinical and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including cGCPs for conducting, monitoring, recording and reporting the results of preclinical and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and

comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, 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, the FDA will determine that any of our future clinical trials will comply with cGCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in cGMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design our planned clinical trials for our product candidates, for the foreseeable future CROs will conduct all of our planned clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less day-to-day control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs 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, regulatory requirements or for other reasons, any preclinical studies or clinical trials with which such CROs are associated with may be extended, delayed or terminated. In such cases, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates in the subject indication could be harmed, our costs could increase and our ability to generate revenue could be delayed.

The successful development of biopharmaceuticals and cell-based therapies is highly uncertain.

Successful development of biopharmaceuticals and cell-based therapies is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Bone marrow transplant and cell-based therapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- preclinical study results may show the therapies to be less effective than desired or to have harmful or problematic side effects;
- clinical trial results may show the therapies to be less effective than expected (e.g., the trial failed to meet its primary endpoint) or to have unacceptable side effects or toxicities;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical trials, length of time to achieve study endpoints, additional time requirements for data analysis, or biologics license application, or BLA, preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the therapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the therapy from being commercialized.

Success in preclinical studies and early clinical trials do not ensure that large-scale clinical trials will be successful. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one therapy to the next, and may be difficult to predict.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payers, including government payers such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payers could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payers were not to provide adequate coverage and reimbursement levels for any of our products if approved, market acceptance and commercial success would be reduced.

In addition, if one of our product candidates is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third party providers) comply with the FDA's current Good Manufacturing Practices, or cGMPs, and the FDA's current Good Clinical Practices, or GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates' post-market approval could have a material adverse effect on our business, financial condition and results of operations.

We may never obtain FDA approval for any of our product candidates in the United States, and even if we do, we may never obtain approval for or commercialize any of our product candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

MGTA-456 has been affected by contamination issues in the past, and any future contamination in our or our third parties' manufacturing process, shortages of raw materials or reagents or failure of any of our key suppliers to deliver necessary components of our product candidates could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. For example, prior to our 2017 license of the product candidate from Novartis, our third-party manufacturer for MGTA-456 experienced contaminations, including microbial contaminations, in connection with the clinical manufacture of MGTA-456 which required disposal of contaminated product and led to delays in the manufacturing process. While we have not experienced contamination events in connection with the manufacture of MGTA-456 for our clinical use since licensing the product candidate, we cannot guarantee that we or our third-party vendors will be able to successfully prevent and remediate contaminations in the future in connection with the manufacture of MGTA-456 or our other current or future product candidates. Any contamination could materially adversely affect our or our third-party vendors' ability to produce our product candidates on schedule and could therefore harm our results of operations and cause reputational damage.

The raw materials required in our and our third-party vendors' manufacturing processes are derived from biological sources. We cannot assure you that we or our third-party vendors have, or will be able to obtain on commercially reasonable terms, or at all, sufficient rights to these materials derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall or be of insufficient quality. For example, if a selected umbilical cord blood unit is of insufficient quality for manufacture of MGTA-456, we may experience a delay in our clinical trial while MGTA-456 is manufactured using an alternative, back-up umbilical cord blood unit. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the clinical and commercial manufacturing of our product candidates, which could materially and adversely affect our operating results and development timelines.

We rely on third-party suppliers for the supply and manufacture of certain components of our technology and product candidates, including a single supplier in some cases. For example, an affiliate of the University of Minnesota is our only manufacturing partner for MGTA-456, and Bachem Americas, Inc. is currently the sole manufacturer of MGTA-145. Should our ability to procure the necessary components for our product candidates from our suppliers be compromised, our ability to continuously operate would be impaired until an alternative supplier is sourced, qualified and tested, which could delay or limit our ability to produce a clinical and commercial supply of our product candidates and harm our business.

If we use biological materials in a manner that causes injury, we may be liable for damages.

Our research and development activities involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials complies with federal, state and local laws and regulations, we cannot

entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. We do not carry specific biological waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended or terminated.

Third-party manufacturers and any third-party collaborators may be unable to successfully scale-up manufacturing of MGTA-456 or our other current or future product candidates in sufficient quality and quantity, which would delay or prevent us from developing MGTA-456 or our other product candidates and commercializing approved products, if any.

In order to conduct clinical trials of MGTA-456 and our other current and future product candidates, we will need to work with third-party manufacturers to manufacture them in sufficient quantities. Our manufacturing partners or our third-party collaborators may be unable to successfully increase the manufacturing capacity of MGTA-456 and our other current or future product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners or collaborators are unable to successfully scale up the manufacture of our current or future product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

The commercial success of any of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA in the United States, the EMA in the European Union and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance of physicians, patients and health care payors of our product candidates as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy, durability and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA or the European Commission;
- the willingness of physicians to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party payor coverage and adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

If we are unable to successfully develop our current programs into a comprehensive portfolio of product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our current and future product candidates.

We are developing our product candidates so that they can each be used individually or in combination with each other. In particular, we are focused on a product development strategy that includes leveraging the synergies among a comprehensive portfolio of our product candidates. Our success may depend, in part, on our ability to develop a complementary product portfolio with product candidates that, together or individually, will address the major unmet needs inherent to the existing bone marrow transplant process. Given our limited experience in developing product candidates that have received marketing approval, we may not be successful in developing some of our product candidates. The failure of one of our product candidates to obtain regulatory approval or market acceptance may affect our ability to expand our market opportunities for our other product candidates or programs. Although we may develop product candidates that ultimately obtain marketing approval, if we are unable to successfully develop our current programs into a comprehensive portfolio of product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our current and future product candidates.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably.

The success of our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to bone marrow transplant, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions 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 are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including 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.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services, the agency responsible for administering the Medicare program, or CMS, reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. Additional state and federal healthcare reform measures are expected to 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 certain pharmaceutical products or additional pricing pressures.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. 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. 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, cost containment initiatives and additional legislative changes.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

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 Affordable Care Act was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, or 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 50% point-of-sale discounts (which will be increased to 70% effective January 1, 2019) 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.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, in Congress, the U.S. House of Representatives passed Affordable Care Act replacement legislation known as the American Health Care Act of 2017 in May 2017, which was not introduced in the Senate. However, The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA 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.” Congress may consider other legislation to repeal or replace certain elements of the Affordable Care Act. In addition, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, the Trump administration has concluded that cost-sharing reduction (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 such 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. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. 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. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 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 of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Much like the Anti-Kickback Statue prohibition in the United States, 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 European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

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

In addition, in most foreign countries, including the European Economic Area, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our product candidates in those countries would be negatively affected.

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

The collection and use of personal health data in the European Union is governed by the provisions of the Data Protection Directive, and as of May 2018 the General Data Protection Regulation, or GDPR. These directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR

regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop, implement and maintain costly compliance programs.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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, 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 collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. 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.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new medicines 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 medicine 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 medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine 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.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. 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. 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 medicine 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. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any medicine 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 medicines, 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 medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines 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 medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition.

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 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 products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- 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.

Our inability to obtain 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 collaborators. Although we currently carry $10,000,000 of clinical trial insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may 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.

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

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

Foreign governments often impose strict price controls on approved products, which may adversely affect our future profitability in those countries, and the re-importation of drugs to the United States from foreign countries that impose price controls may adversely affect our future profitability.

Frequently foreign governments impose strict price controls on newly approved therapeutic products. If we obtain regulatory approval to sell products in foreign countries, we may be unable to obtain a price that provides an adequate financial return on our investment. Furthermore, legislation in the United States may permit re-importation of drugs from foreign countries into the United States, including re-importation from foreign countries where the drugs are sold at lower prices than in the United States due to foreign government-mandated price controls. Such a practice, especially if it is conducted on a widespread basis, may significantly reduce our potential United States revenues from any drugs that we are able to develop.

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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine.

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

Risks Related to Intellectual Property

We are highly dependent on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

In April 2017, we entered into a license agreement with Novartis pursuant to which we were granted a worldwide license to certain intellectual property rights owned or controlled by Novartis, including patents, patent applications, proprietary information, know-how and other intellectual property, to develop, commercialize and sell one or more therapeutic products comprising MGTA-456 in the field of non-gene-edited/-modified HSCs. In addition, in November 2016, we entered into a license agreement with Harvard University, or Harvard, pursuant to which we were granted a worldwide license to research, develop and commercialize one or more therapeutic products under certain conditioning- and mobilization-related patents and patent applications owned or controlled by Harvard. Furthermore, in March 2018, we entered into a research, development option and license agreement with Heidelberg Pharma Research GmbH, or Heidelberg Pharma, pursuant to which we intend to combine our proprietary antibodies and Heidelberg Pharma's amanitin conjugates platform. We are dependent on the patents, know-how and proprietary technology, licensed from Novartis and Harvard. Furthermore, if we commercialize any products utilizing Heidelberg Pharma's amanitin conjugates platform, we will be dependent on the intellectual property rights we license from Heidelberg Pharma. Any termination of these licenses, or a finding that such intellectual property lacks legal effect, could result in the loss of significant rights and could harm our ability to commercialize MGTA-456, C100, C200, C300, G100, MGTA-145, and other product candidates.

Certain of our license agreements, including our agreements with Novartis, Harvard and Heidelberg Pharma, require us to use diligent efforts or meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. If we fail to comply with the obligations under our license agreements, including payment terms and diligence terms, our licensors may have the right to terminate our agreements, in which event we may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of our license agreements or reduction or elimination of our rights under them may result in our having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to develop or commercialize the affected product candidate or cause us to lose our rights under the agreement. In addition with respect to our license agreement with Novartis, Novartis has granted an exclusive license to Intellia Therapeutics, Inc., or Intellia, in the field of gene-modified HSCs under the same intellectual property that Novartis licensed to us. Accordingly, such rights are unavailable to us and in prosecuting, maintaining, enforcing and defending the licensed patents, Novartis may make decisions that may not be in our best interest. Moreover, if Novartis or Intellia take any action with respect to the licensed patents that results in a successful challenge to the licensed patents by any third party, such patents may be invalidated or held to be unenforceable and we may lose our rights under such patents, which would harm our business.

Further, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, disputes may arise between us and our licensor, our licensor and its licensors, regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;

- our involvement in the prosecution of the licensed patents and our licensors' overall patent enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners; and
- the amounts of royalties, milestones or other payments due under the license agreement.

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. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates. If we or any such licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Any disputes with our licensors or any termination of the licenses on which we depend could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology.

Our commercial success depends in large part on our ability to obtain, maintain and protect intellectual property protection through patents, trademarks, and trade secrets in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary position, we have submitted patent applications and may file other patent applications in the United States or abroad related to our product candidates that are important to our business. Although we in-license certain issued patents from Novartis related to our MGTA-456 product candidate, we do not own any issued patents related to our product candidates in any major market and most of the patent applications that we own in the United States are provisional patent applications. Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of the filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. Moreover, the patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

In some instances, agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented, how claims are amended, and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license, including under our agreement with Novartis, and therefore cannot guarantee that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Moreover, some of our in-licensed patents and patent applications are, and our future owned and licensed patents 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 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 may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. 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 of our licensed patents have, or that any of our pending owned or licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage, nor can we assure you that our licenses will remain in force. Other parties have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or

conflict with our patent applications, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate our patent position. 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. In the United States, the natural expiration of a patent is generally twenty 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. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties, such as outside our field, and such third parties may have certain enforcement rights. Thus, patents licensed to us and any patents we own in the future could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.

The patent protection we obtain for our product candidates may not be sufficient enough to provide us with any competitive advantage or our patents may be challenged.

Our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents 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 falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or 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. Currently, a significant portion of our patents and patent applications are in-licensed, though similar risks would apply to any patents or patent applications that we now own or may own or in-license in the future.

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 strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications 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, whether current or future, 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 patents or patent applications, 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.

The patent position of biotechnology and pharmaceutical companies carries uncertainty. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, *ex parte* reexaminations, *inter partes* review, supplemental examinations, or interference proceedings or challenges in district court, in the United States or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or in patent or patent application claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent or patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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.

Pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Competitors may also be able to design around our patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. If these developments were to occur, they could have a material adverse effect on our ability to generate revenue.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting Abbreviated New Drug Applications, or ANDAs, to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our contractors, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our consultants and employees. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights under these agreements 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. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the contractors, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets. Enforcing a claim against a third party that illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing or unwilling to protect trade secrets.

Moreover, our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. Competitors and other third parties could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

Third-party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product discovery and development efforts and have a material adverse effect on our business.

Our commercial success depends in part on our avoiding infringement, misappropriation and other violations of the patents and proprietary 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 interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U.S. patent reform, new procedures including *inter partes* review and post grant review have been implemented. As stated above, this reform will bring uncertainty to the possibility of challenge to our patents in the future. 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.

Third parties may assert that we are employing their proprietary technology without authorization. For example, we are aware of certain patent applications owned by a third party with claims that if issued in their present form could be construed to cover C200. If such patent claims are issued, the third party may seek to allege that our development and commercialization of C200 infringes such patents and file a patent infringement lawsuit against us in the future. While we believe we would have valid defenses against any such allegation or lawsuit, such defenses may be unsuccessful. In this regard, patents issued in the U.S. 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 also be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or 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. Even if we obtained such a license, it may only be non-exclusive, which would permit third parties to use the same intellectual property and compete with us. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize our product candidates or such efforts may be impaired or delayed, which could in turn significantly harm our business.

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, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion. There could also 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 material adverse effect on the price of shares of our common stock.

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. 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 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. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Periodic maintenance 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. While an inadvertent lapse can in many 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 or patent application 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, which would have a material adverse effect on our business.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Many of the intellectual property rights we have licensed are generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy 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 litigation. There could also 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 material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. 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 our existing patents and 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. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

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

Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our 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 drugs and may export otherwise infringing drugs to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These drugs may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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, which could adversely affect our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our current or future licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- 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 intellectual property.

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

Risks Related to Our Dependence on Third Parties

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

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

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

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing.

- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Collaborators with marketing and distribution rights to one or more medicines may not commit sufficient resources to the marketing and distribution of such medicine or medicines.
- Collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our medicines or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated.

If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval, and commercialization described in this Quarterly Report on Form 10-Q apply to the activities of our collaborators.

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

We are developing E478 specifically to partner with gene therapy and genome editing companies. If we are unable to find willing collaborators, this may adversely affect the development of E478 and our business.

We are developing E478 specifically to partner and collaborate with gene therapy and genome editing companies. In particular, we seek to selectively pursue collaboration arrangements with companies that have particular technology, expertise or resources for the development of E478, if approved. However, we may not be able to execute on such collaboration and any collaboration that we may enter into may not be successful. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on a timely basis, on acceptable terms or at all, or if the arrangements we establish are unproductive for us, we may fail to meet our business and development objectives for E478, which may adversely affect our business.

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

Our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, in connection with our license agreement with Novartis, we issued to Novartis, 2,500,000 shares of Series A redeemable convertible preferred stock and 643,550 shares of Series B redeemable convertible preferred stock, causing our stockholders to experience dilution. If in the future, we enter into collaborations with other third parties, we may issue additional equity as part of such collaboration.

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

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

If any party to which we have outsourced certain functions fails to perform its obligations under agreements with us, the development and commercialization of our product candidates and any future product candidates could be delayed or terminated.

To the extent that we rely on third party individuals or other companies to manage the day-to-day conduct of our clinical trials or to manufacture, sell or market our current product candidates or any future product candidates, we will be dependent on the timeliness and effectiveness of their efforts. If a clinical research management organization that we might utilize is unable to allocate sufficient qualified personnel to our studies or if the work performed by it does not fully satisfy the rigorous requirements of the FDA, we may encounter substantial delays and increased costs in completing our clinical trials. If a firm producing humanized forms of our molecular antibody product candidates or a manufacturer of the raw material or finished product for our clinical trials is unable to meet our time schedules or cost parameters, the timing of our clinical trials and development of our product candidates may be adversely affected. Any manufacturer that we select may encounter difficulties in scaling-up the manufacture of new products in commercial quantities, including problems involving product yields, product stability or shelf life, quality control, adequacy of control procedures and policies, compliance with FDA regulations and the need for further FDA approval of any new manufacturing processes and facilities. The manufacture of clinical supplies for studies and commercial quantities of our current product candidates and any future product candidates are likely to be inherently more difficult and costly than typical chemical pharmaceuticals. This could delay commercialization of any of our product candidates, if approved, or reduce the profitability of these candidates for us. If any of these occur, the development and commercialization of our product candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own.

We expect to continue to rely on third parties to manufacture our clinical product supplies, and we intend to 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 and processing facility and must eventually rely on outside vendors to manufacture supplies and process our product candidates. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in therapies that are safe and effective.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements for manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, 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 such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

In addition, should any of our agreements with our contract manufacturers terminate, in particular the agreements with the University of Minnesota and Heidelberg Pharma, they may be difficult to replace if we were no longer able to rely on them.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

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

As our development, manufacturing and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need and are actively recruiting additional managerial, operational, sales, marketing, financial and other personnel. 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, FDA and international regulatory 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 develop, manufacture and 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 financial and other resources, and 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 management and manufacturing. We cannot assure you 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. We cannot assure you 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, 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.

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

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

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, such as a Chief Financial Officer, our ability to identify and develop new or next generation product candidates will be impaired, which could result in loss of market opportunities or market share and could make us less competitive.

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, particularly our Chief Executive Officer, the members of our executive team, and key scientific and medical personnel employees. We

do not currently have a Chief Financial Officer. The inability to attract and retain a Chief Financial Officer and the loss of the services of any of our executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business.

We conduct our operations at our facility in Cambridge, Massachusetts. This 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.

To induce 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 agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. 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.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

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

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.

At September 30, 2018, we had $159.7 million of cash and cash equivalents. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since September 30, 2018, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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

Our operations, and those of our CMOs, our CROs 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. 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.

Our internal computer systems, or those used by our CMOs, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CMOs, future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. If such a system failure or security breach 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 clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we may 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, including potential lawsuits from patients, collaborators, employees and/or stockholders, and the further development and commercialization of our product candidates could be delayed.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event, or AE. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable AE reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

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 laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, 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 will increase significantly, and our costs associated with compliance with such laws 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.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. 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 applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, 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 can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, 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. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. 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, or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. 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;

- 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, among other things, 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 Health Reform Law, 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 the United States Department of Health and Human Services, or 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; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Affordable Care Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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 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 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, 2017, we had U.S. net operating loss carryforwards of approximately $18.7 million and U.S. research and development credits of $1.0 million, which could be limited if we experience an "ownership change."

