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

FORM 10-Q

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

For the quarterly period ended June 30, 2019

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 001-38191

MUSTANG BIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-3828760**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address including zip code of principal executive offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	MBIO	NASDAQ Global Market

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

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

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

Class of Common Stock	**Outstanding Shares as of August 8, 2019**
Class A Common Stock, $0.0001 par value	862,392
Common Stock, $0.0001 par value	39,587,963

MUSTANG BIO, INC.
QUARTERLY REPORT ON FORM 10-Q
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Item 1. Unaudited Condensed Financial Statements

MUSTANG BIO, INC.
Condensed Balance Sheets
($ in thousands, except for share and per share amounts)

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 82,634	$ 16,469
Short-term investments (certificates of deposit)	-	17,604
Other receivables - related party	128	-
Prepaid expenses and other current assets	660	1,052
Total current assets	83,422	35,125
Property, plant and equipment, net	6,513	6,465
Fixed assets - construction in process	699	393
Restricted cash	500	500
Other assets	250	271
Operating lease right-of-use asset, net	1,241	-
Total Assets	**$ 92,625**	**$ 42,754**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,452	$ 5,381
Payables and accrued expenses - related party	759	236
Operating lease liabilities - short-term	157	-
Total current liabilities	6,368	5,617
Deferred rent payable	-	741
Notes payable	12,951	-
Operating lease liabilities - long-term	1,862	-
Total Liabilities	**21,181**	**6,358**
Commitments and Contingencies		
Stockholders' Equity		
Preferred stock ($0.0001 par value), 2,000,000 shares authorized, 250,000 shares of Class A preferred stock issued and outstanding as of June 30, 2019, and December 31, 2018	-	-
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Class A common shares, 862,392 and 1,000,000 shares issued and outstanding as of June 30, 2019, and December 31, 2018, respectively	-	-
Common shares, 39,454,316 and 26,610,183 shares issued and outstanding as of June 30, 2019, and December 31, 2018, respectively	4	3
Common stock issuable, 0 and 709,314 shares as of June 30, 2019, and December 31, 2018, respectively	-	2,085
Additional paid-in capital	170,522	113,378
Accumulated deficit	(99,082)	(79,070)
Total Stockholders' Equity	**71,444**	**36,396**
Total Liabilities and Stockholders' Equity	**$ 92,625**	**$ 42,754**

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

MUSTANG BIO, INC.
Condensed Statements of Operations
($ in thousands, except for share and per share amounts)
(Unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue - related party	$ -	$ -	$ -	$ 50
Operating expenses:				
Research and development	6,823	3,557	13,783	7,849
Research and development - licenses acquired	200	-	650	75
General and administrative	3,189	1,683	5,533	3,793
Total operating expenses	10,212	5,240	19,966	11,717
Loss from operations	(10,212)	(5,240)	(19,966)	(11,667)
Other income (expense)				
Interest income	387	147	539	293
Interest expense	(574)	-	(585)	-
Total other income (expense)	(187)	147	(46)	293
Net Loss	**$ (10,399)**	**$ (5,093)**	**$ (20,012)**	**$ (11,374)**
Net loss per common share outstanding, basic and diluted	$ (0.29)	$ (0.19)	$ (0.62)	$ (0.43)
Weighted average number of common shares outstanding, basic and diluted	36,306,710	27,087,918	32,149,352	26,731,616

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

MUSTANG BIO, INC.
Condensed Statements of Stockholders' Equity
($ in thousands, except for share amounts)
(Unaudited)

For the Three Months Ended June 30, 2019

	Class A Preferred Stock		Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at March 31, 2019	**250,000**	**$ -**	**1,000,000**	**$ -**	**27,561,433**	**$ 3**	**$ -**	**$ 117,158**	**$ (88,683)**	**$ 28,478**
Conversion of Class A common shares to common shares	-	-	(137,608)	-	137,608	-	-	-	-	-
Issuance of common shares, net of offering costs - At-the-Market Offering	-	-	-	-	3,506,222	-	-	21,972	-	21,972
Issuance of common shares - Equity fee on At-the-Market Offering	-	-	-	-	87,656	-	-	495	-	495
Issuance of common shares, net of offering costs - Public Offering	-	-	-	-	7,906,250	1	-	29,484	-	29,485
Issuance of common shares - Equity fee on Public Offering	-	-	-	-	197,656	-	-	791	-	791
Stock-based compensation expenses	-	-	-	-	50,000	-	-	622	-	622
Exercise of warrants	-	-	-	-	7,491	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	(10,399)	(10,399)
Balances at June 30, 2019	**250,000**	**$ -**	**862,392**	**$ -**	**39,454,316**	**$ 4**	**$ -**	**$ 170,522**	**$ (99,082)**	**$ 71,444**

For the Six Months Ended June 30, 2019

	Class A Preferred Stock		Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2018	**250,000**	**$ -**	**1,000,000**	**$ -**	**26,610,183**	**$ 3**	**$ 2,085**	**$ 113,378**	**$ (79,070)**	**$ 36,396**
Issuance of common shares - Founders Agreement	-	-	-	-	709,314	-	(2,085)	2,085	-	-
Issuance of common shares - Equity fee on Horizon Notes to Fortress Biotech	-	-	-	-	108,069	-	-	375	-	375
Issuance of warrants - Horizon Notes	-	-	-	-	-	-	-	888	-	888
Conversion of Class A common shares to common shares	-	-	(137,608)	-	137,608	-	-	-	-	-
Issuance of common shares, net of offering costs - At-the-Market Offering	-	-	-	-	3,506,222	-	-	21,972	-	21,972
Issuance of common shares - Equity fee on At-the-Market Offering	-	-	-	-	87,656	-	-	495	-	495
Issuance of common shares, net of offering costs - Public Offering	-	-	-	-	7,906,250	1	-	29,484	-	29,485
Issuance of common shares - Equity fee on Public Offering	-	-	-	-	197,656	-	-	791	-	791
Stock-based compensation expenses	-	-	-	-	126,000	-	-	1,054	-	1,054
Exercise of warrants	-	-	-	-	65,358	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	(20,012)	(20,012)
Balances at June 30, 2019	**250,000**	**$ -**	**862,392**	**$ -**	**39,454,316**	**$ 4**	**$ -**	**$ 170,522**	**$ (99,082)**	**$ 71,444**

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

MUSTANG BIO, INC.
Condensed Statements of Stockholders' Equity
($ in thousands, except for share amounts)
(Unaudited)

For the Three Months Ended June 30, 2018

	Class A Preferred Stock		Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at March 31, 2018	**250,000**	**$ -**	**1,000,000**	**$ -**	**26,101,554**	**$ 3**	**$ -**	**$ 110,328**	**$ (54,689)**	**$ 55,642**
Stock-based compensation expenses	-	-	-	-	150,000	-	-	971	-	971
Exercise of warrants	-	-	-	-	11,800	-	-	85	-	85
Net loss	-	-	-	-	-	-	-	-	(5,093)	(5,093)
Balances at June 30, 2018	**250,000**	**$ -**	**1,000,000**	**$ -**	**26,263,354**	**$ 3**	**$ -**	**$ 111,384**	**$ (59,782)**	**$ 51,605**

For the Six Months Ended June 30, 2018

	Class A Preferred Stock		Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2017	**250,000**	**$ -**	**1,000,000**	**$ -**	**25,236,255**	**$ 3**	**$ 9,558**	**$ 98,679**	**$ (48,408)**	**$ 59,832**
Issuance of common shares - Founders Agreement	-	-	-	-	834,756	-	(9,558)	9,558	-	-
Stock-based compensation expenses	-	-	-	-	150,000	-	-	2,966	-	2,966
Exercise of warrants	-	-	-	-	42,343	-	-	181	-	181
Net loss	-	-	-	-	-	-	-	-	(11,374)	(11,374)
Balances at June 30, 2018	**250,000**	**$ -**	**1,000,000**	**$ -**	**26,263,354**	**$ 3**	**$ -**	**$ 111,384**	**$ (59,782)**	**$ 51,605**

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

MUSTANG BIO, INC.
Condensed Statements of Cash Flows
($ in thousands)
(Unaudited)

	For the six months ended June 30, 2019	For the six months ended June 30, 2018
Cash Flows from Operating Activities:		
Net loss	$ (20,012)	$ (11,374)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of debt discount	232	-
Issuance of common shares - Equity fee on At-the-Market Offering to Fortress Biotech	495	-
Issuance of common shares - Equity fee on Public Offering to Fortress Biotech	791	-
Issuance of common shares - Equity fee on Horizon Notes to Fortress Biotech	375	-
Research and development - licenses acquired	650	75
Stock-based compensation expenses	1,054	2,966
Depreciation expense	588	122
Amortization of operating lease right-of-use assets	65	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	413	(957)
Interest receivables	-	(303)
Other receivables - related party	(128)	-
Accounts payable and accrued expenses	(279)	155
Payables and accrued expenses - related party	523	50
Deferred rent	-	345
Lease liabilities	(28)	-
Net cash used in operating activities	(15,261)	(8,921)
Cash Flows from Investing Activities:		
Purchase of short-term investment (certificates of deposit)	-	(35,000)
Maturity of certificate of deposit	17,604	26,002
Purchase of research and development licenses	(450)	(75)
Purchase of fixed assets	(955)	(5,418)
Net cash provided by (used in) investing activities	16,199	(14,491)
Cash Flows from Financing Activities:		
Proceeds from Horizon Notes	15,000	-
Debt issuance costs	(1,230)	-
Proceeds from exercise of warrants	-	181
Proceeds from issuance of common shares - At-the-Market Offering	22,515	-
Offering costs for the issuance of common shares - At-the-Market Offering	(543)	-
Proceeds from issuance of common shares - Public Offering	31,625	-
Offering costs for the issuance of common shares - Public Offering	(2,140)	-
Net cash provided by financing activities	65,227	181
Net change in cash, cash equivalents and restricted cash	66,165	(23,231)
Cash, cash equivalents and restricted cash, beginning of the period	16,969	35,475
Cash, cash equivalents and restricted cash, end of the period	**$ 83,134**	**$ 12,244**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 341	$ -
Supplemental disclosure of noncash investing and financing activities:		
Fixed assets (acquired but not paid)	$ 183	$ 818
Unpaid debt issuance costs	$ 163	-
Issuance of common shares - Founders Agreement	$ 2,085	$ 9,558
Research and development licenses included in accounts payable and accrued expenses	$ 200	$ -
Issuance of warrants - Horizon Notes	$ 888	$ -

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

Mustang Bio, Inc.
Notes to the Condensed Financial Statements
(Unaudited)

Note 1 - Organization, Description of Business and Liquidity and Capital Resources

Mustang Bio, Inc. (the "Company" or "Mustang") was incorporated in Delaware on March 13, 2015. Mustang is as a clinical-stage biopharmaceutical company focused on translating today's medical breakthroughs in cell and gene therapy into potential cures for hematologic cancers, solid tumors and rare genetic diseases. The Company may acquire rights to these technologies by licensing the rights or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

The Company is a majority-controlled subsidiary of Fortress Biotech, Inc. ("Fortress" or "Parent").

The Company's common stock is listed on the NASDAQ Global Market and trades under the symbol "MBIO".

Liquidity and Capital Resources

The Company has incurred substantial operating losses and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2019, the Company had an accumulated deficit of $99.1 million.

During the three and six months ended June 30, 2019, the Company issued approximately 3.5 million shares of common stock under an At-the-Market Issuance Sales Agreement for aggregate total gross proceeds of approximately $22.5 million at an average selling price of $6.42 per share, resulting in net proceeds of approximately $22.0 million after deducting commissions and other transactions costs. Also during the three and six months ended June 30, 2019, the Company issued approximately 7.9 million shares of common stock through an underwritten public offering for aggregate total gross proceeds of approximately $31.6 million at a price of $4.00 per share, resulting in net proceeds of approximately $29.5 million after deducting commissions and other transactions costs.

The Company has funded its operations to date primarily through the sale of equity and its venture debt financing agreement (the "Loan Agreement") with Horizon Technology Finance Corporation ("Horizon"), herein referred to as the "Horizon Notes". The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, including financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its cash and cash equivalents balances at June 30, 2019 are sufficient to fund its anticipated operating cash requirements for at least one year from the date of this Form 10-Q.

The Company will be required to expend significant funds in order to advance the development of its product candidates. The Company will require additional financings through equity and debt offerings, collaborations and licensing arrangements or other sources to fully develop, prepare regulatory filings, obtain regulatory approvals and commercialize its existing and any new product candidates.

Note 2 - Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. They may not include all of the information and footnotes required by GAAP for complete financial statements. Therefore, these financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2018, which were included in the Company's Form 10-K and filed with the SEC on March 18, 2019. The results of operations for any interim periods are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Use of Estimates

The Company's unaudited condensed financial statements include certain amounts that are based on management's best estimates and judgments. The Company's significant estimates include, but are not limited to, assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Due to the uncertainty inherent in such estimates actual results could differ from those estimates.

Research and Development Costs

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings, laboratory costs and other supplies.

In accordance with Accounting Standards Codification ("ASC") 730-10-25-1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. Such licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and have no alternative future use.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies previously disclosed in the Company's Form 10-K filed with the SEC on March 18, 2019, with the exception of the adoption of the Financial Accounting Standards Board (FASB) Accounting Standard Updates (ASU) ASU 2016-02, *Leases,* and 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*

Leases

Effective January 1, 2019, the Company accounts for its leases under ASC 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheet as both a right of use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right of use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right of use asset result in straight-line rent expense over the lease term. Variable lease expenses are recorded when incurred. In calculating the right of use asset and lease liability, the Company elects to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

The Company continues to account for leases in the prior period financial statements under ASC Topic 840.

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates.

For stock-based compensation awards to non-employees, prior to the adoption of ASU 2018-07 on January 1, 2019, the Company remeasured the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards were recognized as compensation expense in the period of change. Subsequent to the adoption of ASU 2018-07, the Company recognizes non-employee compensation costs over the requisite service period based on a measurement of fair value for each stock award.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model or 409A valuations, as applicable. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326)*: Measurement of Credit Losses on Financial Instruments. ASU 2016-13 requires that expected credit losses relating to financial assets are measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective on January 1, 2020 and may be adopted earlier. The Company is currently evaluating the impact, if any, that ASU 2016-13 will have on its condensed consolidated financial statements and related disclosures.

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-13, *Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its condensed financial statements.

Recently Adopted Accounting Standards

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule became effective on November 5, 2018. The Company included the required presentation of changes in stockholders' equity in this Form 10-Q.

In June 2018, the FASB issued ASU 2018-07, *"Improvements to Nonemployee Share-Based Payment Accounting"*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU No. 2018-07 as of January 1, 2019. The adoption of this update did not have a material impact on the Company's condensed financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and 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*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The adoption of this ASU on January 1, 2019, did not have a material impact on its condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods), using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carry forward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019, rather than as of the earliest period presented, and elected the package of practical expedients described above. Based on the analysis, on January 1, 2019, the Company recorded right of use assets of approximately $1.2 million, lease liability of approximately $2.0 million and eliminated deferred rent of approximately $0.7 million.

Mustang Bio, Inc.
Notes to the Condensed Financial Statements
(Unaudited)

Note 3 - License, Clinical Trial and Sponsored Research Agreements

Research and Development Expenses - All Licenses

For the three and six months ended June 30, 2019 and 2018, the Company recorded the following expense in research and development for licenses acquired:

	For the three months ended June 30,		For the six months ended June 30,	
($ in thousands)	**2019**	**2018**	**2019**	**2018**
City of Hope				
CD123	$ -	$ -	$ 250	$ -
CS1	200	-	200	-
Manufacturing	-	-	-	75
Nationwide Children's Hospital - C134	-	-	200	-
Total	$ 200	$ -	$ 650	$ 75

License Agreements

City of Hope

CS1 License (MB-104)

In May 2017, the Company entered into an exclusive license agreement with the City of Hope National Medical Center ("COH") for the use of CS1-specific chimeric antigen receptor ("CAR") engineered T cell ("CAR T") technology. Pursuant to this agreement, the Company paid an upfront fee of $0.6 million and pays an annual maintenance fee of $50,000. Additional payments are due for the achievement of ten development milestones totaling $14.9 million and royalty payments in the mid-single digits are due on net sales of licensed products.