We may not be successful in finding strategic collaborators for continuing development of certain of our product candidates or successfully commercializing or competing in the market for certain indications.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for 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 timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Our competitors include companies focused on developing technologies to improve the distinct steps of bone marrow transplant.

Competitors in our stem cell expansion programs include: Gamida Cell Ltd., Nohla Therapeutics, Inc., ExCellThera Inc., Angiocrine Bioscience, Inc. and Intellia Therapeutics, Inc. In particular, Intellia Therapeutics, Inc. has exclusively licensed from Novartis the aryl hydrocarbon receptor antagonist that we use to manufacture MGTA-456 for expansion of gene-modified HSCs only, and it is likely that the programs developed under this license would compete directly with our E478 program.

We also face competition in our conditioning programs from Actinium Pharmaceuticals, Inc., Stanford University, Forty Seven, Inc. and Molecular Templates, Inc., and in our post-transplant complications program (GvHD) from Bellicum Pharmaceuticals, Inc., Kiadis Pharma NV and Abbvie Inc. Additionally, BioLineRx Ltd. is a competitor in our mobilization program.

In addition, we anticipate competing with the largest pharmaceutical companies in the world, such as Novartis, which is currently conducting research relating to expansion of HSCs that have been modified using CRISPR/Cas9 technology to express therapeutic proteins and delivered to patients for the treatment of potential treatment of blood disorders or primary immune deficiencies, which has greater financial and human resources than we currently have.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

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 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, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We do not currently carry biological or hazardous waste insurance coverage.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates; these decisions may prove to be wrong and may adversely affect our business.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify successful product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of 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 or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained.

In June 2018, we closed our initial public offering. Prior to this offering, there was no public market for our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on The NASDAQ Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The trading price of our common stock is likely to be highly volatile. Securities class action or other litigation involving our company or members of our management team could also substantially harm our business, financial condition and results of operations.

Our stock price is likely to be highly volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the success of existing or new competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of preclinical studies for any of our product candidates;
- the timing and results of clinical trials of MGTA-456 and any other product candidates;
- commencement or termination of collaborations for E478 or any of our current and future programs and product candidates;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the 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 the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in 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 completed 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 $1.0 billion in non-convertible debt during the prior three-year period.

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 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 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.

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. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an emerging growth company.

We will incur 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 and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the SEC, and The NASDAQ Global Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

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

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

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Following the June 2018 closing of our initial public offering, we had outstanding 34,370,267 shares of common stock, of which 27,661,088 shares were subject to restrictions on transfer under 180-day lock-up arrangements with the underwriters of our initial public offering. These restrictions are due to expire on December 17, 2018, resulting in the majority of these shares becoming eligible for public sale on December 18, 2018 if they are registered under the Securities Act of 1933, as amended (the "Securities Act"), or if they qualify for an exemption from registration under the Securities Act including under Rules 144 or 701.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any future debt or credit agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 60% of our capital stock as of October 31, 2018 following the closing of our initial public offering. This concentration of ownership control could delay, defer or prevent a change in control, entrench our management or the board of directors, or impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

We have broad discretion over the use of our cash and cash equivalents and may not use them effectively.

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

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us.

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

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66.67% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in the best interest of our stockholders. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders 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 (4) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated bylaws further provide that the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In

addition, our amended and restated bylaws 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 have chosen the United States District Court for the District of Massachusetts as the exclusive forum for such causes of action because our principal executive offices are located in Cambridge, Massachusetts. Some companies that have adopted similar federal district court forum selection provisions are currently subject to a suit in the Court of Chancery of the State of Delaware brought by stockholders who assert that the federal district court forum selection provision is not enforceable. We recognize that the federal district court forum selection clause may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Alternatively, if the federal district court forum selection provision is found inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have an adverse effect on our business, financial condition or results of operations. The United States District Court for the District of Massachusetts 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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock may be influenced, in part, by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

Use of Proceeds from Initial Public Offering

On June 25, 2018, we completed the initial public offering of our common stock pursuant to which we issued and sold 6,666,667 shares of our common stock at a price to the public of $15.00 per share.

All of the shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-225178), which was declared effective by the SEC on June 20, 2018. Following the sale of the shares in connection with the closing of our initial public offering, the offering terminated. Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC and Cowen & Co. acted as joint book-running managers and Wedbush PacGrow acted as lead manager of our initial public offering.

We received aggregate gross proceeds from our initial public offering of approximately $100.0 million, or aggregate net proceeds of approximately $89.9 million after deducting underwriting discounts and commissions and offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

As of September 30, 2018, we estimate that we have used approximately $13.0 million of the net proceeds from our initial public offering for clinical development of our product candidates and research activities and for working capital and other general corporate purposes. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours. We have invested the remaining net proceeds from the offering in money market accounts. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 21, 2018.

Issuer Purchases of Equity Securities

Period	(a) Total Number of Shares of Common Stock Repurchased	(b) Average Price Paid per Common Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number or Approximate Dollar Value) of Shares that May Yet be Purchased
July 1, 2018 - July 31, 2018	—	—	N/A	N/A
August 1, 2018 - August 31, 2018	46,865(1)	$ 0.026	N/A	N/A
September 1, 2018 - September 30, 2018	—	—	N/A	N/A
Total	46,865	$ 0.026		

(1) Represents shares of restricted common stock of Magenta Therapeutics, Inc. repurchased in connection with the termination of a certain employees' employment with Magenta Therapeutics, Inc. Under the terms of the applicable restricted stock award agreement, such shares were repurchased by Magenta Therapeutics, Inc. at the amount originally paid by such employees for such shares.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-38541) filed with the Securities and Exchange Commission on June 25, 2018).
3.2	Amended and Restated By-laws of the Registrant (Incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-38541) filed with the Securities and Exchange Commission on June 25, 2018).
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-225178) filed with the Securities and Exchange Commission on June 8, 2018).
4.2	Second Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders dated April 2, 2018 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-225178) filed with the Securities and Exchange Commission on June 8, 2018).
10.1*	Agreement, dated as of May 31, 2018, by and between the Registrant and The Richmond Group, Inc.
31.1*	Certification of Principal Executive Officer pursuant to Rules 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.
31.2*	Certification of Principal Financial Officer pursuant to Rules 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.
32.1#	Certifications of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS	XBRL Instance Document.
101SCH	XBRL Taxonomy Extension Schema Document.
101CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith.
\# Furnished herewith.

SIGNATURES

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

MAGENTA THERAPEUTICS, INC.

Date: November 8, 2018

By: /s/ Cindy Driscoll
Cindy Driscoll
Treasurer, Vice President, Finance
(Principal Financial and Accounting Officer)

A191 — Part2
Standard Form of Agreement Between Owner and Design/Builder

TABLE OF ARTICLES

AGREEMENT made as of the 31st day of May in the year of two thousand eighteen (but shall be effective with respect to, and shall govern all services and Work for the Project provided by or on behalf of the Design/Builder prior to such date).

BETWEEN the Owner:
(Name and address)

Magenta Therapeutics, Inc.
50 Hampshire Street, 8th Floor
Cambridge, MA 02139

and the Design/Builder:
(Name and address)

The Richmond Group, Inc.
77 Main Street
Hopkinton, MA 01748

For the following Project:
(Include Project name, location and a summary description.)

Magenta Therapeutics – Tenant Improvements
100 Technology Square, 5th and 6th Floors, Cambridge, MA 02139

The architectural services described in Article 3 will be provided by the following person or entity who is lawfully licensed to practice architecture ("Architect"):

Name and address	**Registration Number**	**Relationship to Design/Builder**
TRIA Architects, Inc. **21 Drydock Avenue, Suite 310W** **Boston, MA 02210**	20468	Consulting Architect

Normal structural, mechanical and electrical engineering services will be provided contractually through the Architect except the “Engineers” as indicated below:

Name, address and discipline	**Registration Number**	**Relationship to Design/Builder**
AHA Consulting Engineers **24 Hartwell Avenue** **Lexington, MA 02421**		Consulting Engineer
HVAC, Fire Protection	41285	
Plumbing	51647	
Electrical	35501	

The Owner and the Design/Builder agree as set forth below.

TERMS AND CONDITIONS—PART 2 AGREEMENT

ARTICLE 1 GENERAL PROVISIONS

§ 1.1 BASIC DEFINITIONS

§ 1.1.1 The Contract Documents consist of this Part 2 Agreement, the Construction Documents approved by the Owner in accordance with Section 3.2.3 and Modifications issued after execution of this Part 2 Agreement. A Modification is a Change Order or a written amendment to this Part 2 Agreement signed by both parties, or a Construction Change Directive issued by the Owner in accordance with Section 8.3. That certain Pre-Construction Services (Part 1) Proposal dated April 18, 2018, from the Design/Builder ("Part 1 Proposal") is incorporated in this Part 2 Agreement only for the purpose of defining the scope of the Design/Builder's responsibilities and obligations with respect to the preparation and administration of the design of the Project. In the event of a conflict or inconsistency between this Part 2 Agreement and the Part 1 Proposal, the terms of this Part 2 Agreement shall govern.

§ 1.1.2 The term "Work" means the construction and services provided by the Design/Builder to fulfill the Design/Builder's obligations.

§ 1.2 EXECUTION, CORRELATION AND INTENT

§ 1.2.1 It is the intent of the Owner and Design/Builder that the Contract Documents include all items necessary for proper execution and completion of the Work. The Contract Documents are complementary, and what is required by one shall be as binding on the Design/Builder as if required by all; performance by the Design/Builder shall be required to the extent consistent with or reasonably inferable from the Contract Documents as being necessary to produce the intended results. Words that have well-known technical or construction industry meanings are used in the Contract Documents in accordance with such recognized meanings.

§ 1.2.2 If the Design/Builder believes or is advised by the Architect or by another design professional retained to provide services on the Project that implementation of any instruction received from the Owner would cause a violation of any applicable law, the Design/Builder shall promptly notify the Owner in writing. Neither the Design/Builder nor the Architect shall be obligated to perform any act which will violate any applicable law.

§ 1.2.3 Nothing contained in this Part 2 Agreement shall create a contractual relationship between the Owner and any person or entity other than the Design/Builder.

§ 1.3 OWNERSHIP AND USE OF DOCUMENTS

§ 1.3.1 Drawings, specifications, and other documents and electronic data furnished by the Design/Builder are instruments of service. The Design/Builder's Architect and other providers of professional services shall retain all common law, statutory and other reserved rights, including copyright in those instruments of service furnished by them, subject to the provisions of Section 1.3.2.

§ 1.3.2 The Owner shall have the non-exclusive, perpetual and irrevocable right (the "License") to obtain, retain, reproduce and distribute copies (including reproducible copies and electronic files or other computer memory storage devices) of and to use all plans, drawings, specifications and other files and documents (whether paper, electronic or other media), and any design or creative concepts contained therein, and any other design materials submitted, created, developed, supplied or generated in connection with the Project by or on behalf of the Design/Builder for use in connection with the construction (including completion following any termination of Design/Builder's services for the Project), reconstruction, renovation, expansion, repair, maintenance, marketing, use and occupancy of the Project. The Design/Builder shall execute and deliver, and cause the architect(s), engineer(s) and other subcontractors performing design services to execute and deliver, instruments requested by the Owner to perfect, confirm or maintain the Owner's rights under the License. The Owner's rights to obtain and use such work product shall be suspended following any non-appealable decision by a court of competent jurisdiction that the Owner has failed to pay any amounts due to the Design/Builder under this Agreement until the Owner has thereafter paid such amounts to the Design/Builder.

§ 1.3.3 [Intentionally omitted].

§ 1.3.4 Submission or distribution of the Design/Builder's documents to meet official regulatory requirements or for similar purposes in connection with the Project is not to be construed as publication in derogation of the rights reserved in Section 1.3.1.

ARTICLE 2 OWNER

§ 2.1 The Owner shall designate a representative authorized to act on the Owner's behalf with respect to the Project. The Owner's authorized representative shall be Christina Isacson. The Owner or such authorized representative shall examine documents submitted by the Design/Builder and shall render decisions in a timely manner and in accordance with the schedule accepted by the Owner. The Owner may obtain independent review of the Contract Documents by a separate architect, engineer, contractor or cost estimator under contract to or employed by the Owner. Such independent review shall be undertaken at the Owner's expense in a timely manner and shall not delay the orderly progress of the Work.

§ 2.2 [Intentionally omitted.]

§ 2.3 The Owner shall cooperate with the Design/Builder in securing building and other permits, licenses and inspections. The fees for such permits, licenses and inspections shall be paid by the Design/Builder within the GMP.

§ 2.4 [Intentionally Omitted]

§ 2.5 The Owner shall disclose, to the extent possessed by the Owner, the results and reports of prior tests, inspections or investigations conducted for the Project involving: structural or mechanical systems; chemical, air and water pollution; hazardous materials; or other environmental and subsurface conditions. The Owner shall disclose, to the extent possessed by the Owner, prior tests or investigations regarding the presence of pollutants at the Project's site.

§ 2.6 The Owner shall furnish all legal, accounting and insurance counseling services as may be desired by the Owner at any time for the Project, including such auditing services as the Owner may require to verify the Design/Builder's Applications for Payment.

§ 2.7 Those services, information, surveys and reports required by Section 2.5 which are within the Owner's possession shall be furnished at the Owner's expense, and the Design/Builder shall be entitled to reasonably rely upon the accuracy and completeness thereof, except to the extent the Owner advises the Design/Builder to the contrary in writing.

§ 2.8 If the Owner requires the Design/Builder to maintain any special insurance coverage, policy, amendment, or rider in excess of the coverages required by this Agreement, the Owner shall pay the additional cost thereof, except as otherwise stipulated in this Part 2 Agreement.

§ 2.9 If the Owner observes or otherwise becomes aware of a fault or defect in the Work or nonconformity with the Design/Builder's Proposal or the Construction Documents, the Owner will endeavor to give prompt written notice thereof to the Design/Builder; provided, however, that any delay in furnishing such notice shall not affect Design/Builder's obligations with respect to any such fault or defect in the Work or the Construction Documents.

§ 2.10 The Owner shall, at the request of the Design/Builder, prior to execution of this Part 2 Agreement, furnish to the Design/Builder reasonable evidence that financial arrangements have been made to fulfill the Owner's obligations under the Contract.

§ 2.11 The Owner shall communicate with persons or entities employed or retained by the Design/Builder through the Design/Builder, unless otherwise directed by the Design/Builder.

ARTICLE 3 DESIGN/BUILDER

§ 3.1 SERVICES AND RESPONSIBILITIES

§ 3.1.1 Design services required by this Part 2 Agreement shall be performed by qualified architects and other design professionals. The contractual obligations of such professional persons or entities are undertaken and performed in the interest of the Design/Builder.

§ 3.1.2 The agreements between the Design/Builder and the persons or entities identified in this Part 2 Agreement, and any subsequent modifications, shall be in writing. These agreements, including financial arrangements with respect to this Project, shall be promptly and fully disclosed to the Owner upon request.

§ 3.1.3 The Design/Builder shall be responsible to the Owner for acts and omissions of the Design/Builder's employees, subcontractors and their agents and employees, and other persons, including the Architect and other design professionals, performing any portion of the Design/Builder's obligations under this Part 2 Agreement.

§ 3.2 BASIC SERVICES

§ 3.2.1 The Design/Builder's Basic Services are described below and in Article 14.

§ 3.2.2 The Design/Builder shall designate a representative authorized to act on the Design/Builder's behalf with respect to the Project. The Design/Builder's authorized representative shall be Keith Kerr

§ 3.2.3 The Design/Builder shall submit Construction Documents for review and approval by the Owner. Construction Documents shall include drawings, specifications, and other documents and electronic data setting forth in detail the requirements for construction of the Work, and shall:

.1 be suitable for the intended purposes of the Project;

.2 provide information for the use of those in the building trades; and

.3 include documents customarily required for regulatory agency approvals.

§ 3.2 4 The Design/Builder, with the assistance of the Owner, shall prepare and file documents required to obtain necessary approvals of governmental authorities having jurisdiction over the Project.

§ 3.2.5 Unless otherwise provided in the Contract Documents, the Design/Builder shall provide or cause to be provided and shall pay for design services, labor, materials, equipment, tools, construction equipment and machinery, water, heat, utilities, transportation and other facilities and services necessary for proper execution and completion of the Work, whether temporary or permanent and whether or not incorporated or to be incorporated in the Work.

§ 3.2.6 The Design/Builder shall be responsible for all construction means, methods, techniques, sequences and procedures, and for coordinating all portions of the Work under this Part 2 Agreement.

§ 3.2.7 The Design/Builder shall keep the Owner informed of the progress and quality of the Work.

§ 3.2.8 The Design/Builder shall be responsible for correcting Work which does not conform to the Contract Documents.

§ 3.2.9 The Design/Builder warrants to the Owner that materials and equipment furnished under the Contract will be of good quality and new unless otherwise required or permitted by the Contract Documents, that the construction will be free from faults and defects, and that the construction will conform with the requirements of the Contract Documents and all applicable legal requirements. Construction and Work not conforming to these requirements, including substitutions not properly approved by the Owner, shall be corrected in accordance with Article 9.

§ 3.2.10 The Design/Builder shall pay all sales, consumer, use and similar taxes which had been legally enacted at the time this Agreement is executed and delivered by the parties, and shall secure and pay for building and other permits and governmental fees, licenses and inspections necessary for the proper execution and completion of the Work, all as a Cost of the Work.

§ 3.2.11 The Design/Builder shall comply with and give notices required by laws, ordinances, rules, regulations and lawful orders of public authorities relating to the Project.

§ 3.2.12 The Design/Builder shall pay as a Cost of the Work all royalties and license fees. The Design/Builder shall defend suits or claims for infringement of copyrights and patent rights and shall indemnify, defend and hold the Owner harmless from loss on account thereof.

§ 3.2.13 The Design/Builder shall keep the premises and surrounding area free from accumulation of waste materials or rubbish caused by operations under this Part 2 Agreement. At the completion of the Work, the Design/Builder shall remove from the site waste materials, rubbish, the Design/Builder's tools, construction equipment, machinery, and surplus materials.

§ 3.2.14 The Design/Builder shall notify the Owner when the Design/Builder believes that the Work for each Phase of the Project or an agreed upon portion thereof is substantially completed. If the Owner concurs, the Design/Builder shall issue a Certificate of Substantial Completion for each Phase of the Project for execution by the

Design/Builder and the Owner which shall establish the Date of Substantial Completion of the applicable Phase, shall state the responsibility of each party for security, maintenance, heat, utilities, damage to the Work and insurance, shall include a list of items to be completed or corrected and shall fix the time within which the Design/Builder shall complete items listed therein. Disputes between the Owner and Design/Builder regarding the Certificate of Substantial Completion shall be resolved in accordance with provisions of Article 10.

§ 3.2.15 The Design/Builder shall maintain at the site for the Owner one record copy of the drawings, specifications, product data, samples, shop drawings, Change Orders and other modifications, in good order and regularly updated to record the completed construction. These shall be delivered to the Owner upon completion of construction and prior to final payment.

§ 3.2.16 The Design/Builder shall prepare a set of reproducible record documents and electronic data showing significant changes in the Work made during construction.

§ 3.2.17 The Design/Builder shall provide assistance in the utilization of equipment or systems such as preparation of operation and maintenance manuals, training personnel for operation and maintenance, and consultation during operation.

§ 3.3 ADDITIONAL SERVICES

§ 3.3.1 The services described in this Section 3.3 are not included in Basic Services unless so identified in Article 14, and they shall be paid for by the Owner as provided in this Part 2 Agreement, in addition to the compensation for Basic Services. The services described in this Section 3.3 shall be provided only if authorized or confirmed in writing by the Owner.

§ 3.3.2 Making revisions in drawings, specifications, and other documents or electronic data when such revisions are required by the enactment or revision of codes, laws or regulations subsequent to the preparation of such documents or electronic data.

§ 3.3.3 Providing consultation concerning replacement of Work damaged by fire or other cause during construction, and furnishing services required in connection with the replacement of such Work.

§ 3.3.4 Providing services in connection with a public hearing, arbitration proceeding or legal proceeding, except where the Design/Builder is a party thereto or pursuant to a request made or subpoena issued by a party other than the Owner.

§ 3.3.5 Providing coordination of the construction performed by the Owner’s own forces or separate contractors employed by the Owner; provided, however, that Design/Builder shall be responsible for coordinating the performance of performance of Work by its own forces, contractors and subcontractors of any tier with the Owner’s and Landlord’s separate contractors.

§ 3.3.6 Intentionally omitted.

§ 3.3.7 Intentionally omitted.

ARTICLE 4 TIME

§ 4.1 Unless otherwise indicated, the Owner and the Design/Builder shall perform their respective obligations as expeditiously as is consistent with reasonable skill and care and the orderly progress of the Project.

§ 4.2 Time limits for the Design/Builder’s performance of the Work stated in the Contract Documents are of the essence. The Work to be performed under this Part 2 Agreement shall commence upon receipt of a notice to proceed unless otherwise agreed and, Substantial Completion for Phase 1 shall be achieved on or before August 17, 2018 (subject to adjustment for time extensions to which the Design/Builder is entitled, the “Mandatory Phase 1 Substantial Completion Date”) and Substantial Completion for Phase 2 shall be achieved on or before October 17, 2018 (subject to adjustment for time extensions to which the Design/Builder is entitled, the “Mandatory Phase 2 Substantial Completion Date”). For purposes of this Project, the term “Phase 1” and “Phase 2” shall be defined in Exhibit M.

§ 4.3 Substantial Completion is the stage in the progress of the Work when the Work or designated portion thereof is sufficiently complete in accordance with the Contract Documents so the Owner can occupy or utilize the Work for its intended use.

§ 4.4 A construction schedule for the performance of all Design/Builder's services and Work is attached hereto as **Exhibit B** ("Construction Schedule").

§ 4.5 If the Design/Builder is delayed at any time in the progress of the Work by a wrongful or negligent act or omission of the Owner, Owner's employees, or separate contractors employed by the Owner, or by discretionary changes ordered by the Owner in the Work, or by labor disputes not directed at Design/Builder or any of its direct or lower tier contractors or subcontractors, fire, unusual delay in deliveries, adverse weather conditions not reasonably anticipatable, unavoidable casualties, or by delay authorized by the Owner pending arbitration, or by other causes beyond the Design/Builder's control which justify delay, then the Contract Time shall be reasonably extended by Change Order or, if elected by the Owner, to the extent reasonably feasible, accelerated with an adjustment in the GMP on account of the verifiable costs solely incurred to accelerate the Work.

ARTICLE 5 PAYMENTS

§ 5.1 Applications for Payment; Progress Payments

§ 5.1.1 Based upon Applications for Payment submitted by the Design/Builder, the Owner shall make progress payments on account of the Contract Sum to the Design/Builder as provided below and elsewhere in the Contract Documents. The Design/Builder's Applications for Payment shall be submitted on AIA Document G702 together with AIA Document G703, along with the required items listed in Section 5.1.4 (which shall collectively comprise the Application for Payment), all in form and substance satisfactory to the Owner.

§ 5.1.2 The period covered by each Application for Payment shall be one calendar month ending on the last day of the month; provided, however, that for any calendar month containing more than thirty days, the Design/Builder may submit two Applications for Payment with the first Application for Payment covering the first thirty days of the month and the second Application for Payment covering the thirty-first day of such month. Each Application for Payment shall be submitted on the last date of the period covered by such Application for Payment. Applications for Payment delivered prior to the last date of the period covered by such Application for Payment shall be deemed to have been submitted on the last date of the period covered by such Application for Payment for all purposes (including, without limitation, M.G.L. c. 149, Section 29E).

§ 5.1.3 If the Owner fails to approve or reject any actual Application for Payment for a periodic progress payment in writing within fifteen days following receipt by the Owner of the Design/Builder's actual Application for Payment (together with all required supporting materials), such actual Application for Payment shall be deemed approved unless the Owner subsequently notifies the Design/Builder in writing that the Owner has determined that withholding of payment on any actual Application for Payment or rejection of any actual Application for Payment is warranted before the date payment is due. The Owner shall pay the Design/Builder the amount approved by the Owner, less applicable retainage, within thirty (30) days following receipt by the Owner of a properly prepared and submitted actual Application for Payment together with all required supporting documentation. For the avoidance of doubt, and notwithstanding anything to the contrary, (i) nothing in the Contract Documents shall preclude the Owner from nullifying any previously issued Certificate for Payment or approved or deemed approved actual Application for Payment in accordance with Section 5.1.10 and (ii) in no event shall any Pencil Requisition be deemed to be an application for a periodic progress payment for purposes of M.G.L. c.149, Section 29E.

§ 5.1.4 As part of each Application for Payment, the Design/Builder shall submit payrolls, petty cash accounts, receipted invoices or invoices with check vouchers attached, and any other evidence required by the Owner to demonstrate that cash disbursements already made by the Design/Builder on account of the Cost of the Work equal or exceed progress payments already received by the Design/Builder, less that portion of those payments attributable to the Design/Builder's Fee, plus payrolls for the period covered by the present Application for Payment, plus retainage. In addition to other required items, each Application for Payment shall include the following:

.1 A certified report from the Design/Builder showing all suppliers who have provided supplies and/or materials to the Project and Subcontractors with whom the Design/Builder has entered into subcontracts, the amounts of such subcontracts, and supply agreements the amount requested for each Subcontractor and supplier in the Application for Payment and the amount to be paid to the Design/Builder from such progress payment;

.2 A duly completed and executed Partial Waiver and Subordination of Lien, together with the Owner's Supplement to Partial Waiver and Subordination of Lien, from the Design/Builder in the forms attached hereto as **Exhibit C;**

.3 A duly completed and executed Payment Acknowledgment and Lien Waiver, in the form attached hereto as **Exhibit D,** from each Subcontractor and supplier (and, to the extent requested by the Owner, each lower tier subcontractor and supplier) for whom payment was made under previous Applications for Payment;

.4 Applications for payment from each Subcontractor on AIA Document G702 together with AIA Document G703, a summary (and copies if requested by the Owner) of all supplier invoices included within such Application for Payment; and

.5 Such other information, documentation and materials as the Owner, Architect or Landlord may reasonably require.

For the avoidance of doubt, and notwithstanding anything else to the contrary, no Application for Payment shall be deemed submitted or complete unless and until all the items listed above in this Section and anything else required by the Contract Documents have been delivered to and received by the Architect and the Owner.

§ 5.1.5 Each Application for Payment shall be based on the most recent schedule of values submitted by the Design/Builder in accordance with the Contract Documents. The schedule of values shall allocate the entire Guaranteed Maximum Price among the various portions of the Work, except that the Design/Builder's Fee and contingency shall be shown as single separate items. The schedule of values shall be prepared in such form and supported by such data to substantiate its accuracy. The initial schedule of values is attached to this Agreement as **Exhibit** A. This schedule, unless objected to by the Owner shall be used as a basis for reviewing the Design/Builder's Applications for Payment.

§ 5.1.5.1 Each Application for Payment shall be deemed to constitute a representation by the Design/Builder that: (1) the design and construction have progressed to the point indicated, the quality of the Work covered by the application is in accordance with the Contract Documents, and the Design/Builder is entitled to payment in the amount requested; (2) the Design/Builder has paid all amounts owed to its Subcontractors and suppliers in accordance with the terms of their respective subcontracts and purchase orders; (3) except as stated in the Application for Payment or supporting documentation therewith, the Design/Builder has no knowledge that any party has filed or threatened to file a Statement of Account to perfect a lien against the Project site; (4) except as stated in the Application for Payment or supporting documentation therewith, the Design/Builder has no knowledge of any basis on which it may assert a claim for an extension of the Contract Time or an increase in the GMP; and (5) except as stated in the Application for Payment or supporting documentation therewith and as provided by applicable laws, the Design/Builder intends to pay all Subcontractors and suppliers for portions of the Work identified in such Application for Payment.

§ 5.1.5.2 The Design/Builder shall pay the Architect, Engineers, contractors and suppliers for whom the Design/Builder included amounts in any Application for Payment the amounts included in such Application for Payment and received by the Design/Builder (the "Subcontractor Requisition Amounts") in accordance with the terms of their respective subcontracts and purchase orders. Pending such payment by the Design/Builder, the Design/Builder shall hold all Subcontractor Requisition Amounts in trust for the benefit of the Owner.

§ 5.1.6 Applications for Payment shall show the percentage of completion of each portion of the Work as of the end of the period covered by the Application for Payment.

§ 5.1.7 Subject to other provisions of the Contract Documents, the amount of each progress payment shall be computed as follows:

.1 Take that portion of the Guaranteed Maximum Price properly allocable to completed Work as determined by multiplying the percentage of completion of each portion of the Work by the share of the Guaranteed Maximum Price allocated to that portion of the Work in the schedule of values, less retainage of five percent (5%);

.2 Add that portion of the Guaranteed Maximum Price properly allocable to materials and equipment purchased directly by the Design/Builder and delivered and suitably stored at the site for subsequent incorporation in the Work, or if approved in advance by the Owner, suitably stored off the site at a location agreed upon in writing, less retainage of five percent (5%);

.3 Add the Design/Builder's Fee, less retainage of five percent (5%). The Design/Builder's Fee shall be computed upon the Cost of the Work described in the two preceding clauses;

.4 [intentionally omitted];

.5 Subtract the aggregate of previous payments made by the Owner;

.6 Subtract the shortfall, if any, indicated by the Design/Builder in the documentation required by Section 5.1.4 to substantiate prior Applications for Payment, or resulting from errors subsequently discovered by the Owner's auditors in such documentation; and

.7 Subtract amounts, if any, for which the Owner has properly and justifiably withheld other than for retainage.

§ 5.1.8 Except with the Owner's prior approval, payments to Subcontractors shall be subject to retainage of five percent (5%) (which amount shall be credited to the Design/Builder as its retainage on Applications for Payment) and the Design/Builder shall not make advance payments to suppliers for materials or equipment which have not been delivered and stored at the site.

§ 5.1.9 The Owner, after giving notice to the Design/Builder of a material default on the part of the Design/Builder under Section 9.5 or of the Design/Builder's failure to dissolve a lien of a subcontractor or supplier in breach of Section 14.8, may make payments on account of labor, materials and/or equipment for the Work directly to the Subcontractors, lower tier subcontractor, suppliers or persons entitled to the same in lieu of paying the Design/Builder therefor or make joint payment to any such person and the Design/Builder. Any amounts so paid shall be credited against the Contract Sum. No such payment shall create any relationship between the recipient thereof and the Owner, nor any duty on the part of the Owner. The Design/Builder shall cooperate with the Owner to facilitate any such direct or joint payments and shall provide such evidence as the Owner may request for purposes of determining any amount to be so paid.

§ 5.1.10 The Owner may withhold payment to the extent as may be necessary in Owner's opinion to protect itself from loss for which Design/Builder is responsible because of:

.1 defective Work not remedied;

.2 third party claims asserted or filed or reasonable evidence indicating probable assertion or filing of such claims unless security acceptable to Owner is provided by Design/Builder;

.3 failure of Design/Builder to make payments properly to design consultants, subcontractors or suppliers for design services, labor, materials or equipment;

.4 reasonable evidence that the Work cannot be completed for the unpaid balance of the GMP;

.5 damage to Owner or another contractor;

.6 reasonable evidence that the Work will not be completed within the Contract Time, and that the unpaid balance would not be adequate to cover actual or liquidated damages for the anticipated delay;

.7 persistent failure to carry out the Work in accordance with the Contract Documents, including failure to maintain as-built drawings at the Project site;

.8 amounts previously paid to Design/Builder in excess of amounts properly due to Design/Builder;

.9 failure of Design/Builder to comply with any of Design/Builder's indemnification obligations as set forth in the Contract Documents;

.10 failure of Design/Builder to maintain the Project site in a clean and safe condition;

.11 failure of Design/Builder to meet any other monetary obligation imposed upon it pursuant to the Contract Documents; or

.12 the expiration, withdrawal or threatened withdrawal prior to completion of any licenses, permits or approvals reasonably required to perform the Work.

When the above reasons for withholding payment are removed, payment will be made for amounts previously withheld.

§ 5.1.11 The Owner shall have no obligation under this Part 2 Agreement to pay or to be responsible in any way for payment to the Architect, another design professional or a contractor performing portions of the Work.

§ 5.1.12 Neither progress payment nor partial or entire use or occupancy of the Project by the Owner shall constitute an acceptance of Work not in accordance with the Contract Documents.

§ 5.1.13 The Design/Builder warrants that title to all construction covered by an Application for Payment will pass to the Owner no later than the time of payment. The Design/Builder further warrants that upon submittal of an Application for Payment all construction for which payments have been received from the Owner shall be free and clear of liens, claims, security interests or encumbrances in favor of the Design/Builder or any other person or entity performing construction at the site or furnishing materials or equipment relating to the construction.

§ 5.2 FINAL PAYMENTS

§ 5.2.1 Neither final payment nor amounts retained, if any, shall become due until the Design/Builder submits to the Owner: (1) an affidavit that payrolls, bills for materials and equipment, and other indebtedness connected with the Work for which the Owner or Owner's property might be responsible or encumbered (less amounts withheld by the Owner) have been paid or otherwise satisfied; (2) a certificate evidencing that insurance required by the Contract Documents to remain in force after final payment is currently in effect and will not be canceled or allowed to expire until at least 30 days' prior written notice has been given to the Owner; (3) a written statement that the Design/Builder knows of no substantial reason that the insurance will not be renewable to cover the period required by the Contract Documents; (4) consent of surety, if any, to final payment; and (5) if required by the Owner, other data establishing payment or satisfaction of obligations, such as receipts, releases and waivers of liens, claims, security interests or encumbrances arising out of the Contract, to the extent and in such form as may be designated by the Owner. If a contractor or other person or entity entitled to assert a lien against the Owner's property refuses to furnish a release or waiver required by the Owner, the Design/ Builder may furnish a bond satisfactory to the Owner to indemnify the Owner against such lien. If such lien remains unsatisfied after payments are made, the Design/Builder shall indemnify the Owner for all loss and cost, including reasonable attorneys' fees incurred as a result of such lien.

Final payment, constituting the entire unpaid balance of the Contract Sum, shall be made by the Owner to the Design/Builder when:

.1 the Design/Builder has fully performed the Contract except for the Design/Builder's responsibility to correct Work which has not been identified as requiring correction at the time of final payment, and to satisfy other requirements, if any, which extend beyond final payment;

.2 the Design/Builder has submitted to the Owner, and the Owner has reviewed and approved, a final accounting for the Cost of the Work and a final Application for Payment together with all required supporting documentation; and

.3 a final Certificate for Payment has been approved in writing by the Owner.

§ 5.2.1.1 All retainage shall be released at the time of final payment except to the extent otherwise provided herein. The Owner shall, within thirty (30) days following submission of the applicable Application for Payment of retainage, release to the Design/Builder all retainage then held; provided, however, that the Owner may, withhold from the payment of retainage any amounted authorized by the Contract Documents and applicable laws.

§ 5.2.1.2 The Owner's final payment to the Design/Builder shall be made no later than 30 days after the issuance of the Owner's approval of a Certificate for Payment following completion of all Punchlist items. The amount of the final payment shall be calculated as follows:

.1 Take the sum of the Cost of the Work substantiated by the Design/Builder's final accounting and the Design/Builder's Fee, but not more than the Guaranteed Maximum Price;

.2 Subtract amounts, if any, for which the Owner properly and justifiably withholds payment as provided in the Contract Documents; and

.3 Subtract the aggregate of previous payments made by the Owner.

§ 5.2.2 Final payment shall not be made until defective or nonconforming Work has been remedied. Any costs incurred by the Design/Builder correct or complete defective or nonconforming Work after the Design/Builder's application for final payment shall not be reimbursed by the Owner.

§ 5.3 INTEREST PAYMENTS

§ 5.3.1 Payments due the Design/Builder under this Part 2 Agreement which are not paid when due shall bear interest from the date due at the rate specified in Section 13.3.