In May 2019 the Company expensed a non-refundable milestone payment of $0.2 million upon the first patient dosed in a Phase 1 clinical study of CS1.

CD123 License (MB-102)

In February 2017, the Company entered into an Amended and Restated Exclusive License Agreement with the COH to acquire intellectual property rights pertaining to CD123-specific CAR T technology. Pursuant to this agreement, the Company and COH acknowledged that an upfront fee was previously paid. In addition, COH is eligible to receive an annual maintenance fee of $25,000 and milestone payments totaling $14.5 million upon the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products.

In the first quarter of 2019, the Company expensed a non-refundable milestone payment of $0.3 million upon the twelfth patient dosed in a Phase 1 clinical study of CD123.

Nationwide Children's Hospital

In February 2019, Mustang announced that it partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital ("Nationwide") to develop their C134 oncolytic virus (MB-108) for the treatment of glioblastoma multiforme ("GBM"). Mustang intends to combine MB-108 with MB-101 (IL13Rα2-specific CAR T) to potentially enhance efficacy in treating GBM. The Company paid $0.2 million in consideration for the license to exclusive, worldwide rights to develop and commercialize products that incorporate data, know-how and/or MB-108 that were developed at Nationwide. Additional payments are due to Nationwide upon achievement of development and commercialization milestones totaling $152.8 million. Royalty payments in the low-single digits are due on net sales of licensed products.

Research and Development Expenses - Sponsored Research and Clinical Trial Agreements

For the three and six months ended June 30, 2019 and 2018, the Company recorded the following expense in research and development for sponsored research and clinical trial agreements:

	For the three months ended June 30,		For the six months ended June 30,	
	2019	**2018**	**2019**	**2018**
($ in thousands)				
City of Hope	$ 500	$ 500	$ 1,000	$ 1,000
City of Hope - CD123	456	114	759	264
City of Hope - IL13Rα2	225	143	567	503
City of Hope - Manufacturing	115	115	229	229
Fred Hutch - CD20	374	418	641	684
BIDMC - CRISPR	-	-	69	-
Total	$ 1,670	$ 1,290	$ 3,265	$ 2,680

Note 4 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

In connection with the Company's, Management Services Agreement (the "MSA") with Fortress for the three and six months ended June 30, 2019 and 2018, respectively, expenses related to the MSA are recorded 50% in research and development expenses and 50% in general and administrative expenses on the condensed statement of operations.

Under the terms of the Second Amended and Restated Founders Agreement, which became effective July 22, 2016, Fortress will receive a grant of shares of our common stock equal to two and one-half percent (2.5%) of the gross amount of any equity or debt financing. In March 2019, the Company issued 108,069 shares of common stock to Fortress, which equaled 2.5% of the gross funded amount of the Horizon Notes. The Company recorded an expense of approximately $0.4 million in general and administrative expenses related to these shares during the six months ended June 30, 2019.

In April 2019, the Company issued 87,656 shares of common stock to Fortress, which equaled 2.5% of the gross proceeds of $22.5 million from the sale of shares of common stock under Mustang's At-the-Market Offering. The Company recorded an expense of approximately $0.5 million in general and administrative expenses related to these shares during the six months ended June 30, 2019.

In May 2019, the Company issued 197,656 shares of common stock to Fortress, which equaled 2.5% of the gross proceeds of $31.6 million from the sale of shares of common stock, before deducting underwriting discounts and commissions and offering expenses under Mustang's Public Offering. The Company recorded an expense of approximately $0.8 million in general and administrative expenses related to these shares during the six months ended June 30, 2019.

City of Hope

In April 2019, COH converted 137,608 shares of the Company's Class A common stock to 137,608 shares of the Company's common stock. COH owns 862,392 shares of the Company's Class A common stock and 431,196 shares of the Company's common stock, representing approximately 3.2% of the Company's outstanding capital stock, and has the right to appoint a director to the Company's Board of Directors (the "Board"). As such, the Company considers COH to be a related party, due to the foregoing rights and ownership, as well as the high proportion of the Company's assets that are licensed from COH.

Payable and Accrued Expenses Related Party

In the normal course of business Fortress pays for certain expenses on behalf of the Company. Such expenses are recorded as Payable and accrued expenses - related party and are reimbursed to Fortress in the normal course of business.

Note 5 - Property and Equipment

Mustang's property and equipment consisted of the following ($ in thousands):

	Estimated Useful Life (in years)	June 30, 2019	December 31, 2018
Computer equipment	3	$ 53	$ 53
Furniture and fixtures	5	137	111
Machinery and equipment	5	3,666	3,143
Leasehold improvements	9	3,877	3,790
Construction in process	N/A	699	393
Total property and equipment		8,432	7,490
Less: accumulated depreciation		(1,220)	(632)
Property and equipment, net		$ 7,212	$ 6,858

Mustang's depreciation expense for the three months ended June 30, 2019 and 2018, was approximately $0.3 million and $0.1 million, respectively, and was recorded in research and development expense in the Condensed Statements of Operations. Mustang's depreciation expense for the six months ended June 30, 2019 and 2018, was approximately $0.6 million and $0.1 million, respectively, and was recorded in research and development expense in the Condensed Statements of Operations.

Note 6 - Commitments and Contingencies

None.

Note 7 - Notes Payable

On March 29, 2019 (the "Closing Date"), the Company entered into a $20.0 million Loan Agreement with Horizon, the proceeds of which will provide the Company with additional working capital to continue development of its gene and cell therapies. In accordance with the Loan Agreement, $15.0 million of the $20.0 million loan was funded on the Closing Date, with the remaining $5.0 million fundable upon the Company achieving certain predetermined milestones.

Each advance under the Horizon Loan Agreement will mature 42 months from the first day of the month following the funding of the advance. The first three advances will mature on October 1, 2022 (the "Loan Maturity Date"). Each advance accrues interest at a per annum rate of interest equal to 9.00% plus the amount by which the one-month LIBOR Rate, as reported in the Wall Street Journal, exceeds 2.50%. The Loan Agreement provides for interest-only payments commencing May 1, 2019, through and including October 1, 2020. The interest-only period may be extended to April 1, 2021, if the Company satisfies the Interest Only Extension Milestone (as defined in the Loan Agreement). Thereafter, commencing May 1, 2021, amortization payments will be payable monthly in eighteen installments of principal and interest. At its option, upon ten business days' prior written notice to Horizon, the Company may prepay all or any portion greater than or equal to $500,000 of each of the outstanding advances by paying the entire principal balance (or portion thereof) and all accrued and unpaid interest, subject to a prepayment charge of 4.0% of the then outstanding principal balance of each advance if such advance is prepaid on or before the Loan Amortization Date (as defined in the Loan Agreement), 3% if such advance is prepaid after the Loan Amortization Date applicable to such Loan, but on or prior to twelve months following the Loan Amortization Date, and 2% thereafter. In addition, a final payment equal to $250,000 for each advance (i.e., $750,000 in aggregate with respect to the initial $15.0 million) is due on the maturity date or other date of payment in full. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding.

Each advance of the loan is secured by a lien on substantially all of the assets of the Company, other than Intellectual Property and Excluded Collateral (in each case as defined in the Loan Agreement), and contains customary covenants and representations, including a liquidity covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Loan Agreement include, among other things, without limitation, and subject to customary grace periods, (1) the Company's failure to make any payments of principal or interest under the Loan Agreement, promissory notes or other loan documents, (2) the Company's breach or default in the performance of any covenant under the Loan Agreement, (3) the occurrence of a material adverse change, (4) the Company making a false or misleading representation or warranty in any material respect, (5) the Company's insolvency or bankruptcy, (6) certain attachments or judgments on the Company's assets, (7) the occurrence of any material default under certain agreements or obligations of the Company involving indebtedness in excess of $250,000, or (8) failing to maintain certain minimum monthly cash balances which range from approximately $8 to $13 million over the term of the loan. If an event of default occurs, Horizon is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Loan Agreement also contains warrant coverage of 5% of the total amount funded. Four warrants (the "Warrants") were issued by the Company to Horizon to purchase a combined 288,184 shares of the Company's common stock with an exercise price of $3.47 and a fair value of $0.9 million. The Warrant is exercisable for ten years from the date of issuance. Horizon may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. The shares of the Company's common stock will, upon request by Horizon, be registered and freely tradeable following a period of six months after issuance.