ARTICLE 6 PROTECTION OF PERSONS AND PROPERTY

§ 6.1 The Design/Builder shall be responsible for initiating, maintaining and providing supervision of all safety precautions and programs in connection with the performance of this Part 2 Agreement.

§ 6.2 The Design/Builder shall take reasonable precautions for the safety of, and shall provide reasonable protection to prevent damage, injury or loss to: (1) employees on the Work and other persons who may be affected thereby; (2) the Work and materials and equipment to be incorporated therein, whether in storage on or off the site, under care, custody, or control of the Design/Builder or the Design/Builder's contractors; and (3) other property at or adjacent thereto, such as trees, shrubs, lawns, walks, pavements, roadways, structures and utilities not designated for removal relocation or replacement in the course of construction.

§ 6.3 The Design/Builder shall give notices and comply with applicable laws, ordinances, rules, regulations and lawful orders of public authorities bearing on the safety of persons or property or their protection from damage, injury or loss.

§ 6.4 The Design/Builder shall promptly remedy damage and loss (other than damage or loss insured under property insurance provided or required by the Contract Documents) to property at the site caused in whole or in part by the Design/Builder, a contractor of the Design/Builder or anyone directly or indirectly employed by any of them, or by anyone for whose acts they may be liable.

§ 6.5 In the event the Design/Builder encounters on the site material reasonably believed to be hazardous under state or federal law which has not been rendered harmless, the Design/Builder shall report the condition to the Owner in writing. The Work in the affected area shall not thereafter be resumed except by written agreement of the Owner and Design/Builder if hazardous or contaminated under state or federal law and has not been rendered harmless. The Work in the affected area shall be resumed in the absence of material defined as hazardous or contaminated under state or federal law, or when it has been rendered harmless, by written notice from the Owner.

§ 6.6 The Design/Builder shall not be required pursuant to Article 8 to perform without consent any Work relating to material defined as hazardous or contaminated under State or Federal law.

§ 6.7 If, without the negligence of the Design/Builder or its contractors, suppliers, lower tier subcontractors or other party Design/Builder is responsible, Design/Builder is held liable by a government agency or any other person for the costs of remediation of a hazardous material or substance previously existing on the Project site and outside the scope of the Work solely by reason of performing Work as required by the Contract Documents, the Owners shall reimburse the Design/Builder for all costs and expenses thereby incurred.

ARTICLE 7 INSURANCE AND BONDS

§ 7.1 DESIGN/BUILDER'S LIABILITY INSURANCE

§ 7.1.1 The Design/Builder shall purchase from and maintain, in a company or companies lawfully authorized to do business in the jurisdiction in which the Project is located, such insurance as will protect the Design/Builder from claims set forth below which may arise out of or result from operations under this Part 2 Agreement by the Design/Builder or by a contractor of the Design/Builder, or by anyone directly or indirectly employed by any of them, or by anyone for whose acts any of them may be liable:

- **.1** claims under workers' compensation, disability benefit and other similar employee benefit laws that are applicable to the Work to be performed;
- **.2** claims for damages because of bodily injury, occupational sickness or disease, or death of the Design/Builder's employees;
- **.3** claims for damages because of bodily injury, sickness or disease, or death of persons other than the Design/Builder's employees;
- **.4** claims for damages covered by usual personal injury liability coverage which are sustained (1) by a person as a result of an offense directly or indirectly related to employment of such person by the Design/Builder or (2) by another person;
- **.5** claims for damages, other than to the Work itself, because of injury to or destruction of tangible property, including loss of use resulting therefrom;
- **.6** claims for damages because of bodily injury, death of a person or property damage arising out of ownership, maintenance or use of a motor vehicle; and
- **.7** claims involving contractual liability insurance applicable to the Design/Builder's obligations under Section 11.5.

§ 7.1.2 The insurance required by Section 7.1.1 shall be written for not less than limits of liability specified in Section 14.11 or required by law, whichever coverage is greater. Coverages, whether written on an occurrence or claims-made basis, shall be maintained without interruption from date of commencement of the Work until date of final payment and termination of any coverage required to be maintained after final payment.

§ 7.1.3 Certificates of Insurance acceptable to the Owner shall be delivered to the Owner immediately after execution of this Part 2 Agreement. These Certificates and the insurance policies required by this Section 7.1 shall contain a provision that coverages afforded under the policies will not be canceled or allowed to expire until at least 30 days' prior written notice has been given to the Owner. If any of the foregoing insurance coverages are required to remain in force after final payment, an additional certificate evidencing continuation of such coverage shall be submitted with the application for final payment. Information concerning reduction of coverage shall be furnished by the Design/Builder with reasonable promptness in accordance with the Design/Builder's information and belief.

§ 7.2 OWNER'S LIABILITY INSURANCE

§ 7.2.1 The Owner shall be responsible for purchasing and maintaining the Owner's usual liability insurance. Optionally, the Owner may purchase and maintain other insurance for self-protection against claims which may arise from operations under this Part 2 Agreement. The Design/Builder shall not be responsible for purchasing and maintaining this optional Owner's liability insurance unless specifically required by the Contract Documents.

§ 7.3 PROPERTY INSURANCE

§ 7.3.1 Unless otherwise provided under this Part 2 Agreement, the Owner shall purchase and maintain, in a company or companies authorized to do business in the jurisdiction in which the principal improvements are to be located, property insurance upon the Work to the full insurable value thereof on a replacement cost. Such property insurance shall be maintained, unless otherwise provided in the Contract Documents or otherwise agreed in writing by all persons and entities who are beneficiaries of such insurance, until Substantial Completion of the entire Project or until no person or entity other than the Owner has an insurable interest in the property required by this Section 7.3 to be insured, whichever is earlier. This insurance shall include interests of the Owner, the Design/Builder, and their respective contractors and subcontractors in the Work. Owner shall deliver to Design/Builder a Certificate of Insurance identifying Design/Builder as an additional insured on such policy.

§ 7.3.2 Property insurance shall be on an all-risk policy form and shall insure against the perils of fire and extended coverage and physical loss or damage, but shall be subject to all of the exclusions, deductibles, limits, sublimits, terms and conditions of the policy. Coverage for other perils shall not be required unless otherwise provided in the Contract Documents.

§ 7.3.3 [Intentionally Omitted]

§ 7.3.4 Unless otherwise provided, the Owner shall purchase and maintain such boiler and machinery insurance required by this Part 2 Agreement or by law, which shall specifically cover such insured objects during installation and until final acceptance by the Owner, but shall be subject to all of the exclusions, deductibles, limits, sublimits, terms and conditions of the policy. This insurance shall include interests of the Owner, the Design/Builder, the Design/Builder's contractors and subcontractors in the Work, and the Design/Builder's Architect and other design professionals. The Owner and the Design/Builder shall be named insureds.

§ 7.3.5 A loss insured under the Owner's property insurance shall be adjusted by the Owner and made payable to the Owner for the insureds, as their interests may appear, subject to requirements of any applicable mortgagee clause and of Section 7.3.10. The Design/Builder shall pay contractors their shares of insurance proceeds received by the Design/Builder, and by appropriate agreement, written where legally required for validity, shall require contractors to make payments to their subcontractors in similar manner.

§ 7.3.6 Before an exposure to loss may occur, the Owner shall file with the Design/Builder a complete copy of each policy that includes insurance coverages required by this Section 7.3. Each policy shall contain all generally applicable conditions, definitions, exclusions and endorsements related to this Project. The Owner shall not permit any such policy to expire or be cancelled sooner than 30 days before giving notice thereof to the Design/Builder.

§ 7.3.7 If the Design/Builder requests in writing that insurance for risks other than those described herein or for other special hazards be included in the property insurance policy, the Owner shall, if possible, obtain such insurance, and the cost thereof shall be charged to the Design/Builder by appropriate Change Order.

§ 7.3.8 The Owner and the Design/Builder waive all rights against each other and the Architect and other design professionals, contractors, subcontractors, agents and employees, each of the other, for damages caused by fire or other perils to the extent covered by property insurance obtained pursuant to this Section 7.3 or other property insurance applicable to the Work, except such rights as they may have to proceeds of such insurance held by the Owner. The Design/ Builder shall require from contractors and subcontractors by appropriate agreements, written where legally required for validity, similar waivers each in favor of other parties enumerated in this Section 7.3. The policies shall provide such waivers of subrogation by endorsement or otherwise. A waiver of subrogation shall be effective as to a person or entity even though that person or entity would otherwise have a duty of indemnification, contractual or otherwise, did not pay the insurance premium directly or indirectly, and whether or not the person or entity had an insurable interest in the property damaged.

§ 7.3.9 [Intentionally omitted].

§ 7.3.10 The Owner shall have power to adjust and settle a loss with insurers.

§ 7.3.11 Partial occupancy or use prior to Substantial Completion shall not commence until the insurance company or companies providing property insurance have consented to such partial occupancy or use by endorsement or otherwise to the extent such consent is required by the Owner's property insurance policy. The Owner and the Design/Builder shall take reasonable steps to obtain consent of the insurance company or companies and shall not, without mutual written consent, take any action with respect to partial occupancy or use that would cause cancellation, lapse or reduction of coverage.

§ 7.4 LOSS OF USE OF INSURANCE

§ 7.4.1 The Owner, at the Owner's option, may purchase and maintain such insurance as will insure the Owner against loss of use of the Owner's property due to fire or other hazards, however caused. The Owner waives all rights of action against the Design/Builder for loss of use of the Owner's property, including consequential losses due to fire or other hazards, however caused.

§ 7.5 ERRORS & OMISSIONS INSURANCE

§ 7.5.1 Limitation of Liability: The Architect and Engineers shall each purchase and maintain in force professional errors and omissions insurance in an amount not less than $1,000,000. The total liability of the Design/Builder to the Owner on account of professional errors or omissions by the Architect or its subconsultants or the Engineers in the performance of design services under this Contract shall be limited to the insurance proceeds recoverable and paid under such Professional Liability Insurance policy(ies).

ARTICLE 8 CHANGES IN THE WORK

§ 8.1 CHANGES

§ 8.1.1 Changes in the Work may be accomplished after execution of this Part 2 Agreement, without invalidating this Part 2 Agreement, by Change Order or Construction Change Directive, subject to the limitations stated in the Contract Documents, including, without limitation, Section 14.4.

§ 8.1.2 A Change Order shall be based upon agreement between the Owner and the Design/Builder; a Construction Change Directive may be issued by the Owner without the agreement of the Design/Builder; an order for a minor change in the Work may be issued by the Design/Builder alone.

§ 8.1.3 Changes in the Work shall be performed under applicable provisions of the Contract Documents, and the Design/Builder shall proceed promptly, unless otherwise provided in the Change Order, Construction Change Directive, or order for a minor change in the Work.

§ 8.1.4 If unit prices are stated in the Contract Documents or subsequently agreed upon, and if quantities originally contemplated are so changed in a proposed Change Order or Construction Change Directive that application of such unit prices to quantities of Work proposed will cause substantial inequity to the Owner or the Design/ Builder, the applicable unit prices shall be equitably adjusted.

§ 8.2 CHANGE ORDERS

§ 8.2.1 A Change Order is a written instrument prepared by the Design/Builder and signed by the Owner and the Design/Builder, stating their agreement upon all of the following:

- **.1** a change in the Work;
- **.2** the amount of the adjustment, if any, in the GMP; and
- **.3** the extent of the adjustment, if any, in the Contract Time.

§ 8.2.2 [Intentionally omitted].

§ 8.3 CONSTRUCTION CHANGE DIRECTIVES

§ 8.3.1 A Construction Change Directive is a written order prepared and signed by the Owner, directing a change in the Work prior to agreement on adjustment, if any, in the Guaranteed Maximum Price or Contract Time, or both.

§ 8.3.2 Except as otherwise agreed by the Owner and the Design/Builder, the adjustment to the Guaranteed Maximum Price shall be determined on the basis of reasonable expenditures and savings of those performing the Work attributable to the change, including the expenditures for design services and revisions to the Contract

Documents. In case of an increase in the Guaranteed Maximum Price, the increase shall include a corresponding increase to the Fixed Fee equal to five and three-quarters percent (5.75%) of the corresponding increase to the Cost of the Work on account thereof. In such case, the Design/Builder shall keep and present an itemized accounting together with appropriate supporting data for inclusion in a Change Order. Unless otherwise provided in the Contract Documents, costs for these purposes shall be limited to the Cost of the Work as defined in Article 13.

§ 8.3.3 Pending final determination of cost to the Owner, amounts not in dispute may be included in Applications for Payment accompanied by a Change Order indicating the parties' agreement with part or all of such costs. The amount of credit to be allowed by the Design/Builder to the Owner for deletion or change which results in a net decrease in the GMP will be actual net cost. When both additions and credits covering related Work or substitutions are involved in a change, the increase for overhead and profit shall be figured on the basis of the net increase, if any, to the Cost of the Work.

§ 8.3.4 When the Owner and the Design/Builder agree upon the adjustments in the Guaranteed Maximum Price and Contract Time, such agreement shall be effective immediately and shall be recorded by preparation and execution of an appropriate Change Order.

§ 8.4 [INTENTIONALLY OMITTED]

§ 8.5 CONCEALED CONDITIONS

§ 8.5.1 If conditions are encountered at the site which are (1) subsurface or otherwise concealed physical conditions which differ materially from those indicated in the Contract Documents, or (2) unknown physical conditions of an unusual nature which differ materially from those ordinarily found to exist and generally recognized as inherent in construction activities of the character provided for in the Contract Documents, then notice by the observing party shall be given to the other party promptly before conditions are disturbed and in no event later than 21 days after first observance of the conditions. The Guaranteed Maximum Price shall be equitably adjusted for such concealed or unknown conditions by Change Order upon a timely claim by either party as required above. Any such Change Order shall be deemed an Owner Discretionary Scope Change.

§ 8.6 REGULATORY CHANGES

§ 8.6.1 The Design/Builder shall be compensated for changes in the construction necessitated by the enactment or revisions of codes, laws or regulations subsequent to the execution of this Part 2 Agreement.

ARTICLE 9 CORRECTION OF WORK

§ 9.1 The Design/Builder shall promptly correct Work rejected by the Owner or known by the Design/Builder to be defective or failing to conform to the requirements of the Contract Documents, whether observed before or after Substantial Completion and whether or not fabricated, installed or completed. The Design/Builder shall bear costs of correcting such rejected Work, including additional testing and inspections.

§ 9.2 If, within one (1) year after the date of Substantial Completion of the Work or, after the date for commencement of warranties established in a written agreement between the Owner and the Design/Builder, or by terms of an applicable special warranty required by the Contract Documents, any of the Work is found to be not in accordance with the requirements of the Contract Documents, the Design/Builder shall correct it promptly after receipt of a written notice from the Owner to do so unless the Owner has previously given the Design/ Builder a written acceptance of such condition.

§ 9.3 Nothing contained in this Article 9 shall be construed to establish a period of limitation with respect to other obligations which the Design/Builder might have under the Contract Documents. Establishment of the time period of one (1) year as described in Section 9.2 relates only to the specific obligation of the Design/Builder to correct the Work, and has no relationship to the time within which the obligation to comply with the Contract Documents may be sought to be enforced, nor to the time within which proceedings may be commenced to establish the Design/Builder's liability with respect to the Design/Builder's obligations other than specifically to correct the Work.

§ 9.4 If the Design/Builder fails to promptly correct nonconforming Work as required or fails to carry out Work in accordance with the Contract Documents and Construction Documents, the Owner, by written order signed personally or by an agent specifically so empowered by the Owner in writing, may order the Design/Builder to stop the Work, or any portion thereof, until the cause for such order has been eliminated; however, the Owner's right to stop the Work shall not give rise to a duty on the part of the Owner to exercise the right for benefit of the Design/Builder or other persons or entities.

§ 9.5 If the Design/Builder defaults or neglects to carry out the Work in accordance with the Contract Documents and fails within seven (7) days after receipt of written notice from the Owner to commence and continue correction of such default or neglect with diligence and promptness, the Owner may give a second written notice to the Design/Builder and, seven (7) days following receipt by the Design/Builder of that second written notice and without prejudice to other remedies the Owner may have, correct such deficiencies. In such case an appropriate Change Order shall be issued deducting from payments then or thereafter due the Design/ Builder, the costs of correcting such deficiencies. If the payments then or thereafter due the Design/Builder are not sufficient to cover the amount of the deduction, the Design/Builder shall pay the difference to the Owner. Such action by the Owner shall be subject to dispute resolution procedures as provided in Article 10.

ARTICLE 10 DISPUTE RESOLUTION

§ 10.1 Any Claims, disputes or other matters in question between the parties to this Part 2 Agreement arising out of or relating to this Part 2 Agreement or breach thereof arising at any time shall be resolved, if possible, by negotiations between duly authorized representatives of the Design/Builder and the Owner. If such duly authorized representatives are unable to resolve any Claim within ten days after written notice of such dispute together with all relevant supporting documentation is given by either party to the other, the matter may be submitted by either party for mediation as a condition precedent to the institution of legal or equitable or other binding dispute resolution proceedings by either party which, unless the parties mutually agree otherwise, shall be in accordance with the Construction Industry Mediation Rules of the American Arbitration Association currently in effect. Demand for mediation shall be filed in writing with the other party to this Part 2 Agreement and with the American Arbitration Association. A demand for mediation shall be made within a reasonable time after the claim, dispute or other matter in question has arisen. In no event shall the demand for mediation be made after the date when institution of legal or equitable proceedings based on such claim, dispute or other matter in question would be barred by the applicable statutes of repose or limitations. The mediation shall be conducted by a single mediator agreed to by the parties (or, if the parties fail to agree upon a single mediator within fifteen (15) days following the date that such dispute is submitted to the American Arbitration Association, by a mediator appointed by the American Arbitration Association). Each party shall bear its own attorney's fees and costs of the mediation and the parties shall share in the fees and expenses of the mediator. All mediation sessions shall be conducted in Boston, Massachusetts.

§ 10.2 The parties agree that all offers, promises, conduct and statements, whether oral or written, made in the course of any settlement discussions or any mediation proceedings by any of the parties, their agents, employees, experts and attorneys, or by the mediator or any AAA employees, are confidential and privileged and shall not be the subject or object of discovery or be admissible for any purpose, including impeachment, in any arbitration, litigation or other adversary proceedings involving the parties, provided that evidence that is otherwise admissible or discoverable shall not be rendered inadmissible or non-discoverable as a result of its use in mediation.

§ 10.3 Agreements reached in mediation shall be enforceable as settlement agreements in any court having jurisdiction thereof.

§ 10.4 Claims which have not been resolved by mediation, shall be subject to litigation by either party. Any suit by either party shall be brought only in Boston, Massachusetts. The parties hereto waive any argument that this venue is not appropriate or that the forum is inconvenient. The Design/Builder and the Owner waive any argument that this venue is not appropriate or that the forum is inconvenient. THE DESIGN/BUILDER AND THE OWNER WAIVE ALL RIGHTS, IF ANY, TO A JURY TRIAL IN ANY DISPUTES ARISING FROM OR RELATING TO THE PROJECT OR THE CONTRACT DOCUMENTS.

§ 10.5 In the event of any mediation, arbitration or legal proceeding between Owner and any third-party arising out of or relating to the Project, the Design/Builder agrees that the Owner may join the Design/Builder in any such proceedings and that the Owner may consolidate any such proceedings with any proceeding between the Design/Builder and the Owner under the Contract Documents. The Design/Builder also agrees that the Owner may make persons other than the Owner and the Design/Builder parties to any dispute resolution proceeding hereunder with respect to any claim, dispute or other matter in question arising out the Project.

§ 10.6 A claim by either party, including Claims by the Design/Builder seeking extension of time, additional money or other relief, must be reported to the other party in writing within twenty-one (21) days after occurrence of the event giving rise to such claim or within twenty-one **(**21**)** days after the party asserting the claim first recognizes the condition giving rise to the claim, whichever is later. The parties expressly agree that failure of the party to initiate a claim within the time limits specified in this paragraph shall result in such claim being waived.

ARTICLE 11 MISCELLANEOUS PROVISIONS

§ 11.1 Unless otherwise provided, this Part 2 Agreement shall be governed by the law of the place where the Project is located.

§ 11.2 SUBCONTRACTS

§ 11.2.1 The Design/Builder, as soon as practicable after execution of this Part 2 Agreement, shall furnish to the Owner in writing the names of the persons or entities the Design/Builder will engage as contractors for the Project.

§ 11.3 WORK BY OWNER OR OWNER'S CONTRACTORS

§ 11.3.1 The Owner reserves the right to perform construction or operations related to the Project with the Owner's own forces, and to award separate contracts in connection with other portions of the Project or other construction or operations on the site under conditions of insurance and waiver of subrogation identical to the provisions of this Part 2 Agreement. If the Design/Builder claims that delay or additional cost is involved because of such action by the Owner, the Design/Builder shall assert such claims as provided in Article 10.

§ 11.3.2 The Design/Builder shall afford the Owner's separate contractors reasonable opportunity for introduction and storage of their materials and equipment and performance of their activities and shall connect and coordinate the Design/Builder's construction and operations with theirs as required by the Contract Documents.

§ 11.3.3 Costs caused by delays or by improperly timed activities or defective construction shall be borne by the party responsible therefor.

§ 11.4 [Intentionally omitted].

§ 11.5 INDEMNIFICATION

§ 11.5.1 To the fullest extent permitted by law, the Design/Builder shall defend, indemnify and hold harmless Owner, Landlord, Alexandria Real Estate Equities, Inc., any lender or mortgagee with respect to the property or building affiliated with the Project, any project manager or property manager engaged by the Owner or Landlord and each of their respective trustees, officers, directors, members, managers, partners, shareholders, employees, agents and representatives, and such other persons designated by the Owner from time to time, and anyone else acting for or on behalf of any of them (each, an "Indemnitee," and collectively, "Indemnitees") from and against any and all claims, demands, causes of action, damages, costs, expenses, losses or liabilities, in law or in equity, of every kind and nature whatsoever, including without limitation, costs of defense, settlement and attorneys' fees, to the extent arising out of or resulting from (or alleged to be arising out of or resulting from) performance of the seivices or Work, or the acts or omissions of the Design/Builder, Architect, an Engineer, a contractor, a subcontractor, a lower tier subcontractor, a supplier, a materialmen, an invitee or visitor or guest of any such party, or anyone directly or indirectly employed by any of them or anyone for whose acts they may be liable, or any injury, sickness, disease, death or loss to or suffered by an invitee or visitor or guest of any such party, regardless of whether or not such claim, damage, loss or expense is caused in part by a party indemnified hereunder (collectively, "Indemnified Claims"). Such obligation shall not be construed to negate, abridge, or reduce other rights or obligations of indemnity which would otherwise exist as to a party or person described in this Section 11.5.

§ 11.5.2 No performance bond or insurance protection required by the Contract Documents, or otherwise provided by the Design/Builder, shall in any way limit the responsibility to indemnify, defend and hold harmless the Indemnitees as herein provided.

§ 11.5.3 Each subcontract shall contain an indemnification in favor of the Indemnitees and the Design/Builder, which affords the Indemnitees the same benefits as the Design/Builder.

§ 11.5.4 [Intentionally omitted.]

§ 11.5.5 In any and all Indemnified Claims against the Indemnitees by any employee of the Design/Builder, Architect, Engineer, contractor, subcontractor, sub-subcontractor, supplier, materialmen, anyone directly or indirectly employed by any of them or anyone for whose acts they may be liable, the indemnification obligation hereunder shall not be limited in any way by any limitation on the amount or type of damages, compensation or benefits payable by or for the Design/Builder, Architect, Engineer, contractor, subcontractor, sub-subcontractor, or any such other party under workers' or workmen's compensation acts, disability benefit acts or other employee benefit acts.

§ 11.5.6 The Design/Builder shall pay its share of any judgment finally awarded in any Indemnified Claim which is brought against any Indemnitee, regardless of whether the Indemnitee or the Design/Builder directs the defense thereof, and shall pay any amounts payable in settlement or compromise of any such Indemnified Claim to which the Design/Builder has agreed.

§ 11.5.7 In the event that the Design/Builder is requested but refuses in bad faith to honor its indemnity obligations hereunder, then the Design/Builder shall, in addition to its other obligations, pay the cost of bringing any action to enforce the Design/Builder's indemnity obligations, including, without limitation, attorneys' and consultants' fees, expenses, and court costs, to the party requesting indemnity.

§ 11.5.8 Any sum or sums chargeable to the Design/Builder under this Section 11.5 may, at the election of the Owner, be deducted from any payments otherwise due or to become due to the Design/Builder under this or any other contract between the Owner and the Design/Builder, or the Owner may sue the Design/Builder and recover damages therefor.

§ 11.6 SUCCESSORS AND ASSIGNS

§ 11.6.1 The Owner and Design/Builder, respectively, bind themselves, their partners, successors, assigns and legal representatives to the other party to this Part 2 Agreement and to the partners, successors and assigns of such other party with respect to all covenants of this Part 2 Agreement. The Design/Builder shall not assign this Part 2 Agreement without the written consent of the Owner. The Owner may assign this Part 2 Agreement to the Landlord, and the Design/Builder agrees to execute all consents reasonably required to facilitate such an assignment. If either party makes such an assignment, that party shall nevertheless remain legally responsible for all obligations under this Part 2 Agreement, unless otherwise agreed by the other party.

§ 11.7 TERMINATION OF PROFESSIONAL DESIGN SERVICES

§ 11.7.1 Prior to termination of the services of the Architect or any other design professional designated in this Part 2 Agreement, the Design/Builder shall identify to the Owner in writing another architect or other design professional with respect to whom the Owner has no reasonable objection, who will provide the services originally to have been provided by the Architect or other design professional whose services are being terminated.

§ 11.8 EXTENT OF AGREEMENT

§ 11.8.1 This Part 2 Agreement represents the entire agreement between the Owner and the Design/Builder and supersedes prior negotiations, representations or agreements, either written or oral. This Part 2 Agreement may be amended only by written instrument and signed by both the Owner and the Design/Builder.

ARTICLE 12 TERMINATION AND SUSPENSION OF THE AGREEMENT

§ 12.1 TERMINATION BY THE OWNER

§ 12.1.1 Termination of Design/Builder for Convenience. The Owner may, at any time, for the Owner's convenience and without cause, terminate any portion of Work or any subcontract or design agreement or all remaining Work by giving five (5) days' prior written notice to the Design/Builder specifying the portion of the Work or subcontract or design agreement to be terminated and the effective date of termination. The Design/Builder shall continue to prosecute the portion of the Work not terminated.

§ 12.1.1.1 Upon receipt of written notice from the Owner of such termination for the Owner's convenience, the Design/Builder shall: (a) cease operations as directed by the Owner in the notice; (b) take actions necessary, or that the Owner may direct, for the protection and preservation of the Work; (c) except for Work directed to be performed prior to the effective date of termination stated in the notice, terminate all existing design agreements and subcontracts except for the design agreements and subcontracts, if any, that the Owner elects to assume pursuant to the rights set forth in Section 14.7, terminate all purchase orders and enter into no further design agreements, subcontracts and purchase orders; and (d) assign all permits or approvals for the Work to the Owner or its designee, and otherwise cooperate in all reasonable respects with the Owner's efforts to suspend or transition the Work.

§ 12.1.1.2 In case of such termination for the Owner's convenience, the Design/Builder shall be entitled to receive payment for Work properly executed in accordance with the Contract Documents (the basis for such payment shall be as provided in this Part 2 Agreement) and for costs incurred by the Design/Builder directly related to the termination of the Work including reasonable demobilization and cancellation charges and costs of and an extension

of time for redesign necessitated by a partial termination, provided such costs are authorized in advance by the Owner. No payment shall be made by the Owner, however, to the extent that such Work or subcontract or design agreement is, was, or could have been terminated without payment to the Design/Builder under the Contract Documents or if an equitable adjustment is made or denied under another provision of the Contract Documents. The Design-Builder shall be entitled to that portion of its Fixed Fee that the sum of the costs payable in accordance with this Section 12.1.1 bears to the estimated Cost of the Work included in the GMP (the "Earned Portion of Fixed Fee"). In the event of termination for the Owner's convenience, the Owner will issue a Construction Change Directive or authorize a Change Order making any required adjustment to the Contract Time and/or the GMP. For the remainder of the Work, the Contract Documents shall remain in full force and effect. The Design/Builder shall not be entitled to consequential or incidental damages, including, but not limited to, damages for loss of anticipated profits on Work not performed, on account of any termination. Upon any determination that the Design/Builder was wrongfully terminated pursuant to Section 12.1.2, such termination will be deemed converted to a termination for convenience pursuant to Section 12.1.1 and Design/Builder's remedy for wrongful termination shall be limited to the recovery of the payments for termination for convenience as set forth in this paragraph.

§ 12.1.2 Termination of Design/Builder for Cause. If the Design/Builder defaults or persistently fails or neglects to carry out the Work in accordance with the Contract Documents or fails to perform the provisions of this Part 2 Agreement, the Owner may give written notice that the Owner intends to terminate this Part 2 Agreement. If the Design/Builder fails to correct the defaults, failure or neglect within fourteen seven (14) days after being given notice, the Owner may then without prejudice to any other remedy terminate the employment of the Design/Builder and take possession of the site and of all materials, equipment, tools and construction equipment and machinery thereon owned by the Design/Builder and finish the Work by whatever method the Owner may deem expedient. If the unpaid balance of the GMP exceeds the expense of finishing the Work and all damages incurred by the Owner, such excess shall be paid to the Design/Builder after the Work has been completed. If the expense of completing the Work and all damages incurred by the Owner exceeds the unpaid balance, the Design/Builder shall pay the difference to the Owner. This obligation for payment shall survive termination of this Part 2 Agreement.

§ 12.2 TERMINATION BY THE DESIGN/BUILDER

§ 12.2.1 If the Owner fails to make payment of undisputed amounts within thirty (30) days of the date when due, the Design/Builder may give written notice of the Design/ Builder's intention to terminate this Part 2 Agreement. If the Design/Builder fails to receive payment of such undisputed amounts within seven (7) days after receipt of such notice by the Owner, the Design/Builder may give a second written notice and, if such undisputed amounts have not been paid within seven (7) days after receipt of such second written notice by the Owner, may terminate this Part 2 Agreement and recover from the Owner payment for Work properly executed in accordance with the Contract Documents prior to the date of termination.

§ 12.3 SUSPENSION BY THE OWNER

§ 12.3.1 The Owner may, without cause, order the Design/Builder in writing to suspend, delay or interrupt the Work in whole or in part for such period of time as the Owner may determine. The GMP and Contract Time shall be adjusted for increases in the cost and time caused by any such suspension, delay or interruption ordered by the Owner pursuant to this Section. No adjustment shall be made to the extent: (a) that performance is, was or would have been so suspended, delayed or interrupted by another cause for which the Design/Builder is responsible; or (b) that an equitable adjustment is made or denied under another provision of this Part 2 Agreement.

ARTICLE 13 BASIS OF COMPENSATION

The Owner shall compensate the Design/Builder in accordance with Article 5, Payments, and the other provisions of this Part 2 Agreement as described below.

§ 13.1 COMPENSATION

§ 13.1.1 For the Design/Builder's performance of the Work, as described in Section 3.2 and including any other services listed in Article 15 as part of Basic Services, the Owner shall pay the Design/Builder in current funds the Contract Sum:

13.1.1.1 The Contract Sum shall be the Cost of Work (as defined below), including the Fixed Supervision Cost of $**546,520** and the Fixed General Conditions Cost of $**27,600,** plus the Fixed Fee of $**310,678** ("Fixed Fee"), but in no event shall the Contract Sum exceed the Guaranteed Maximum Price of $**5,713,781** ("Guaranteed Maximum Price" or "GMP").

The difference between the Cost of the Work plus the Fixed Fee (as determined at Substantial Completion) and the GMP shall be "savings." Savings shall be shared equally by Owner and Design/Builder: 50% of Savings shall be returned to the Owner to reduce the GMP and 50% of Savings shall be paid to the Contractor as additional fee. The contingency shall not be excluded from the shared savings provision.

The GMP is subject to Change Orders as provided in the Contract Documents.

On changes that increase the Cost of the Work, Design/Builder's Fixed Fee and the GMP shall be increased by 5.75% of the net change to the Cost of the Work.

Design/Builder's total compensation for the Cost of the Work items listed in **Exhibit H** (collectively, the "General Conditions Items") shall be fixed at $27,600.

Design/Builder's total compensation for the Cost of the Work items for supervision shall be determined by multiplying the hours of the supervision performed by the personnel listed in **Exhibit K** by the corresponding hourly rate ("Supervision Costs"), provided that such amount shall be fixed at $546,520.

Design/Builder's total compensation for the all architectural, engineering and design consultant services rendered during the construction phase of this Agreement shall be fixed at $257,117.

Design/Builder has included an amount equal to five percent of the Cost of the Work as its contingency ("Contingency") in the initial schedule of values. The Contingency may be used by the Design/Builder to pay for unanticipated Costs of the Work otherwise reimbursable in accordance with this Agreement, provided that use of the Contingency for General Condition Items, Supervision Costs or Design Costs shall be subject to the Owner's prior written approval. The parties acknowledge that the Design/Builder shall not be obligated to apply the Contingency to Costs of the Work that would otherwise entitle the Design/Builder to an increase in the GMP.

Design/Builder acknowledges having received zero Dollars ($0) as of the Effective Date of the agreement on account of the design and professional services required under the Part 1 Proposal and hereby unconditionally waives all rights, including, lien rights, to the same. As of the date of this Part 2 Agreement, the remaining balance of compensation for the services required by the Part 1 Proposal is a lump sum equal to two hundred seven thousand, one hundred seventeen Dollars ($207,117), which shall only be increased on account of Owner Discretionary Scope Changes as defined in Section 14.4.3 of this Part 2 Agreement.

13.1.1.2 The term "Cost of the Work" shall mean costs necessarily and actually incurred by the Design/Builder in the proper performance of the Work. Such costs shall be at rates not higher than the standard paid at the place of the Project except with prior written consent of the Owner. The Cost of the Work shall include only the items listed in this Section 13.1.1.2. Where any cost is subject to the Owner's prior consent or approval, the Design/Builder shall obtain this consent or approval in writing prior to incurring the cost. Except as otherwise agreed in writing by the Owner, the Design/Builder must competitively bid any trade Work or the purchase or rental of materials or equipment with an anticipated cost of Two Thousand Five Hundred Dollars ($2,500) or more, including Work that the Design/Builder wishes to perform with the Design/Builder's own forces, or through an affiliate of Design/Builder. If any of the costs to be reimbursed arise from a transaction between the Design/Builder and an affiliate of Design/Builder, the Design/Builder shall notify the Owner of the specific nature of the contemplated transaction, including the identity of the affiliated party and the anticipated cost to be incurred, before any such transaction is consummated or cost incurred. If the Owner, after such notification, authorizes the proposed transaction, then the cost incurred shall be included as a Cost of the Work to be reimbursed, and the Design/Builder shall procure the Work, equipment, goods or service from the affiliated party as a Design/Builder, according to the terms of the Contract Documents. If the Owner fails to authorize the transaction, the Design/Builder shall procure the Work, equipment, goods or service from some person or entity other than an affiliated party according to the terms of the Contract Documents.

(1) LABOR COSTS

(a) Wages of construction workers directly employed by the Design/Builder to perform the construction of the Work at the site or, with the Owner's agreement, at off-site workshops at the hourly rates specified in **Exhibit K.**

(b) Wages or salaries of the Design/Builder's supervisory and administrative personnel wherever stationed, so long as they are working on this Project (incl. in Fixed Supervision Cost).

(c) Wages and salaries of the Design/Builder's supervisory or administrative personnel engaged, at factories, workshops or on the road, in expediting the production or transportation of materials or equipment required for the Work, but only for that portion of their time required for the Work (incl. in Fixed Supervision Cost).

(d) Costs paid or incurred by the Design/Builder for taxes, insurance, contributions, assessments and benefits required by law or collective bargaining agreements and, for personnel not covered by such agreements, customary benefits such as sick leave, medical and health benefits, holidays, vacations and pensions (incl. in Fixed Supervision cost and Fixed General Conditions Cost).