The Company paid Horizon an initial commitment fee of $0.2 million and reimbursed Horizon for $30,000 of legal fees in connection with the Loan Agreement. The Company incurred approximately $1.2 million of legal and other direct costs in connection with the Loan Agreement.

All fees, warrants and costs paid to Horizon and all direct costs incurred by the Company are recognized as a debt discount to the funded loans and are amortized to interest expense using the effective interest method over the term of the Loan Agreement.

Amortization of the debt discount associated with the funded loans was approximately $0.2 million during the three and six months ended June 30, 2019, and was included in interest expense in the Condensed Statements of Operations.

($ in thousands)	June 30, 2019	December 31, 2018	Interest Rate	Maturity
Horizon Notes *(1)*	$ 15,750	$ -	9.00%	October - 2022
Less: Discount on notes payable	2,799	-		
Total notes payable	$ 12,951	$ -		

(1) Balance includes $0.75 million final payment fee

Note 8 - Leases

On October 27, 2017, Mustang entered into a lease agreement with WCS - 377 Plantation Street, Inc., a Massachusetts nonprofit corporation. Pursuant to the terms of the lease agreement, Mustang agreed to lease 27,043 sf from the landlord, located at 377 Plantation Street in Worcester, MA (the "Facility"), through November 2026, subject to additional extensions at Mustang's option. Base rent, net of abatements of $0.6 million over the lease term, totals approximately $3.6 million, on a triple-net basis.

The terms of the lease also require that Mustang post an initial security deposit of $0.8 million, in the form of $0.5 million letter of credit and $0.3 million in cash, which shall increase to $1.3 million ($1.0 million letter of credit, $0.3 million in cash) when the Facility is fully occupied by Mustang. After the fifth lease year, the letter of credit obligation is subject to reduction.

The Facility began operations for the production of personalized CAR T and gene therapies in 2018.

The Company leases office space and copiers under agreements classified as operating leases that expire on various dates through 2026. Most of the Company's lease liabilities result from the lease of its Facility in Massachusetts, which expires in 2026, and its copiers, which expires in 2021. Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right of use assets as the Company is not reasonably certain to exercise the options. The Company does not act as a lessor or have any leases classified as financing leases. At June 30, 2019, the Company had operating lease liabilities of $2.0 million and right of use assets of $1.2 million, which were included in the condensed balance sheet.

The following summarizes quantitative information about the Company's operating leases:

($ in thousands)	**For the Six Months Ended June 30, 2019**
Lease cost	
Operating lease cost	$ 157
Variable lease cost	363
Total	$ 520

($ in thousands)	**For the Six Months Ended June 30, 2019**
Operating cash flows from operating leases	$ 120
Right of use assets exchanged for operating lease liabilities	$ 2,047
Weighted-average remaining lease term - operating leases	5.0
Weighted-average discount rate - operating leases	8.96%

Maturities of our operating leases, excluding short-term leases, are as follows:

($ in thousands)	
Six months ended December 31, 2019	$ (338)
Year ended December 31, 2020	461
Year ended December 31, 2021	467
Year ended December 31, 2022	476
Year ended December 31, 2023	489
Thereafter	1,458
Total	3,013
Less present value discount	(994)
Operating lease liabilities	$ 2,019

At December 31, 2018, the total future minimum lease payments under all leases were:

($ in thousands)		
2019	$	276
2020		460
2021		467
2022		476
2023		489
Beyond		1,458
Total minimum lease payments	$	3,626

Note 9 - Stockholders' Equity

Common Stock

Under the terms of the Second Amended and Restated Founders Agreement, which became effective July 22, 2016, Fortress will receive a grant of shares of our common stock equal to two and one-half percent (2.5%) of the gross amount of any equity or debt financing. On March 29, 2019, the Company issued 108,069 shares of common stock to Fortress, which equaled 2.5% of the gross funded amount of the Horizon note. The Company recorded an expense of approximately $0.4 million in general and administrative expenses related to these shares during the six months ended June 30, 2019.

In April 2019, the Company issued 87,656 shares of common stock to Fortress, which equaled 2.5% of the gross proceeds of $22.5 million from the sale of shares of common stock under Mustang's At-the-Market offering. The Company recorded an expense of approximately $0.5 million in general and administrative expenses related to these shares during the six months ended June 30, 2019.

In May 2019, the Company issued 197,656 shares of common stock to Fortress, which equaled 2.5% of the gross proceeds of $31.6 million from the sale of shares of common stock under Mustang's underwritten public offering. The Company recorded an expense of approximately $0.8 million in general and administrative expenses related to these shares during the six months ended June 30, 2019.

In April 2019, COH converted 137,608 shares of the Company's Class A common stock to 137,608 shares of the Company's common stock.

Mustang At-the-Market Offering

On July 13, 2018, Mustang filed a shelf registration statement No. 333-226175 on Form S-3, as amended on July 20, 2018 (the "Mustang S-3"), which was declared effective in August 2018. Under the Mustang S-3, Mustang may sell up to a total of $75.0 million of its securities. In connection with the Mustang S-3, the Company entered into an At-the-Market Issuance Sales Agreement (the "Mustang ATM") with B. Riley FBR, Inc., Cantor Fitzgerald & Co., National Securities Corporation, and Oppenheimer & Co. Inc. (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the Mustang ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the three and six months ended June 30, 2019, the Company issued approximately 3.5 million shares of common stock at an average price of $6.42 per share for gross proceeds of $22.5 million. In connection with these sales, Mustang paid aggregate fees of approximately $0.5 million for net proceeds of approximately $22.0 million. No sales were made under the Mustang ATM in 2018.

Mustang Public Offering of Common Stock

On April 30, 2019, we announced the pricing of an underwritten public offering, whereby we sold 6,875,000 shares of common stock, (plus a 30-day option to purchase up to an additional 1,031,250 shares of common stock, which was fully exercised) at a price of $4.00 per share for gross proceeds of approximately $31.6 million, before deducting underwriting discounts and commissions and offering expenses. In connection with the public offering, the Company paid aggregate fees of approximately $2.1 million for net proceeds of approximately $29.5 million. The shares were sold under the Mustang S-3, filed with the Securities and Exchange Commission. The offering closed on May 2, 2019, and the over-allotment closing was on May 8, 2019.

As of June 30, 2019, approximately $20.9 million of the Mustang S-3 remains available for sales of securities.

Stock Awards

Stock Options

The Company has in effect the 2016 Incentive Plan (the "Incentive Plan"). The Incentive Plan was adopted in 2016 by our stockholders and the compensation committee of the Company's board of directors and is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan initially authorized grants to issue up to 2,000,000 shares of authorized but unissued common stock, expires 10 years from adoption, and limits the term of each option to no more than 10 years from the date of grant. In June 2018, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 3,000,000 shares, for a total of 5,000,000 shares. Total shares available for the issuance of stock-based awards under the Incentive Plan was 1,987,439 shares at June 30, 2019.

The following table summarizes stock option activities for the six months ended June 30, 2019:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding at December 31, 2018	1,241,675	$ 5.73	8.31
Options granted	-	-	-
Outstanding at June 30, 2019	1,241,675	5.73	7.81
Options vested and exercisable at June 30, 2019	310,417	$ 5.73	7.81

As of June 30, 2019, the Company had unrecognized stock-based compensation expense related to options of $0.8 million, which is expected to be recognized over the remaining weighted average vesting period of approximately 1.6 years. This amount does not include, as of June 30, 2019, 310,419 stock options outstanding which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Restricted Stock

The following table summarizes restricted stock award activities for the six months ended June 30, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2018	502,636	$ 5.76
Granted	50,000	3.80
Nonvested at June 30, 2019	552,636	$ 5.58

As of June 30, 2019, the Company had unrecognized stock-based compensation expense related to restricted stock of $1.6 million, which is expected to be recognized over the remaining weighted average vesting period of approximately 2.2 years. This amount does not include, as of June 30, 2019, 68,160 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Restricted Stock Units

Certain employees and consultants have been awarded restricted stock units with time-based vesting. The following table summarizes restricted stock units activities for the six months ended June 30, 2019:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2018	1,032,084	$ 7.77
Granted	309,000	2.99
Forfeited	(296,750)	7.98
Vested	(76,000)	10.81
Nonvested at June 30, 2019	968,334	$ 5.94

As of June 30, 2019, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately $2.9 million, which is expected to be recognized over the remaining weighted average vesting period of approximately 1.9 years.