(2) SUBCONTRACT COSTS

Payments made by the Design/Builder to subcontractors (including design subcontractors) in accordance with the requirements of the subcontracts.

(3) COSTS OF MATERIALS AND EQUIPMENT INCORPORATED IN THE COMPLETED CONSTRUCTION

Costs, including transportation, of materials and equipment incorporated or to be incorporated in the completed construction. Unused or excess materials that cannot be returned to the supplier for a refund shall become property of the Owner or, at the Owner's election, sold by the Design/Builder. Any amounts refunded or realized from the sales shall be credit to the Owner as a deduction from the Cost of the Work.

(4) COSTS OF OTHER MATERIALS AND EQUIPMENT, TEMPORARY FACILITIES AND RELATED ITEMS

(a) Costs, including transportation, installation, maintenance, dismantling and removal of materials, supplies, temporary facilities, machinery, equipment, and hand tools not customarily owned by the construction workers, which are provided by the Design/Builder at the site and fully consumed in the performance of the Work (incl. in Fixed General Conditions Costs).

(b) Rental charges for temporary facilities, machinery, equipment, and hand tools not customarily owned by the construction workers, which are provided by the Design/Builder at the site, whether rented from the Design/Builder or others, and costs of transportation, installation, minor repairs and replacements, dismantling and removal thereof (incl. in Fixed General Conditions Cost)

(c) Costs of removal of debris from the site (incl. in Fixed General Conditions Cost).

(d) Costs of telegrams and long distance telephone calls, postage and parcel delivery charges, telephone service at the site and reasonable petty cash expenses of the site office (incl. in Fixed General Conditions Cost).

(e) That portion of the reasonable travel and subsistence expenses of the Design/Builder's personnel incurred while traveling in discharge of duties connected with the Work (incl. in Fixed General Conditions Cost).

(5) MISCELLANEOUS COSTS

(a) That portion directly attributable to this Contract of premiums for insurance required by this Part 2 Agreement in an amount not to exceed 1.25 percent of the Cost of the Work (less insurance).

(b) Sales, use or similar taxes imposed by governmental authority which are related to the Work and for which the Design/Builder is liable.

(c) Fees and assessments for the building permit and for other permits, licenses and inspections for which the Design/Builder is required by the Contract Documents to pay.

(d) Fees of testing laboratories for tests required by the Contract Documents, except those related to defective or non-confirming Work, which costs shall be borne by the Design/Builder without reimbursement.

(e) Royalties and license fees paid for the use of a particular design, process or product required by the Contract Documents and with the prior written approval of such fees by the Owner; the cost of defending suits or claims for infringement of patent rights arising from such requirement by the Contract Documents; payments made in accordance with legal judgments against the Design/Builder resulting from such suits or claims and payments of settlements made with the Owner's consent.

(f) Deposits lost for causes of the Owner's fault or negligence.

(6) OTHER COSTS

EMERGENCIES: REPAIRS TO DAMAGED, DEFECTIVE OR NONCONFORMING WORK: The Cost of the Work shall also include the following costs which are incurred by Design/Builder:

(a) In taking action to prevent threatened damage, injury or loss in case of an emergency affecting the safety of persons and property, unless such emergency resulted from the fault or negligence of Design/Builder or its contractors, direct or lower tier subcontractors or others for whom Design/Builder is responsible.

(b) [Intentionally Omitted]

(c) In repairing damaged Work other than that described above, provided such damage did not result from the fault or negligence of the Design/Builder or its contractors, direct or lower tier subcontractors or others for whom Design/Builder is responsible, and only to the extent that the cost of such repairs is not recoverable by the Design/Builder from others and the Design/Builder is not compensated therefor by insurance or otherwise.

(d) In correcting defective or nonconforming Work performed or supplied by a Subcontractor or material supplier and not corrected by them, provided such defective or nonconforming Work did not result from the fault or neglect of the Design/Builder or the Design/Builder's personnel adequately to supervise and direct the Work of the Subcontractor or material supplier, and only to the extent that the cost of correcting the defective or nonconforming Work is not recoverable by the Design/Builder from the Subcontractor or material supplier.

13.1.1.3 Costs included in the Cost of the Work shall be actual costs paid by the Design/Builder, less all discounts, rebates, refunds and salvages. Notwithstanding the breakdown or categorization of any costs in the Contract Documents, there shall be no duplication of payment in the event any particular items for which payment is requested can be characterized as falling into more than one of the types of compensable or reimbursable categories.

13.1.1.4 The Cost of the Work shall not include the items listed below: (a) expenses of the Design/Builder's principal office and offices other than the site office; (b) overhead and general expenses, except as may be expressly included the General Conditions Items; (c) the Design/Builder's capital expenses, including interest on the Design/Builder's capital employed for the Work; (d) costs due to the fault, negligence or failure to fulfill a specific responsibility of the Design/Builder, contractors, direct or lower tier subcontractors and suppliers or anyone directly or indirectly employed by any of them or for whose acts any of them may be liable, including but not limited to costs for the correction of damaged, defective or nonconforming Work, disposal and replacement of materials and equipment incorrectly ordered or supplied, and correcting damage to property not forming part of the Work; (e) any cost not specifically and expressly described in Sections 13.1.1.2 above; (f) costs that would cause the Guaranteed Maximum Price to be exceeded; (g) labor, material, and equipment costs or any other costs incurred which should be back-charged to any contractor, any direct or lower tier subcontractor or supplier, or any other party for whom the Design/Builder is responsible; (h) costs or losses resulting from lost, damaged or stolen tools and equipment; (i) costs of bonding or securing liens or defending claims filed by any contractor, direct or lower tier subcontractor or supplier or any other party for whom any of such parties or the Design/Builder is responsible arising from nonpayment, unless such nonpayment is caused solely by the Owner's unexcused or wrongful failure to pay the Design/Builder undisputed amounts as and when due under the Contract Documents; (j) costs of self-insured losses *(e.g.,* losses within the deductible limits maintained by the Design/Builder, any contractor or any direct or indirect subcontractor or supplier), costs covered by any insurance carried by Design/Builder, any contractor or any direct or lower tier subcontractor or supplier, costs which would have been covered by the insurance required to be carried by Design/Builder, a contractor or a direct or lower tier subcontractor or supplier, and costs which would have been covered by insurance but for failure of the Design/Builder, a contractor or direct or lower tier subcontractor or supplier to properly submit, process or give notice of the occurrence or claim; (k) costs of employee bonuses and executive bonuses whether or not based in whole or in part on performance related to the Work; (1) costs incurred or paid for recruiting employees (whether to third party recruiters or to employees); (m) severance or similar payments on account of terminated employees; (n) costs incurred after the Design/Builder's application for final payment; (o) costs of relocation or temporary living expenses; (q) costs of commuting to or from the Project site or charges for vehicles used by supervisory or administrative personnel; (p) amounts required to be paid by Design/Builder for

federal, state or local income or franchise taxes; (q) costs associated with Design/Builder's failure to (i) obtain any and all applicable permits that are Design/Builder's responsibility under the Contract Documents in a timely manner or (ii) coordinate and schedule inspections and commissionings; (r) penalties, extensions or fines imposed by any governmental authority caused by or arising out of conduct of the Design/Builder, any contractor, any direct or lower tier subcontractor or supplier, or any other party for whom the Design/Builder is responsible; (s) any costs or expenses in connection with any indemnity provided by Design/Builder pursuant to the Contract Documents; and (t) check processing fees associated with the payment of contractors, vendors and other payees.

13.1.1.5 Cash discounts obtained on payments made by the Design/Builder shall accrue to the Owner. Trade discounts, rebates, refunds and amounts received from sales of surplus materials and equipment shall accrue to the Owner, and the Design/Builder shall make provisions so that they can be obtained. Amounts that accrue to the Owner in accordance with the provisions of this paragraph shall be credited to the Owner as a deduction from the Cost of the Work. Discounts, rebates, refunds or dividends, and a proportion of any volume rebates earned with purchase of material charged to this Project, shall accrue to the Owner and be credited to the Owner as a deduction from the Cost of the Work, and the Design/Builder shall make provisions so that they can be obtained.

§ 13.2 REIMBURSABLE EXPENSES

§ 13.2.1 [Intentionally omitted.]

§ 13.2.2 [Intentionally omitted.]

§ 13.3 INTEREST PAYMENT

§ 13.3.1 The rate of interest for past due payments shall be as follows:

The applicable Base Rate of Bank of America or its successor plus three percentage points.

(Usury Laws and requirements under the Federal Truth in Lending Act, similar state and local consumer credit laws and other regulations at the Owner's and Design/ Builder's principal places of business, at the location of the Project and elsewhere may affect the validity of this provision. Specific legal advice should be obtained with respect to deletion, modification or other requirements, such as written disclosures or waivers.)

ARTICLE 14 OTHER CONDITIONS AND SERVICES

The provisions of this Article 14 supersede any inconsistent provisions in the Contract Documents.

§ 14.1 Design and Other Basic Services; Construction Documents.

§ 14.1.1 The Design/Builder shall cause the Architect, Engineer and/or other design consultants duly licensed in the jurisdiction where the Project is located to provide all services required to design and engineer the Project for its intended purpose (including, without limitation, architectural design, analysis of the Project's compliance with applicable codes and regulations for design and construction, structural systems design and engineering, plumbing system design and engineering, fire protection systems design and engineering, electrical systems design and engineering, and design and engineering of the heating, ventilation and air conditioning system), each as necessary to obtain all regulatory approvals for and to construct and occupy the Project for its intended purpose. Such services shall be governed by this Part 2 Agreement even though they are or have been (i) performed by the Architect or by a design consultant or subcontractor retained by or through the Design/Builder and (ii) performed prior to or after the date hereof. The Design/Builder shall cause design services to be performed as necessary to enable the Design/Builder to deliver a complete, fully functioning and operable Project to the Owner as described herein. The Design/Builder shall not directly perform design or other professional services for the Project that would be excluded from coverage under the Design/Builder's commercial general liability insurance policy.

§ 14.1.2 Supplementing the provisions of Section 3.2.3, each iteration of the Construction Documents submitted to the Owner for approval shall show by clouding all changes from the previous versions (including changes from the preliminary design documents prepared prior to the execution of this Part 2 Agreement), and shall be accompanied by a statement from the Design/Builder or the Architect delineating with specificity the nature and extent of all such changes. The Construction Documents, when completed, will set forth in detail all requirements for the construction and installation of the Project and will be sufficiently complete so that a prudent contractor, following generally accepted industry procedures, could undertake and complete the Project.

§ 14.1.3 Supplementing the provisions of Section 3.2.10, the Design/Builder shall obtain as a Basic Service within the Guaranteed Maximum Price all designated or required governmental inspections and all required certificates of occupancy and operating permits for machinery and equipment included in the Project.

§ 14.1.4 Notwithstanding anything to the contrary, the Design/Builder shall prepare and deliver to the Owner prior to final payment reproducible sets of the Construction Documents (including drawings, specifications, addenda, Change Orders, Construction Change Directives and other Modifications), in print and electronic format acceptable to the Owner, showing (a) deviations from the Construction Documents made during construction, (b) details in the Work not previously shown, (c) changes to existing conditions or existing conditions found to differ from those shown on the Construction Documents, (d) the actual installed position of cable, equipment, piping, conduits, light switches, electric fixtures, circuiting, ducts, dampers, access panels, openings, control valves, drains, stub-outs and similar items, and (e) such other information as the Owner may reasonably request (the "Record Documents"). This shall be done as a Basic Service within the Guaranteed Maximum Price.

§ 14.1.5 Notwithstanding anything to the contrary, any services which are required of the Design/Builder and its direct or lower tier consultants (including the Architect) due to errors or omissions of the Design/Builder or its direct or lower tier subcontractors or consultants shall not be considered Additional Services or a Cost of the Work.

§ 14.2 Compliance with Laws. In the performance of its services hereunder, the Design/Builder shall make a diligent investigation of all laws, statutes, ordinances, building codes, rules and regulations applicable to the design and construction of the Project (collectively, the "Laws"), including, without limitation, requirements of the Americans With Disabilities Act, all as interpreted and applied by governmental officials with jurisdiction over the design and construction of the Project, and any energy efficiency requirements, and shall prepare all Construction Documents and perform the Work in compliance with all Laws, to the extent in force and effect at the time the Design/Builder renders such services.

§ 14.3 Unit Prices and Allowances. Unit prices, if any, are listed in **Exhibit E** attached hereto and made a part hereof. Allowances, if any, are listed in **Exhibit F** attached hereto and made a part hereof. Unless otherwise provided in the Contract Documents, unit prices cover and allowances include all design fees, all costs of materials and equipment delivered at the site, all costs for unloading and handling at the site, all labor and installation costs, all required taxes, and all other required expenses, less applicable trade discounts. The Guaranteed Maximum Price shall be increased or decreased, as applicable, by the difference between the actual cost of the Work attributable to the allowance items listed in **Exhibit F** and the aggregate of the amounts specified in **Exhibit F** for such allowance items. If the Design/Builder determines that the cost associated with any allowance item is likely to exceed the corresponding allowance amount for such allowance item, the Design/Builder shall promptly notify the Owner in writing before incurring such cost to allow the Owner a reasonable opportunity to direct the redesign and/or reselection of such allowance item to reduce the anticipated cost of furnishing or constructing such item. Once the scope of any allowance item has been sufficiently identified to allow the Design/Builder to procure such item, and the Design/Builder has awarded subcontract(s) therefore in amounts approved by the Owner, the adjustment (if any) to the Guaranteed Maximum Price on account of such allowance item shall be established based on the amount(s) of the awarded subcontract(s) and shall no longer be subject to further adjustment in accordance with this paragraph.

§ 14.4 Changes.

§ 14.4.1 No change in the Work shall proceed and no claim for additional monies or additional time for any extra Work will be valid unless such Work is done pursuant to a written Change Order or Construction Change Directive.

§ 14.4.2 The Work included within the Guaranteed Maximum Price includes all items shown on the Contract Documents and all other items which are reasonably inferable from the Contract Documents or otherwise necessary to accomplish the design intent of the Contract Documents. By executing this Part 2 Agreement, the Design/Builder acknowledges and agrees that (a) the drawings, specifications, requirements and other information and materials describing the Project existing as of the date hereof and listed in **Exhibit G** attached hereto and made a part hereof (the "Existing Design and Requirement Documents") are anticipated to require further development, (b) the Existing Design and Requirement Documents describe the scope, construction requirements and design intent of the Work in sufficient detail to enable the Design/Builder to establish firmly the Guaranteed Maximum Price and the Contract Time, and (c) the Design/Builder has provided in the Guaranteed Maximum Price and the Contract Time for such further development consistent with the Existing Design and Requirement Documents or reasonably inferable therefrom.

§ 14.4.3 The Design/Builder shall not be permitted to claim any adjustment in the Guaranteed Maximum Price or the Contract Time in connection with any items that do not constitute an Owner Discretionary Scope Change (as hereinafter defined) or for which another provision of this Agreement entitles the Design/Builder to an equitable adjustment or a Change Order. An "Owner Discretionary Scope Change" means, and is limited to, a discretionary

Scope Change (as hereinafter defined) directed by the Owner in writing after the date of execution of this Part 2 Agreement which is not (i) dictated by legal requirements or agreements with municipal authorities, (ii) adopted in order to serve good construction practice or to satisfy any governmental official, (iii) required to correct any error, inconsistency or omission in the Construction Documents, or (iv) made to serve some other non-discretionary purpose. A "Scope Change" is hereby deemed to mean Work which is not reasonably inferable from the Existing Design and Requirement Documents or otherwise necessary to accomplish the design intent of the Existing Design and Requirement Documents to the extent such Work constitutes a change in the quantity, quality, or kind of materials, finishes or equipment, a change in programmatic requirements, or other substantial deviation from the design intent reflected in the Existing Design and Requirement Documents. For the avoidance of all doubt, and without limiting the generality of the foregoing, the Design/Builder shall not be entitled to any increase in the Guaranteed Maximum Price or any extension of the Contract Time due to errors, inconsistencies or omissions in the Construction Documents or any other problems with the Construction Documents (such as lack of construction feasibility, coordination, completeness or internal consistency).

§ 14.4.4 Unit prices, if any, shall be set forth in **Exhibit F.** Unless otherwise provided in the Contract Documents, unit prices shall cover the cost to the Design/Builder of (1) materials and equipment delivered at the site and all required taxes, less applicable trade discounts, and (2) unloading, handling and installation costs; however, unit prices do not include the Fixed Fee therefor. The GMP shall be adjusted by differences between the anticipated number of units specified in **Exhibit F** by the actual number of units incorporated in the Work, as verified by receipts.

§ 14.5 Contract Time.

§ 14.5.1 The Design/Builder shall perform and deliver the Work in accordance with the schedule for the Work attached hereto as **Exhibit B** (as amended from time to time with the written approval of the Owner or otherwise in accordance with the Contract Documents, the "Construction Schedule"), shall achieve Substantial Completion of the Work by the applicable Mandatory Substantial Completion Date, and shall achieve satisfy all conditions to final payment within thirty days following Substantial Completion Phase 2. The Construction Schedule includes dates that are critical in ensuring the timely and orderly completion of the Work in accordance with the Contract Documents. If, at any time, the performance of the Work has not progressed or reached the level of completion required by the Construction Schedule (as extended for permitted extensions of the Contract Time to which the Design/Builder is entitled), the Owner shall have the right to compel the Design/Builder to take corrective measures to expedite the progress of the Work, including, without limitation, (i) working additional shifts or overtime and/or (ii) supplying additional manpower, equipment and facilities (collectively, "Acceleration Measures") unless the Design/Builder demonstrates to the Owner's reasonable satisfaction that the Design/Builder is likely to achieve Substantial Completion of all portions of the Work for the applicable Phase by the date(s) therefor specified in the Contract Documents and Construction Schedule. Such Acceleration Measures shall be performed at no additional cost to the Owner and shall continue until the progress of the Work complies with the level of completion required by the Construction Schedule. The Design/Builder shall not be entitled to any adjustment in the GMP in connection with Acceleration Measures required by the Owner to maintain the progress required by the Construction Schedule (as extended for permitted extensions of the Contract Time).

§ 14.5.2 The Design/Builder acknowledges and agrees that, notwithstanding anything to the contrary: (i) no adjustments to the Contract Time shall be made unless events described in Section 4.5 shall have the effect of actually delaying completion of components of the Work on the critical path indicated in the Construction Schedule; (ii) adjustments to the Contract Time will be permitted in connection with any such delay only to the extent such delay (1) is not caused, or could not have been avoided, by the Design/Builder without additional costs (unless the Owner agrees in writing to cover such additional costs), (2) could not be limited or avoided by the Design/Builder's timely notice to the Owner of the delay, and (3) has no concurrent or contributing cause for which the Design/Builder would not be entitled to an extension of the Contract Time; (iii) any extension in the Construction Schedule or Contract Time shall be net of any then-available contingency or "float" time included in the Construction Schedule; and (iv) the Design/Builder shall not be entitled to any extension of the Contract Time or any increase in the Guaranteed Maximum Price on account of any labor action directed at the Design/Builder, any direct or lower tier design consultant, contractor, subcontractor, supplier or any other party for whom the Design/Builder is responsible.

§ 14.5.3 If any events entitle the Design/Builder to an extension of the Contract Time, the sole remedy of the Design/Builder shall be such extension of the Contract Time and the Design/Builder shall not be entitled to any adjustment of the Guaranteed Maximum Price, except as otherwise provided in the following sentence. If and to the extent that the Contract Time is extended on account of Compensable Delay Occurrences only, the Guaranteed Maximum Price shall be increased by the Design/Builder's reasonable and verified additional costs of performing

the Work to the extent directly and solely attributable to extensions of the Contract Time on account Compensable Delay Occurrences. As used herein, the term "Compensable Delay Occurrences" means, and is limited to, permitted extensions of the Contract Time to the extent attributable to: (i) wrongful or negligent acts or omissions of the Owner (excluding those acts or omissions taken in the exercise of rights under the Contract Documents); and (ii) Owner Discretionary Scope Changes.

§ 14.5.4 The Design/Builder acknowledges and agrees that if the Design/Builder fails to achieve Substantial Completion of the Work on or before the applicable Mandatory Substantial Completion Date (a) the Owner will sustain damages, the exact amount of which are difficult to ascertain at this time, and (b) the Owner shall be entitled to retain or recover from the Design/Builder, as liquidated damages solely for delayed Substantial Completion of either Phase of the Work and not as a penalty, (a) One Thousand Dollars ($1,000) for each calendar day commencing on the twenty-second (22nd) day after the Mandatory Phase 1 Substantial Completion Date and continuing each calendar day thereafter until the date that Substantial Completion of Phase 1 has been achieved and (b) One Thousand Dollars ($1,000) for each calendar day commencing on the twenty-second (22nd) day after the Mandatory Phase 2 Substantial Completion Date and continuing each calendar day thereafter until the date that Substantial Completion of Phase 2 has been achieved. Such liquidated damages are hereby agreed to be (i) a reasonable pre-estimate of damages the Owner will incur as a result of delayed Substantial Completion of each Phase of the Work, and (ii) the Owner's sole and exclusive damage remedy on account of the Design/Builder's delay in achieving Substantial Completion of each Phase of the Work, except as otherwise provided in this Section. Such liquidated damages are not intended to cover, and shall not limit the Owner's remedies against the Design/Builder attributable to, any cause other than a delay in achieving Substantial Completion of the Work.

§ 14.6 Completion of the Work.

§ 14.6.1 Supplementing the provisions of Section 4.3, the Owner and the Design/Builder agree that all of the following must be satisfied in order for the Work or designated portion thereof to be sufficiently complete in accordance with the Contract Documents so the Owner can occupy or utilize the Work for its intended use: (a) all Project systems included in the Work are operational as designed and specified; (b) all building systems have been successfully started-up and balanced, and reports therefor have been issued and accepted by the Owner; (c) all designated or required governmental inspections have been successfully completed (including, without limitation, all trade inspections, final Fire Marshall inspection, building inspection), and certificates of occupancy have been obtained, in each case to the extent required to occupy and use the Project for its intended use; and (d) all finishes required by the Contract Documents are in place except for Punchlist items which do not materially detract from the utility of the Project as intended, the completion or correction of which shall not interfere in any material respect with the beneficial use and occupancy of the Project as intended.

§ 14.6.2 Subject to compliance with all requirements of the Contract Documents and to the submission of Applications for Payment with supporting materials as required thereby and M.G.L c.149, Section 29F ("Retainage Law") (which Applications for Payment may be submitted for the purposes of the payment of retainage following the expiration of sixty (60) days after (i) the date of Substantial Completion of the entire Project as determined under the Contract Documents or (ii) in the case of a dispute with respect to the SC Notice, final and binding resolution of such dispute), the Owner shall, within thirty (30) days following submission of the applicable Application for Payment, release to the Design/Builder all retainage then held less the sum of: (a) for incomplete, incorrect or missing deliverables, the greater of (1) the value assigned to such deliverables in the schedule of values for the Project or (2) the reasonable value of the deliverables (which, in the case of this clause (2), shall not exceed 2.5% of the final Guaranteed Maximum Price); plus (b) for incomplete or defective work, one hundred fifty percent (150%) of the reasonable cost to complete or correct such items; plus (c) for any outstanding claims, the reasonable value of such claims plus costs and attorneys' fees. For the avoidance of doubt, the Owner shall not be required to release at Substantial Completion of the entire Project any amounts for services and Work not then complete (including, without limitation, a reasonable portion of the Guaranteed Maximum Price attributable to construction administration services and Work required to be performed by the Design/Builder following Substantial Completion of the entire Project).

§ 14.6.3 Not later than fourteen (14) days after the Design/Builder believes that Substantial Completion of each Phase of the Work has been reached, the Design/Builder shall submit to the Owner a notice of Substantial Completion (an "SC Notice") for the applicable Phase, substantially in the form required by the Retainage Law, stating the date on which the Design/Builder asserts that Substantial Completion of the applicable Phase of the Work was achieved. In transmitting such notice to the Owner, and in order to be effective for all purposes (including for triggering the fourteen (14) day review period under the Retainage Law), the transmittal shall prominently state in capital letters the following: "THE OWNER MUST ACCEPT OR REJECT THIS NOTICE OF SUBSTANTIAL COMPLETION WITHIN 14 DAYS OF RECEIPT. UNLESS THE OWNER REJECTS THIS NOTICE BY GIVING THE DESIGN/BUILDER NOTICE OF THE FACTUAL AND CONTRACTUAL BASIS FOR REJECTION AND CERTIFYING THE SAME AS MADE IN GOOD FAITH WITHIN SUCH 14 DAY PERIOD, THE OWNER SHALL BE DEEMED TO HAVE ACCEPTED THIS NOTICE."

§ 14.6.4 Simultaneously with the submission by the Design/Builder to the Owner of the SC Notice, the Design/Builder shall prepare and submit to the Owner (i) a comprehensive list of incomplete or defective Work for the applicable Phase together with the Design/Builder's estimated value of completing or correcting such Work and (ii) all certificates of occupancy, permits and approvals referred to in the Contract Documents for the applicable Phase. The Owner shall have the right to modify and supplement such list of items and to modify or, for items added by the Owner, establish, the estimated value of completing or correcting such Work. Not later than fourteen (14) days after the express or deemed acceptance of the SC Notice or, in the case of a dispute, final and binding resolution of the dispute, the Owner shall submit to the Design/Builder a written list, certified by the Owner as made in good faith, describing all incomplete or defective Work items for the applicable Phase (as modified and delivered by the Owner to the Design/Builder pursuant to this paragraph, the "Punchlist") and deliverables then required of the Design/Builder under the Contract Documents and the values assigned to such Punchlist and deliverables, which shall not exceed the limitations provided in the Retainage Law. The failure to include any items on the Punchlist does not alter the responsibility of the Design/Builder to complete all Work in accordance with the Contract Documents.

§ 14.6.5 Upon receipt of the SC Notice, the Owner will make an inspection to determine whether the Work or designated portion thereof is Substantially Complete. The Owner shall accept or reject the SC Notice within fourteen (14) days of receipt of the SC Notice. The Owner shall indicate its acceptance by signing the SC Notice in the space provided and shall deliver the signed SC Notice to the Design/Builder within the same 14-day period. If the Owner rejects the SC Notice, the Owner shall, within fourteen (14) days of receipt of the SC Notice, notify the Design/Builder in writing of the rejection and include in the rejection the factual and contractual basis for the rejection and a certification that the rejection is made in good faith. If the Design/Builder shall dispute such rejection of the SC Notice, such rejection shall be subject to dispute resolution in accordance with the dispute resolution provisions of this Agreement, which, notwithstanding any provision in the Contract Documents to the contrary, shall be commenced by the Design/Builder within seven (7) days of receipt of the rejection by the Owner of the SC Notice. The Design/Builder and Owner shall prosecute any such dispute resolution diligently, expeditiously and in good faith. Upon acceptance of an SC Notice by the Owner, the date of Substantial Completion of the Work for the applicable Phase shall be the date stated in the Design/Builder's notice for all purposes (but only for purposes) of the Retainage Law and the acceptance shall be final and binding on the Owner and its successors and assignees for all purposes (but only for purposes) of the Retainage Law. If the Design/Builder does not dispute such rejection of the SC Notice, the Design/Builder shall complete or correct the factual and contractual basis for the Owner's rejection, whereupon the process specified in this paragraph shall be repeated. Notwithstanding anything to the contrary, the Owner's acceptance or deemed acceptance of the SC Notice shall not limit or preclude the effect of any warranty, guarantee or other obligation on the part of the Design/Builder or any third party to repair, replace or correct defective Work after substantial or final completion, including without limitation, warranties and obligations set forth in the Contract Documents or in third party contracts, all of which shall remain in full force and effect after such acceptance or deemed acceptance.

§ 14.6.6 When Substantial Completion of the Work or designated portion thereof has been achieved, the Design/Builder will prepare and submit to the Owner for acceptance or rejection a Certificate of Substantial Completion that shall state the date of Substantial Completion of the applicable Phase, shall establish responsibilities of the Owner and Design/Builder for security, maintenance, heat, utilities, damage to the Work and insurance, and shall fix the time within which the Design/Builder shall finish all items on the Punchlist. Warranties required by the Contract Documents shall commence on the date of Substantial Completion of the Work or designated portion thereof set forth in the Certificate of Substantial Completion as accepted and executed by the Owner unless otherwise provided in the Certificate of Substantial Completion (without regard to any date set forth in an SC Notice or otherwise determined for purposes of the Retainage Law). The Certificate of Substantial Completion prepared by the Design/Builder shall be submitted to the Owner for the Owner's written acceptance. Similarly, the date of Substantial Completion of the Work for each Phase for purposes of determining whether Substantial Completion of the Work was achieved on or before the Mandatory Phase 1 Substantial Completion Date and Mandatory Phase 2 Substantial Completion Date and, if not, any damages arising therefrom, shall be the date of Substantial Completion of the Work for the applicable Phase set forth in the Certificate of Substantial Completion accepted by the Owner in writing, without regard to any date set forth in an SC Notice or otherwise determined for purposes of the Retainage Law (without regard to any date set forth in an SC Notice or otherwise determined for purposes of the Retainage Law).

§ 14.6.7 The Design/Builder shall achieve final completion of the Work not later than thirty (30) consecutive calendar days (or as otherwise agreed to by the Owner) following the date of Substantial Completion of the entire Project. Final completion of the Work shall not be deemed to have occurred, and final payment shall not become due and payable unless and until, all Work has been fully completed and Design/Builder has delivered to Owner, and Owner has approved, the following items: (1) conditional final lien waivers from Design/Builder, all Subcontractors and all suppliers (and, to the extent required by the Owner or the Landlord, each lower tier subcontractor and supplier) in form and substance satisfactory to the Owner demonstrating receipt by such parties of all prior payments and confirming that the only outstanding amounts payable with respect to the Work are amounts to be paid out of the final payment; and (2) the As-Built Documents and Operating Manuals. As an additional condition to be satisfied prior to final payment, the Design/Builder's personnel or Subcontractors' or suppliers' personnel, as appropriate, shall provide the property management and operations personnel at the Property with training in the operation and maintenance of building systems and controls installed as part of the Work.

§ 14.7 Subcontractors and Design Consultants.

§ 14.7.1 Following the execution of this Part 2 Agreement, the Design/Builder, with the participation of the Owner, shall select design consultants, subcontractors and suppliers who shall provide design services, labor, equipment and materials related to completion of the Work. The agreements between the Design/Builder and its subcontractors and design consultants, and any subsequent modifications, shall (a) be in writing, (b) allow the assignment described in Section 14.7.3 hereof and (c) allow termination without penalty or premium in the event of any termination of the Design/Builder's services for the Project. These agreements, including financial arrangements with respect to the Project, shall be promptly and fully disclosed to the Owner upon request. The Design/Builder shall not employ design consultants or subcontractors in the performance of the design and/or construction services under the Contract Documents without the prior written approval of the Owner as to each such design consultant and subcontractor, nor shall the Design/Builder's design or construction responsibilities under the Contract Documents be delegated, without the prior written approval of the Owner. The Design/Builder shall remain responsible for the quality and timeliness of performance of all subcontractors and design consultants. All subcontractors and design consultants shall be qualified and properly licensed to perform the design and construction services. The Design/Builder shall be responsible for all acts and omissions of the Design/Builder, its subcontractors and design consultants (including their respective agents and employees), and all other persons performing any portion of the Design/Builder's obligations under the Contract Documents.

§ 14.7.2 Supplementing the provisions of Sections 1.2.3 and 3.1.1, (a) the Owner shall be an intended third-party beneficiary of the services performed by the Design/Builder's design consultants (including the Architect), subcontractors and all parties providing labor, materials or services for the Project and (b) the contractual obligations of such persons or entities shall be undertaken and performed in the interest of the Design/Builder and the Owner.

§ 14.7.3 Each agreement between the Design/Builder and a subcontractor or design consultant is assigned by the Design/Builder to the Owner, provided that such assignment is effective only after termination of the Design/Builder's services with respect to the Project by the Owner and only for those agreements which the Owner accepts by notifying the Design/Builder and the applicable subcontractor or design consultant in writing. The Owner shall have no liability to any subcontractor or design consultant under an assigned agreement for obligations arising prior to the effectiveness of any such assignment.

§ 14.8 Liens. In the event that any direct or indirect subcontractor, supplier or any other party for whom the Design/Builder is responsible establishes a lien against the Project and/or the Project site, the Design/Builder shall, within five (5) days of receipt of notice from the Owner regarding such lien, cause the lien to be discharged (either by obtaining and recording a lien discharge bond from a surety and in a form acceptable to the Owner or otherwise) at no cost to the Owner, except to the extent any such lien is attributable to the Owner's failure to pay undisputed amounts as and when due under the Contract Documents (other than amounts for which withholding is permitted under the Contract Documents). The Owner shall have the right to withhold all payment of 200% of the amount of the lien to the Design/Builder until the lien is discharged. The Owner may either (a) apply amounts so withheld to discharging such lien or (b) retain such amounts until such lien is discharged or released by the Design/Builder or the lienor, and shall thereafter credit to the Design/Builder any amounts remaining after payment of the fees and expenses the Owner incurs in connection with such lien. The Design/Builder agrees to indemnify and hold harmless the Owner from all costs and expenses incurred by the Owner in connection with such liens, except to the extent any such lien is attributable to the Owner's failure to pay undisputed amounts as and when due under the Contract Documents (other than amounts for which withholding is permitted under the Contract Documents).

§ 14.9 Supervision. The Design/Builder shall employ a competent project manager and superintendent (individually and collectively the "Management Staff) and necessary competent assistants who shall be in attendance at the jobsite at reasonable times during the progress of the Work. The Design/Builder shall employ, and the Management Staff shall include, a competent superintendent and necessary assistants who shall be in attendance at the Project site during performance of the Work. The project manager shall be approved by the Owner. The Design/Builder's project manager shall have full authority to act on behalf of the Design/Builder. The Design/Builder shall authorize the project manager to receive and act on the Design/Builder's behalf upon instructions from the Owner given pursuant to the Contract Documents. The project manager shall represent the Design/Builder, and written communications given to him or her shall be as binding as if given to the Design/Builder.

§ 14.10 Lease. The Design/Builder acknowledges that the Work is to be performed in premises subleased by Owner from Novartis Institutes for Biomedical Research, Inc. pursuant to a prime lease with ARE-Tech Square, LLC (collectively, "Landlord"). Notwithstanding anything to the contrary in the Contract Documents, the Design/Builder acknowledges and agrees that: (a) the Design/Builder shall comply, and shall cause the Architect, Engineer, and all direct and lower tier subcontractors and suppliers to comply, with any requirements, rules or procedures imposed by Landlord, a copy of which are attached hereto as **Exhibit L** which relate to the design of the Project or performance of the Work or payment for the Work with no increase in the Guaranteed Maximum Price or extension of the Contract Time (including, without limitation, any requirement that subcontractors or suppliers be approved by Landlord); (b) Landlord, and not the Owner, shall be providing property insurance for the building where the Project is located, which property insurance shall include only the coverages and limits, and shall be subject to the terms and conditions, actually carried by the Landlord; (c) the Design/Builder shall cooperate with the Owner in connection with the Owner's efforts to satisfy any requirements imposed upon the Owner by Landlord in connection with the Work or payment for the Work with no increase in the Guaranteed Maximum Price or extension of the Contract Time, which cooperation shall include, without limitation, executing and delivering such certificates and other documentation as may be required by Landlord, (d) it shall consent to and required its Subcontractors and suppliers to consent to, and execute all documents reasonably requested by the Owner in connection with, the assignment of the Contract, the Drawings and Specifications and warranties associated with the Work to the Landlord, (e) reasonably cooperate with the Owner in obtaining the Landlord's prior approval of proposed Subcontractors before Design/Builder executes a subcontract with the same and (f) Design/Builder shall not engage any Subcontractor (of any tier) that will create any difficult, whether in the nature of a labor dispute or otherwise, with separate contractors engaged by the Owner or the Landlord. The Landlord may appoint a representative which shall have the right to inspect, or designate an agent to inspect, the Work. Without limiting the generality of the foregoing, the Design/Builder shall:

.1 Deliver a copy of the proposed Construction Documents to the Landlord for its review, comment and/or approval, provide for at least ten (10) days to receive such comments or approval from the Landlord and incorporate comments from the Landlord (as directed by the Owner) in the proposed Construction Documents.