The following table summarizes stock-based compensation expense for the three and six months ended June 30, 2019 and 2018 (in thousands).

	For the three months ended June 30,		For the six months ended June 30,	
	2019	2018	2019	2018
General and administrative	$ 333	$ 393	$ 669	$ 936
Research and development	289	578	385	2,030
Total stock-based compensation expense	$ 622	$ 971	$ 1,054	$ 2,966

Warrants

A summary of warrant activities for six months ended June 30, 2019 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2018	5,210,698	$ 8.32	3.10
Granted	288,184	3.47	9.75
Exercised	(65,358)	-	-
Outstanding as of June 30, 2019	5,433,524	$ 8.16	2.92

Upon the exercise of warrants, the Company will issue new shares of common stock.

Note 10 - Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period less unvested restricted stock. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common shares pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of warrants or outstanding Class A preferred shares, as their inclusion would be anti-dilutive.

The table below summarizes potentially dilutive securities that were not considered in the computation of diluted net loss per share because they would be anti-dilutive.

	For the six months ended June 30,	
	2019	2018
Warrants	5,433,524	5,210,975
Options	1,241,675	1,241,675
Class A Preferred Shares	250,000	250,000
Unvested restricted stock awards	552,636	230,000
Unvested restricted stock units	968,334	613,000
Total	8,446,169	7,545,650

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

Forward-Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this Form 10-Q. Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words “expect,” “anticipate,” “intend,” “believe,” “may,” “plan”, “seek” or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading “Risk Factors” herein.

Overview

Mustang Bio, Inc. (“Mustang”, “We”, “Us” or the “Company”) is a clinical-stage biopharmaceutical company focused on translating today’s medical breakthroughs in cell and gene therapies into potential cures for hematologic cancers, solid tumors and rare genetic diseases. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

Our pipeline is currently focused in three core areas: gene therapy programs for rare genetic disorders, chimeric antigen receptor (“CAR”) engineered T cell (“CAR T”) therapies for hematologic malignancies and CAR T therapies for solid tumors. For each therapy we have partnered with world class research institutions. For our gene therapy programs we have partnered with St. Jude Children’s Research Hospital (“St. Jude”) in the development of a first-in-class *ex vivo* lentiviral treatment of X-linked severe combined immunodeficiency (“XSCID”) and for our CAR T therapies we have partnered with the City of Hope National Medical Center (“COH”), Fred Hutchinson Cancer Research Center (“Fred Hutch”) and Nationwide Children’s Hospital (“Nationwide”).

Gene Therapy

In partnership with St. Jude, our gene therapy program (MB-107) is being conducted under an exclusive license to develop a potentially curative treatment for XSCID, a rare genetic immune system condition in which affected patients do not live beyond infancy without treatment. This first-in-class *ex vivo* lentiviral gene therapy is currently in two Phase 1/2 clinical trials sponsored by St. Jude and the National Institutes of Health (“NIH”). Results in these two trials have been promising, and we plan to transfer St. Jude’s Investigational New Drug Application (“IND”) to Mustang in the second half of 2019 following completion of the technology transfer.

CAR T Therapies

Our pipeline of CAR T therapies is being developed under exclusive licenses from several world class research institutions. Our strategy is to license these technologies, support preclinical and clinical research activities by our partners and transfer the underlying technology to our cell processing facility located in Worcester, Massachusetts, to conduct our own clinical trials.

We are developing CAR T therapies for hematologic malignancies in partnership with COH targeting CD123 (MB-102) and CS1 (MB-104) and with Fred Hutch targeting CD20 (MB-106). Phase 1 clinical trials sponsored by COH for MB-102 and by Fred Hutch for MB-106 are underway, and a COH sponsored Phase 1 clinical trial for MB-104 opened in April 2019. The U.S. Food and Drug Administration (“FDA”) recently approved our IND application to initiate a multi-center Phase 1/2 clinical trial of MB-102, and our clinical trial will begin later in 2019. We expect to file an IND for MB-104 in the second half of 2019 and to initiate our own Phase 1 clinical trial shortly thereafter for the treatment of patients with multiple myeloma. We also plan to file an IND and initiate our own clinical trial for MB-106 for the treatment of patients with non-Hodgkin lymphoma and chronic lymphocytic leukemia.

We are also developing CAR T therapies for solid tumors in partnership with COH targeting IL13Rα2 (MB-101), HER2 (MB-103) and PSCA (MB-105). In addition, we have partnered with Nationwide for the C134 oncolytic virus (MB-108) in order to enhance the activity of MB-101 for the treatment of patients with glioblastoma multiforme (“GBM”). Phase 1 clinical trials sponsored by COH for MB-101 and MB-103 are underway, and a COH sponsored Phase 1 clinical trial for MB-105 opened for accrual of patients with prostate cancer in the second quarter of 2019. A Phase 1 clinical trial sponsored by the University of Alabama at Birmingham for MB-108 is scheduled to commence in the second half of 2019. We also plan to file INDs and initiate our own clinical trials for MB-103 for the treatment of patients with metastatic breast cancer to brain, for MB-105 for the treatment of patients with prostate and pancreatic cancer and for the combination of MB-101 and MB-108 for the treatment of patients with GBM.

Additionally, we hold complementary patent licenses relating to the use, delivery and possible enhancement of our proprietary CAR T technologies. In particular, we licensed intellectual property from Harvard University pertaining to CRISPR/Cas9 gene editing of CAR T cells, and we hope to use this technology to enhance the activity of our CAR T cell therapies.

Recent Events

CD123 (MB-102)

On August 5, 2019, we announced that the FDA has approved our IND application to initiate a multi-center Phase 1/2 clinical trial of MB-102 (CD123 CAR T) in acute myeloid leukemia ("AML"), blastic plasmacytoid dendritic cell neoplasm ("BPDCN") and high-risk myelodysplastic syndrome ("MDS"). We will initiate our MB-102 clinical trial later in 2019 and process patient cells in our manufacturing facility, which opened in June 2018.

In July 2019, we announced that the FDA has granted Orphan Drug Designation to MB-102 (CD123 CAR T) for the treatment of AML. The FDA also previously granted Orphan Drug Designation to MB-102 for the treatment of BPDCN. The FDA grants Orphan Drug Designation to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials and prescription drug user fee waivers. If a product holding Orphan Drug Designation receives the first FDA approval for the disease in which it has such designation, the product is entitled to seven years of market exclusivity, which is independent from intellectual property protection.

HER2 (MB-103)

In July 2019, the California Institute for Regenerative Medicine announced that it has awarded a $9.3 million grant to Dr. Saul Priceman at COH to conduct a Phase 1 clinical trial evaluating the safety and effectiveness of intraventricular delivery of HER2-directed CAR T cells to the brains of patients with HER2-positive breast cancer with brain metastases. City of Hope has exclusively licensed MB-103 to us.

Horizon Notes

In April 2019, we announced that we entered into a $20 million debt financing agreement with Horizon Technology Finance Corporation (NASDAQ: HRZN) ("Horizon"), a leading specialty finance company that provides capital in the form of secured loans to venture-backed companies in the technology, life sciences, healthcare information and services and cleantech industries. $15 million of the $20 million loan funded upon closing, and the remaining $5 million may be funded upon the achievement by us of certain predetermined milestones. Each advance of the loan will be repaid in 42 monthly payments consisting of 18 monthly payments of interest only, followed by 24 monthly payments of principal and accrued interest, payable monthly in arrears. The interest-only period may be extended to 24 months contingent upon our achieving certain milestones. In connection with the debt financing, we issued Horizon warrants to purchase up to 288,184 of our common shares at an exercise price of $3.47 per share.

At-the-Market Offering

On July 13, 2018, we filed a shelf registration statement No. 333-226175 on Form S-3, as amended on July 20, 2018 (the "Mustang S-3"), which was declared effective in August 2018. Under the Mustang S-3, we may sell up to a total of $75.0 million of its securities. In connection with our S-3, we entered into an At-the-Market Issuance Sales Agreement (the "Mustang ATM") with B. Riley FBR, Inc., Cantor Fitzgerald & Co., National Securities Corporation, and Oppenheimer & Co. Inc. (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the Mustang ATM, Mustang pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the three and six months ended June 30, 2019, we issued approximately 3.5 million shares of common stock at an average price of $6.42 per share for gross proceeds of $22.5 million. In connection with these sales, we paid aggregate fees of approximately $0.5 million for net proceeds. No sales were made under the Mustang ATM in 2018.

Public Offering of Common Stock

On April 30, 2019, we announced the pricing of an underwritten public offering, whereby we sold 6,875,000 shares of common stock, (plus a 30-day option to purchase up to an additional 1,031,250 shares of common stock, which has been exercised in full) at a price of $4.00 per share for gross proceeds of approximately $31.6 million, before deducting underwriting discounts and commissions and offering expenses of approximately $2.1 million. The shares were sold under the Mustang S-3, filed with the Securities and Exchange Commission. The offering closed on May 2, 2019, and the over-allotment option closed on May 8, 2019.

As of June 30, 2019, approximately $20.9 million of the Mustang S-3 remains available for sales of securities.

XSCID Gene Therapy (MB-107)

In April 2019, St. Jude published Phase 1/2 clinical data in the *New England Journal of Medicine* that underscored the potential of MB-107 as a novel approach for newly diagnosed infants with XSCID. It is anticipated that the IND will be transferred from St. Jude to Mustang by the end of 2019, after which patients' cells from all three participating clinical trial sites will be processed at our Worcester, Massachusetts facility.

Oncolytic Virus C134 (MB-108)

In May 2019, Mustang and Nationwide announced that the FDA has granted Orphan Drug Designation to MB-108 (oncolytic virus C134) for the treatment of malignant glioma, a type of brain cancer with a median survival of less than 18 months. Nationwide Children's has exclusively licensed oncolytic virus C134 to us.

CS1 (MB-104)

On May 8, 2019, COH announced that it had begun enrolling patients with relapsed or treatment-resistant multiple myeloma in an innovative CS1 CAR T cell therapy trial. We expect to file an IND for MB-104 in the second half of 2019 and to initiate our own Phase 1 clinical trial shortly thereafter for the treatment of patients with multiple myeloma.

To date, we have not received approval for the sale of our product candidates in any market and, therefore, have not generated any product sales from our product candidates. In addition, we have incurred substantial operating losses since our inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2019, we have an accumulated deficit of $99.1 million.

We are a majority-controlled subsidiary of Fortress Biotech, Inc. ("Fortress"). As a "Controlled Company" we rely on the exemption provided by Nasdaq Listing Rule 5615(c)(2), which permits us to maintain less than a majority of independent directors on our board.

Critical Accounting Policies and Use of Estimates

See Note 2 to our Financial Statements.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

	For the three months ended June 30,		Change	
	2019	2018	$	%
($ in thousands)				
Operating expenses:				
Research and development	$ 6,823	$ 3,557	$ 3,266	92%
Research and development - licenses acquired	200	-	200	100%
General and administrative	3,189	1,683	1,506	89%
Total operating expenses	10,212	5,240	4,972	95%
Loss from operations	(10,212)	(5,240)	(4.972)	95%
Other income (expense)				
Interest income	387	147	240	163%
Interest expense	(574)	-	(574)	100%
Total other income (expense)	(187)	147	(334)	-227%
Net Loss	**$ (10,399)**	**$ (5,093)**	**$ (5,306)**	**104%**

Research and Development Expenses

Research and development expenses primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third-party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings, laboratory costs and other supplies.

For the three months ended June 30, 2019 and 2018, research and development expenses were $6.8 million and $3.6 million, respectively. The increase of $3.3 million is primarily due to $1.0 million for personnel costs due to the hiring of research and development employees, $1.1 million for laboratory supplies, $0.4 million for our sponsored research and clinical trial agreements, $0.3 million in connection with our CD123 clinical trial and $0.3 million for consulting and outside services, partially offset by a $0.3 million decrease in stock-based compensation expense for equity awards to employees and consultants.

For the three months ended June 30, 2019 and 2018, research and development expenses for licenses acquired were approximately $0.2 million and $0, respectively. For the three months ended June 30, 2019, we expensed $0.2 million related to achievement of a development milestone for our CS1 license with COH.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with the following:

- employee-related expenses, which include salaries and benefits;
- license fees and milestone payments related to in-licensed products and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and our preclinical activities;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses, including stock-based compensation, for executives and other administrative personnel; recruitment expenses, professional fees and other corporate expenses, including investor relations; legal activities including patent fees; and facilities-related expenses.

For the three months ended June 30, 2019 and 2018, general and administrative expenses were $3.2 million and $1.7 million, respectively. The increase of $1.5 million is attributed primarily to the 2.5% common stock equity fee paid to Fortress Biotech.

We anticipate general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded research and development activities, including additional product candidates entering the clinic;

- stock compensation granted to key employees and non-employees;

- support of business development activities; and

- increased professional fees and other costs associated with the regulatory requirements and increased compliance associated with being a publicly traded company.

Other Income or Expense

For the three months ended June 30, 2019 and 2018, other income or expense was a $0.2 million loss and a $0.1 million gain, respectively. The decrease of $0.3 million is attributed to higher interest expense related to the Horizon Notes of approximately $0.6 million, offset by higher interest income of $0.2 million.

Comparison of the Six Months Ended June 30, 2019 and 2018

	For the six months ended June 30,		Change	
($ in thousands)	**2019**	**2018**	**$**	**%**
Revenue - related party	$ -	$ 50	$ (50)	-100%
Operating expenses:				
Research and development	13,783	7,849	5,934	76%
Research and development - licenses acquired	650	75	575	767%
General and administrative	5,533	3,793	1,740	46%
Total operating expenses	19,966	11,717	8,249	70%
Loss from operations	(19,966)	(11,667)	(8,299)	71%
Other income				
Interest income	539	293	246	84%
Interest expense	(585)	-	(585)	100%
Total other income (expense)	(46)	293	(339)	-116%
Net Loss	**$ (20,012)**	**$ (11,374)**	**$ (8,638)**	**76%**

Research and Development Expenses

For the six months ended June 30, 2019 and 2018, research and development expenses were $13.8 million and $7.8 million, respectively. The increase of $5.9 million is primarily attributable to $2.3 million for personnel related costs due to the hiring of research and development employees, $2.2 million for laboratory supplies, $1.1 million in connection with our Mustang sponsored CD123 clinical trial, $0.6 million for our sponsored research and clinical trial agreements, $0.7 million for consulting and outside services and $0.5 million related to depreciation, offset by lower stock-based compensation expense of $1.6 million.

For the six months ended June 30, 2019 and 2018, research and development expenses - licenses acquired were approximately $0.7 million and $0.1 million, respectively. For the six months ended June 30, 2019, we expensed $0.2 million related to an upfront fee for our license with Nationwide, $0.3 million related to our CD123 license with COH and $0.2 million related to our CS1 license with COH. For the six months ended June 30, 2018, we expensed $0.1 million related to an upfront fee for our manufacturing license with COH.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with the following:

- employee-related expenses, which include salaries and benefits, and rent expense;
- license fees and milestone payments related to in-licensed products and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and our preclinical activities;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses, including stock-based compensation, for executives and other administrative personnel; recruitment expenses, professional fees and other corporate expenses, including investor relations; legal activities including patent fees; and facilities-related expenses.

For the six months ended June 30, 2019 and 2018, general and administrative expenses were comparable at $5.5 million and $3.8 million, respectively. The increase of $1.7 million is attributed primarily to the 2.5% common stock equity fee paid to Fortress Biotech.

Other Income or Expense

For the six months ended June 30, 2019 and 2018, other income or expense was approximately $0 million and a $0.3 million gain, respectively. The decrease of $0.3 million is attributed to higher interest expense related to the Horizon Notes of approximately $0.6 million, offset by higher interest income of $0.2 million.

Liquidity and Capital Resources

The Company has incurred substantial operating losses and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2019, the Company had an accumulated deficit of $99.1 million.