.2 Prior to commencing the Work, deliver the following to the Owner for the benefit of the Landlord (a) a copy of the building permit to the Landlord, (b) a construction schedule with detail reasonably acceptable to the Landlord, (c) a list identifying for itself and each Subcontractor (i) the name, (ii) address, (iii) telephone number, (iv) trade, and (v) union affiliation, (d) the name and telephone number of each member of the Design/Builder's Management Staff, (e) proof of insurance required by this Part 2 Agreement, and (e) notice of any ongoing or threatened labor dispute.

.3 Design/Builder shall, and cause all persons entering the Project site, including employees of the Architect, Engineer, Subcontractors (of any tier) and suppliers, to adhere to any and all security and confidentiality requirements of the Landlord.

.4 Within 24 hours of any injury during the course of the Work, the Design/Builder shall provide a written report to the Landlord (or its designated property manager) with details reasonably acceptable to the Landlord;

.5 Upon achieving Substantial Completion of each Phase of the Work, the Design/Builder shall deliver to the Owner for the Landlord's benefit a copy of a Certificate of Substantial Completion for such Phase on the current version of the AIA Document G704.

.6 With the Design/Builder's final application for payment, deliver to the Owner for the Landlord's benefit (a) one (1) hard copy and two (2) electronic copies (in a format reasonably acceptable to the Landlord) of the final As-Build Documents, Operation and Maintenance Manuals and warranties, and (b) the final Certificate of Occupancy.

.7 Within thirty (30) days of receipt of final payment, deliver to the Landlord a final, unconditional waiver of lien from itself, the Architect, the Engineer, and each first tier Subcontractor on a form reasonably satisfactory to the Landlord.

§ 14.11 Design/Builder's Insurance.

§ 14.11.1 Supplementing Article 7 of this Agreement, the Design/Builder shall procure and maintain, at the Design/Builder's expense, the following insurance coverages (which insurance shall be placed with insurance companies having an AM Best's Rating of A or better and a Financial Size Category of X or larger and which are licensed to do business in the state where the Project is located):

(a) Workers' Compensation Insurance as required by law and Employer's Liability Insurance with minimum limits of $1,000,000 each accident for Bodily Injury by Accident, $1,000,000 each employee for Bodily Injury by Disease, and $1,000,000 policy limit for Bodily Injury by Disease. Such insurance shall be endorsed to include Other States Coverage and to include a Waiver of Our Right to Recover from Others Endorsement in favor of the Owner.

(b) Commercial General Liability Insurance, including coverage for Premises-Operations (including X-C-U), Independent Design/Builders' Protective, Products-Completed Operations, Blanket Contractual Liability, Personal Injury and Broad Form Property Damage (including coverage for Explosion, Collapse and Underground hazards), and including Cross Liability and Severability of Interests, with the following minimum limits:

(i) $1,000,000 Each Occurrence;

(ii) $2,000,000 General Aggregate;

(iii) $1,000,000 Personal and Advertising Injury; and

(iv) $2,000,000 Products-Completed Operations Aggregate.

Such policy shall be endorsed to have the General Aggregate on a per project basis. The Contractual Liability Insurance shall include coverage sufficient to meet the obligations in this Agreement.

(c) Automobile Liability Insurance (covering all owned, non-owned and hired vehicles) for bodily injury and property damage with a minimum limit of $1,000,000 combined single limit per accident.

(d) Umbrella Liability Insurance (excess of primary commercial general liability, automobile liability and employer's liability insurance) with a minimum limit of $25,000,000 each occurrence and $45,000,000 annual aggregate.

(e) Pollution Liability Insurance covering liability of the Design/Builder arising out of any sudden and/or non-sudden pollution or impairment of the environment, including clean-up costs and defense, that arise from the operations under Contract (whether by the Design/Builder or a direct or lower tier Subcontractor). Coverage under this policy shall have a limit of liability of not less than $5,000,000 each occurrence and $5,000,000 aggregate, with no exclusion or sublimit for mold and no sunset clause. Coverages under this policy shall also include, without limitation, emergency response costs, transportation coverage and non-owned disposal site (NODS) coverage.

(f) Professional Liability Insurance covering the liability of the Design/Builder for any and all errors or omissions committed in the performance of the Work. The coverage shall be maintained during the entire term of the operations, and for at least six (6) years following completion of the Project. The policy shall have limits of liability of not less than $1,000,000 per claim and in the annual aggregate, with no exclusion or sublimit for mold, and with limits reinstated annually.

(g) All Risk Property Insurance covering physical loss or damage to all property of the Design/Builder used in the performance of the Work. The policy shall have limits of liability adequate to cover all property of the Design/Builder (including personal property of others in Design/Builder's care, custody, or control) and shall include a waiver of subrogation against the Owner.

§ 14.11.2 The Design/Builder shall require the Architect, Engineers and all direct and lower tier contractors to comply with the identical insurance requirements as required of Design/Builder under clauses (a), (b), (c), (d) and (g) above and meeting the corresponding requirements of Sections 14.11.2 through 14.11.5 below; provided, however, that (i) the minimum limits of the Employer's Liability Insurance to be maintained by the Architect, Engineers and all direct and lower tier contractors shall be not less than $500,000 each accident for Bodily Injury by accident, $500,000 each employee for Bodily Injury by disease, and $500,000 policy limit for Bodily Injury by disease, (ii) the Commercial General Liability Insurance, alone or in combination with Umbrella Liability Insurance to be maintained by Subcontractors shall have limits of not less than $5,000,000 each occurrence and $5,000,000 annual aggregate unless otherwise approved by Owner in writing, (iii) the Design/Builder shall also cause the Architect, Engineers and any other contractors providing design, engineering or other professional services for the Project to carry Professional Liability Insurance with limits of liability of not less than $1,000,000 per claim and in

the annual aggregate with limits reinstated annually for at least six (6) years following completion of the Project; and (v) the Design/Builder shall cause any contractor transporting or disposing of hazardous materials or waste, as well as any disposal site operator, to carry adequate levels of pollution legal liability insurance naming the Owner and Landlord as an additional insured (complying with the terms of Section 14.11.4).

§ 14.11.3 All insurance shall be written on an occurrence basis. The "other insurance" clause shall be deleted from each policy of insurance carried by the Design/Builder and the Architect, Engineers and any other contractors so as to make it clear that the coverage of such policy is primary and any coverage under any policy or policies of insurance held by the Owner or any other Indemnitee or additional insured is secondary. Each policy of insurance carried by the Design/Builder shall be endorsed to provide a separate general aggregate limit for the Work performed under this Contract, and will, by its terms, specifically cover the entire term of this Contract. Coverages shall be maintained without interruption from the date of commencement of the Work until the date of final payment and, if later, termination of any coverage required to be maintained after final payment, and, with respect to the Design/Builder's completed operations coverage, for a minimum period equal to the greater of (a) the period under which a claim can be asserted under the applicable statutes of limitations and/or repose or (b) six (6) years after final payment. Each policy shall include an endorsement requiring that the insurance company give written notice to Owner at least thirty (30) days prior to the modification, cancellation, non-renewal or reduction in the coverage limits of such policy. The liability policies shall include a contractual liability endorsement covering the indemnification obligations under the Contract Documents.

§ 14.11.4 The Owner, Landlord, Alexandria Real Estate Equities, Inc., any lender or mortgagee with respect to the property or building affiliated with the Project, any project manager or property manager engaged by the Owner or Landlord and each of their respective trustees, officers, directors, members, managers, partners, shareholders, employees, agents and representatives, and such other persons designated by the Owner from time to time, and anyone else acting for or on behalf of any of them (using CG2010 (11/85) or equivalent, which includes coverage for each additional insured for ongoing operations and completed operations equal to the full policy limits) on all insurance policies required hereunder (except Workers' Compensation and Professional Liability Insurance), on a primary and non-contributory basis. In the event that the Design/Builder has in force any insurance coverage with coverages broader and/or limits higher than the minimum coverage amounts specified hereunder, (1) such broader and higher limits shall insure and be available to all additional insureds and (2) this Contract shall be deemed to require such broader and higher limits. The Design/Builder shall, upon demand, provide the Owner with proof that the insurance requirements have been met, which shall be in the form of either insurance policies or certificates of insurance (Accord Form 27) as directed by, and in form and substance reasonably acceptable to, the Owner. Renewal certificates for all policies that expire during the term of this Contract must also be provided at least thirty (30) days prior to each policy's respective expiration. Nothing in this Section, or any failure of Design/Builder to secure required coverages or otherwise comply with the insurance provisions of the Contract Documents, shall modify or limit the Design/Builder's liability or other obligations under the Contract Documents. In the event of any failure by Design/Builder to comply with the insurance requirements of the Contract Documents, Owner may, without any obligation to do so and without compromising or waiving any right or remedy at law or in equity, purchase such insurance at Design/Builder's expense. Any purchase of insurance by the Owner shall not relieve or excuse the Design/Builder from its obligation to obtain and maintain such insurance amounts and coverages. No deductible or self-retention amount in any insurance required to be carried by the Design/Builder hereunder shall apply to the Owner or any other additional insured. If, despite the preceding sentence, any deductible or self-insured retention amount in any such insurance does apply to the Owner or any other additional insured, the Design/Builder shall be required to fund the cost of such deductible or self-insured retention.

§ 14.11.5 Notwithstanding anything to the contrary in the Contract Documents, the Design/Builder, the Architect, Engineers and any other contractors, collectively and individually hereby waive all rights of recovery (including rights of subrogation) against the Owner and each other additional insured, and the trustees, beneficiaries, officers, directors, shareholders, members, managers, partners, principals, employees and agents of any of them, and their respective agents, representatives and servants, for any claim, injury, loss or damage arising from any occurrence that (1) is covered by any insurance maintained by the Design/Builder the Architect, Engineers, contractor or (2) would have been covered by any insurance required to be maintained by the Design/Builder the Architect, Engineers, contractor under the Contract Documents. All of the Design/Builder's insurance policies and the policies the Architect, Engineers, contractor shall include a waiver of subrogation clause or endorsement denying to the insurer rights of subrogation against the Owner and such other parties. The provisions of this paragraph shall be deemed incorporated into each subcontract to the extent necessary to achieve the result intended.

§ 14.12 Owner's Insurance. Notwithstanding anything to the contrary in the Contract Documents: (a) the Owner's property insurance shall not be required to cover portions of the Work stored off site or portions of the Work in transit; (b) the Owner shall have the sole right to adjust and settle claims with its property insurers and shall have no obligation to post any bond for performance of its duties; (c) although the Owner shall be required to act in good faith in adjusting any claims with its property insurers and thereafter applying any insurance proceeds received from its property insurers, the Owner shall not be a fiduciary of the Design/Builder or any subcontractor or design consultant; (d) the Design/Builder (and not the Owner) shall be required to pay for all losses within deductibles for all causes other than Acts of God (which deductible shall not exceed $2,500 per occurrence); (e) any liability insurance maintained by the Owner is and shall be secondary to and excess of any insurance maintained by the Design/Builder or any subcontractor or design consultant; and (f) the Owner may satisfy its obligation to deliver evidence of the property insurance by delivering certificates of insurance rather than copies of the underlying insurance policies.

§ 14.13 Key Personnel. The following members of the Design/Builder's staff assigned to and primarily responsible for supervising and/or performing the Work have been presented by the Design/Builder to, and approved by, the Owner:

Name	Position
Keith Kerr	Project Manager
Matt Birmingham	Project Superintendent

Such key members of the Design/Builder's staff shall not be changed without the written consent of the Owner, unless such person becomes unable to perform his or her duties due to death, disability or termination of employment, or unless the Owner requests removal. If a key member is no longer capable of performing, or is removed by the Owner, the Owner and the Design/Builder shall agree on a mutually acceptable substitute.

§14.14 [Intentionally omitted.]

§ 14.15 Owner's Audit Rights. The Design/Builder shall keep full and detailed accounts and exercise such controls as may be necessary for proper financial management under this Part 2 Agreement, and the accounting and control systems shall be satisfactory to the Owner. The Owner or its representatives shall have the right to audit, examine, and copy, at reasonable times and places, all records, books, correspondence, instructions, drawings, receipts, subcontracts, purchase orders, vouchers, memoranda and other data relating to this Part 2 Agreement, the Project and the Work, and the Design/Builder shall preserve these for a period of three (3) years after final payment, or for such longer period as may be required by law; provided, however, that such right shall be limited to the extent Owner deems necessary to determine or confirm matters relating to any adjustment to the Guaranteed Maximum Price (whether arising from changes in the Work or otherwise) or the cost of any Work performed on a cost plus or time and materials basis. The Design/Builder shall require the Architect, Engineers and all contractors to comply with the provision of this Section 14.15 by insertion of the provisions hereof in each subcontractor; provided, however, that the Owner's right to review and audit records of lump sum subcontractors shall be limited to the extent necessary to confirm adjustments in the subcontract amounts or for any work performed on a cost plus or time and material basis. If any inspection or audit by the Owner reveals an overcharge, the Design/Builder shall pay the Owner upon demand an amount equal to such overcharge, as reimbursement for said overcharge (whether before or after final payment).

§ 14.16 [Intentionally omitted].

§ 14.17 Certificates. The Design/Builder shall, upon the request of the Owner and without additional consideration, execute and/or deliver (and cause any subcontractor or design consultant to execute or deliver) any certificates reasonably requested in connection with the financing, leasing, permitting or development of the Project (including, without limitation, certifications regarding the compliance of the Project with all applicable codes, ordinances, rules and regulations of all public authorities having jurisdiction over the Project, such as building code and life safety code); provided, however, that Design/Builder will not be required to execute certificates that would require knowledge, services or responsibilities beyond the scope of this Part 2 Agreement.

§ 14.18 Reproduction of Construction Documents. The Design/Builder shall provide the Owner with three hard copy and one electronic copy of the complete set of the Construction Documents. The Design/Builder shall arrange for the reproduction of the Contract Documents and Construction Documents as necessary, and the cost of such reproduction shall be included within the Guaranteed Maximum Price.

§ 14.19 Non-Recourse. No partner, member, manager, shareholder, director, officer, agent, representative or employee of the Owner or Design/Builder, or any of the foregoing shall have any personal liability arising out of the Contract Documents or the Project.

§ 14.20 Owner's Representative; Design/Builder's Representative. The Owner shall designate in writing a representative who shall have express authority to bind the Owner with respect to all matters requiring the Owner's approval or authorization (the "Owner's Representative"). Notwithstanding anything to the contrary: (a) no party (including, without limitation, any project manager selected by the Owner) other than the person(s) designated as Owner's Representative(s) from time to time shall have authority to take any action, make any agreement, give any instruction or otherwise make any commitment on the Owner's behalf that would result in (i) an increase of the Guaranteed Maximum Price, (ii) an extension of the Contact Time or (iii) a change in the scope of the Work; and (b) whenever any approval, assent, consent or commitment of the Owner is requested or required with respect to the items listed in the foregoing clause (a) of this sentence, the approval, assent, consent or commitment must be in writing and signed by one of the person(s) designated as the Owner's Representative(s) from time to time. The Owner shall have the right to change any such Owner's Representative(s) and/or add additional Owner's Representative(s) by written notice to the Design/Builder.

§ 14.21 Notices. Any notice provided for herein shall be in writing and shall be delivered by hand or sent by certified mail (return receipt requested) or a nationally recognized delivery service that obtains delivery receipts. Notices to the Owner shall be sent to the Owner's Representative (at the address specified for the Owner's Representative in this Part 2 Agreement), with copies to:

Magenta Therapeutics, Inc.
50 Hampshire Street, 8th Floor
Cambridge, MA 02139
Attn: Chief Legal Officer

Notices to the Design/Builder shall be sent to the Design/Builder at the address for the Design/Builder's Representative specified in this Part 2 Agreement. Either party can change their address for notices by delivering written notice of such change to the other party. A hand-delivered notice shall be effective upon delivery; a notice sent by certified mail shall be effective three (3) days after mailing; and a notice by overnight delivery service shall be effective as of the date of delivery as confirmed by the delivery receipt.

§ 14.22 Counterparts. This Part 2 Agreement may be executed in one or more counterparts, each of which shall be deemed an original binding on the parties hereto.

List of Schedules and Exhibits

Exhibit A	Initial Schedule of Values
Exhibit B	Construction Schedule
Exhibit C	Form Partial Waiver and Subordination of Lien with Owner's Supplement
Exhibit D	Form Payment Acknowledgement and Lien Waiver
Exhibit E	Not used
Exhibit F	Allowances
Exhibit G	Existing Design and Requirement Documents
Exhibit H	General Conditions Items
Exhibit I	Not used
Exhibit J	Not used
Exhibit K	Hourly Wages of Design/Builder's, Architect's and Engineer's Personnel
Exhibit L	Landlord Rules, Regulations and Design Requirements
Exhibit M	Phase Drawing

This Agreement entered into as of the day and year first written above.

OWNER	**DESIGN/BUILDER**
Magenta Therapeutics, Inc.	**The Richmond Group, Inc.**
/s/ Christina Isacson	/s/ David Mello
(signature)	*(Signature)*
Christina Isacson, Chief Business Officer	David Mello, Executive Vice President
Christina Isacson	
(Printed name and title)	*(Printed name and title)*
/s/ Zoran Zdraveski	
(Signature)	
Zoran Zdraveski, Chief Legal Officer	
(Printed name and title)	

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(A) / RULE 15D-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Jason Gardner, D.Phil., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Magenta 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) (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: November 8, 2018

/s/ Jason Gardner
Jason Gardner, D.Phil.
Director, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13A-14(A) / RULE 15D-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Cindy Driscoll, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Magenta 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) (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: November 8, 2018

/s/ Cindy Driscoll
Cindy Driscoll
Treasurer, Vice President, Finance
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Quarterly Report on Form 10-Q of Magenta Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his or her knowledge:

1. the Report 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.

Dated: November 8, 2018

/s/ Jason Gardner
Jason Gardner, D.Phil.
Director, President and Chief Executive Officer
(Principal Executive Officer)

/s/ Cindy Driscoll
Cindy Driscoll
Treasurer, Vice President, Finance
(Principal Financial and Accounting Officer)