The Company has funded its operations to date primarily through the sale of equity and the Horizon Notes. The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, including financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its available cash and cash equivalents balances at June 30, 2019 are sufficient to fund its anticipated operating cash requirements for at least one year from the date of this Form 10-Q.

The Company will be required to expend significant funds in order to advance the development of its product candidates. The Company will require additional financings through equity and debt offerings, collaborations and licensing arrangements or other sources to fully develop, prepare regulatory filings, obtain regulatory approvals and commercialize its existing and any new product candidates.

Cash Flows for the Six Months Ended June 30, 2019 and 2018

	For the six months ended June 30,	
	2019	2018
($ in thousands)		
Statement of cash flows data:		
Total cash (used in) provided by:		
Operating activities	$ (15,261)	$ (8,921)
Investing activities	16,199	(14,491)
Financing activities	65,227	181
Net change in cash, cash equivalents and restricted cash	$ 66,165	$ (23,231)

Operating Activities

Net cash used in operating activities was $15.3 million for the six months ended June 30, 2019, compared to $8.9 million for the six months ended June 30, 2018.

Net cash used in operating activities for the six months ended June 30, 2019, was primarily due to approximately $20.0 million in net loss partially offset by $0.5 million in change in operating assets and liabilities, $0.2 million of accretion of debt discount, $1.7 million of equity fee on issuance of common shares to Fortress Biotech, $1.1 million of non-cash stock compensation expenses, $0.6 million of depreciation and $0.7 million of research and development-licenses acquired.

Net cash used in operating activities for the six months ended June 30, 2018 was primarily due to approximately $11.4 million in net loss and $0.7 million in change in operating assets and liabilities, partially offset by $3.0 million of non-cash stock compensation expenses, $0.1 million of depreciation and $0.1 million of research and development-licenses acquired, expensed.

Investing Activities

Net cash provided by investing activities was $16.2 million for the six months ended June 30, 2019, representing our $17.6 million in maturities of certificates of deposits, offset by $0.5 million in purchases of research and development licenses and $1.0 million in purchases of fixed assets.

Net cash used in investing activities was $14.5 million for the six months ended June 30, 2018, representing our purchase of $35.0 million investment in certificates of deposits held to maturity, $5.4 million in purchases of fixed assets and construction in process, and $0.1 million in acquisition costs of acquired licenses, offset by $26.0 million in maturities of certificates of deposits.

Financing Activities

Net cash provided by financing activities was $65.2 million during the six months ended June 30, 2019, due to net proceeds of $13.8 million from the Horizon Notes; gross proceeds of $22.5 million, net of offering costs of $0.5 million, from the Mustang ATM; and gross proceeds of $31.6 million, net of offering costs of $2.1 million, from our May 2019 underwritten public offering.

Net cash provided by financing activities was $0.2 million during the six months ended June 30, 2018, due to net proceeds from the exercise of warrants.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

During the six months ended June 30, 2019, there were no material changes to our interest rate risk disclosures, market risk disclosures or foreign currency exchange rate risk disclosures reported in our Annual Report on Form 10-K for the year ended December 31, 2018.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Principal Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended June 30, 2019, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, the Company’s Chief Executive Officer and Principal Financial Officer have concluded that the Company’s disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2019, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should carefully consider the risks described below. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business and Industry

We currently have no products for sale. We are heavily dependent on the success of our product candidates, and we cannot give any assurances that any of our product candidates will receive regulatory approval or be successfully commercialized.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. We have not demonstrated our ability to perform the functions necessary for the successful acquisition, development or commercialization of the technologies we are seeking to develop. As an early stage company, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Our future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize such product candidates. Our product candidates are currently in preclinical development or in early stage clinical trials. Our business depends entirely on the successful development and commercialization of our product candidates, which may never occur. We currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product.

The successful development, and any commercialization, of our technologies and any product candidates would require us to successfully perform a variety of functions, including:

- developing our technology platform;
- identifying, developing, manufacturing and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- participating in regulatory approval processes;
- formulating and manufacturing products;
- obtaining sufficient quantities of our product candidates from our third-party manufacturers as required to meet clinical trial needs and commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- conducting sales and marketing activities including hiring, training, deploying and supporting our sales force and creating market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote our product candidates that we may later establish; and
- maintaining patent protection and regulatory exclusivity for our product candidates.

Our operations have been limited to organizing our company, acquiring, developing and securing our proprietary technology and identifying and obtaining preclinical data or clinical data for various product candidates. These operations provide a limited basis for you to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

Each of our product candidates will require additional preclinical and clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we are planning for certain clinical trials relating to our product candidates, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities; however, we will have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the 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 the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. 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.

We may not receive regulatory approval for our product candidates, or their approval may be further delayed, which would have a material adverse effect on our business and financial condition.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the US and by the European Medicines Agency and similar regulatory authorities outside the US. Failure to obtain marketing approval for one or more of our product candidates or any future product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. One or more of our product candidates or any future product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates or any future product candidate receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

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

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

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates or any future product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the commercial prospects for one or more of our product candidates or any future product candidate.

Moreover, in all interactions with regulatory authorities, we are exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

If any of our product candidates is approved and we or our contract manufacturer(s) fail to produce the product in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of our product candidates or be unable to meet market demand, and may lose potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We may enter into development and supply agreements with contract manufacturers for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies for one or more of our product candidates. Any termination or disruption of our relationships with our contract manufacturers may materially harm our business and financial condition and frustrate any commercialization efforts for each respective product candidate.

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program, and we have little control over their compliance with these regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product and customer confidence in our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If the commercial manufacturers upon whom we may rely to manufacture one or more of our product candidates, and any future product candidate we may in-license, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

Our approach to the discovery and development of our product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value.

Our products candidates are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to identify commercially viable drugs to treat human patients with cancer or other diseases.

If serious adverse or unacceptable side effects are identified during the development of one or more of our product candidates or any future product candidate, we may need to abandon or limit our development of some of our product candidates.

If one or more of our product candidates or any future product candidate are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause serious side effects that prevented further development of the compound. In the event that our clinical trials reveal a high or unacceptable severity and prevalence of side effects, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of one or more of our product candidates or any future product candidate for any or all targeted indications. The FDA could also issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve a product candidate. The number of requests for additional data or information issued by the FDA in recent years has increased and has resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by one or more of our product candidates or any future product candidate could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating market acceptance and revenues from the sale of that product candidate. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

Additionally, if one or more of our product candidates or any future product candidate receives marketing approval and we or others later identify undesirable side effects caused by this product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any of our product candidates or any future product candidate or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

Even if one or more of our product candidates receives regulatory approval, it and any other products we may market will remain subject to substantial regulatory scrutiny.

One or more of our product candidates that we may license or acquire will also be subject to ongoing requirements and review of the FDA and other regulatory authorities. These requirements include labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping of the drug, and requirements regarding our presentations to and interactions with health care professionals.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

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

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the US or other countries until we have completed a rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the US Patent and Trademark Office (PTO). The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the US and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us 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 we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- 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 obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of certain approved drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014 and is annually updated; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the US generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

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

Among policy makers and payors in the US and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the US, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, a sweeping law intended 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 the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;

- the new requirements under the federal Open Payments program and its implementing regulations;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;

- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, 2018, Texas federal district court judge Reed O'Connor issued a ruling declaring that the ACA in it is entirety is unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome through the appeals process may have a significant impact on our business.

The Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applied to biosimilars beginning in 2019.

The 116th Congress has explored legislation intended to address the cost of prescription drugs. Notably, the major committees of jurisdiction in the Senate (Finance Committee, Health, Education, Labor and Pensions Committee, and Judiciary Committee), have marked up legislation intended to address various elements of the prescription drug supply chain. Proposals include a significant overhaul of the Medicare Part D benefit design, addressing patent "loopholes", and efforts to cap the increase in drug prices. The House Energy and Commerce Committee approved drug-related legislation intended to increase transparency of drug prices and also curb anti-competitive behavior in the pharmaceutical supply chain. In addition, the House Ways & Means Committee approved legislation intended to improve drug price transparency, including for drug manufacturers to justify certain price increases. While we cannot predict what proposals may ultimately become law, the elements under consideration could significantly change the landscape in which the pharmaceutical market operates.

The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services ("HHS") finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program, which has been overturned by the courts. HHS also has signaled its intent to pursue reimbursement policy changes for Medicare Part B drugs as a whole that likely would reduce hospital and physician reimbursement for these drugs.

HHS has made numerous other proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. These proposals include giving Medicare Advantage and Part D plans flexibility in the availability of drugs in "protected classes," more transparency in the cost of drugs, including the beneficiary's financial liability, and less costly alternatives and permitting the use of step therapy as a means of prior authorization. HHS has also proposed requiring pharmaceutical manufacturers disclose the prices of certain drugs in direct-to-consumer television advertisements. The proposal related to protected classes has been withdrawn and the disclosure requirements have been rejected by the courts. In addition, a proposed rule that would have passed drug rebates to consumers at the point of sale also has been withdrawn. However, it appears the Trump Administration will continue to explore its authority to make regulatory changes to the pharmaceutical industry. For example, the Trump Administration released an Advance Notice of Proposed Rulemaking related to an international price index model. It is unclear what eventually will be proposed, but the President has alluded to the concept of "most favored nation" pricing with regards to U.S. drug purchasing. In addition, HHS, in conjunction with the FDA, announced that it will be exploring a reimportation pathway in certain instances and for certain drugs.

HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits and less generous coverage. The Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative proposals such as expanding the Medicaid drug rebate program to the Medicare Part D program, providing authority for the government to negotiate drug prices under the Medicare Part D program and lowering reimbursement for drugs covered under the Medicare Part B program have been raised in Congress, but have been met with opposition and have not been enacted so far.

The administration can rely on its existing statutory authority to make policy changes that could have an impact on the drug industry. For example, the Medicare program has in the past proposed to test alternative payment methodologies for drugs covered under the Part B program and currently is proposing to pay hospitals less for Part B-covered drugs purchased through the 340B Drug Pricing Program.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the US Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Public concern regarding the safety of drug products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of the US Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving any of our product candidates, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of any of our product candidates, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize our product candidates may be otherwise adversely impacted.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for one or more of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Available therapies for the indications we are pursuing can also affect enrollment in our clinical trials. Patient enrollment is affected by other factors including, but not necessarily limited to:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the number of clinical trials sponsored by other companies for the same patient population;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Our product candidates are in scientific areas of intense competition from many large pharmaceutical and biotechnology companies, many of which are significantly further along in development or are already on the market with competing products. We expect competition for our product candidates will intensify, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render one or more of our product candidates obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render one or more of our product candidates obsolete or noncompetitive.

Competitors may seek to develop alternative formulations that do not directly infringe on our in-licensed patent rights. The commercial opportunity for one or more of our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

· capital resources;

· development resources, including personnel and technology;

· clinical trial experience;

· regulatory experience;

· expertise in prosecution of intellectual property rights; and

· manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize one or more of our product candidates. Our competitors may also develop drugs that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products.

Our commercial success depends upon us attaining significant market acceptance of our product candidates, if approved for sale, among physicians, patients, healthcare payors and major operators of cancer and other clinics.

Even if we obtain regulatory approval for one or more of our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including, but not necessarily limited to:

· the efficacy and safety as demonstrated in clinical trials;

· the timing of market introduction of such product candidate as well as competitive products;

· the clinical indications for which the drug is approved;

· acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;

· the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;

· the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

· the availability of adequate reimbursement and pricing by third-party payors and government authorities;

· changes in regulatory requirements by government authorities for our product candidates;

· the relative convenience and ease of administration of the product candidate for clinical practices;

· the product labeling or product insert required by the FDA or regulatory authority in other countries;

· the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;

· the prevalence and severity of adverse side effects; and

· the effectiveness of our sales and marketing efforts.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is not perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

If approved, our product candidates will face competition from less expensive generic products of competitors, and, if we are unable to differentiate the benefits of our product candidates over these less expensive alternatives, we may never generate meaningful product revenues.

Generic therapies are typically sold at lower prices than branded therapies and are generally preferred by hospital formularies and managed care providers of health services. We anticipate that, if approved, our product candidates will face increasing competition in the form of generic versions of branded products of competitors that have lost or will lose their patent exclusivity. In the future, we may face additional competition from a generic form when the patents covering it begin to expire, or earlier if the patents are successfully challenged. If we are unable to demonstrate to physicians and payers that the key differentiating features of our product candidates translate to overall clinical benefit or lower cost of care, we may not be able to compete with generic alternatives.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. We intend to seek approval to market our product candidates in the US, the EU and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective or less cost-effective than existing or future introduced products, and third-party payors may not approve our product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In some foreign countries, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

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

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidate that receives marketing approval, we would need to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development and regulatory approval of one or more of our product candidates or any future product candidate, we expect to build a targeted specialist sales force to market or co-promote the product. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include, but are not necessarily limited to:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;

- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

As an alternative to establishing our own sales force, we may choose to partner with third parties that have well-established direct sales forces to sell, market and distribute our products.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.

We rely on third-party contract research organizations and site management organizations to conduct some of our preclinical studies and all of our clinical trials for our product candidates and for any future product candidate. We expect to continue to rely on third parties, such as contract research organizations, site management organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct some of our preclinical studies and all of our clinical trials. The agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice (GLP) as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices (GCPs) for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, 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 by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties with whom we have contracted to help perform our preclinical studies or clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If any of our relationships with these third-party contract research organizations or site management organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or site management organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and may also do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or any future product candidate or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

While we have opened our own cell processing facility in Worcester, Massachusetts in order to supply product candidates for all clinical trials that will be conducted under IND applications to be filed by us, currently we rely on third parties for the manufacture of our product candidates for preclinical and clinical testing. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or any future product candidate or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We may also rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of one or more product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including, but not necessarily limited to:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We rely on our third-party manufacturers to produce or purchase from third-party suppliers the materials and equipment necessary to produce our product candidates for our preclinical and clinical trials, in particular the lentiviral vectors used to transduce patients' cells for our XSCID program (MB-107) and for all six of our CAR T programs. There are a limited number of suppliers for raw materials and equipment that we use (or that are used on our behalf) to manufacture our drugs, and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials and equipment necessary to produce our product candidates for our preclinical and clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials or equipment by our third-party manufacturers. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing preclinical or clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials or equipment after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations for manufacture of our product candidates. Third-party manufacturers may not be able to comply with the cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

One or more of the product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers. The DEA restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for one or more of our product candidates.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we seek to develop product candidates with validated mechanisms of action and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. Further, such clinical data and results may be based on products or product candidates that are significantly different from our product candidates or any future product candidate. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates or future product candidate, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised.

If we breach any of the agreements under which we license rights to one or more of product candidates from others, we could lose the ability to continue to develop and commercialize such product candidate.

Because we have in-licensed the rights to all of our product candidates from COH, Fred Hutch, St. Jude and Nationwide, and in the future will continue to in-license from additional third parties, if there is any dispute between us and our licensor regarding our rights under our license agreement, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under our license agreement could result in our loss of exclusive rights to our product candidate and may lead to a complete termination of our related product development efforts.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and may have to limit their commercialization.

The use of one or more of our product candidates and any future product candidate we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product we develop allegedly causes injury or is 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. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- suspension or termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;

- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

We will obtain limited product liability insurance coverage for any and all of our upcoming clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our future growth depends on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on *ex vivo* lentiviral gene therapy for rare genetic diseases and on novel combinations of CAR T cells with immuno-oncology antibodies, other biologics, and small molecule kinase inhibitors. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including, but not necessarily limited to:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management’s time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

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. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future 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.

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 harm 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. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for one or more of our product conducts could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of one or more of our product candidates may be delayed.

We are currently reliant on the City of Hope National Medical Center, the Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, and the University of Alabama at Birmingham ("UAB") for a substantial portion of our research and development efforts and the early clinical testing of our product candidates.

A substantial portion of our research and development has been and will continue to be conducted by COH, Fred Hutch, St. Jude, and UAB pursuant to a sponsored research agreement and/or clinical trial agreements with each of those parties. As a result, our future success is heavily dependent on the results of research and development efforts of Dr. Stephen Forman and his laboratory team at COH, of Dr. Brian Till and his laboratory team at Fred Hutch, of Drs. Stephen Gottschalk and Ewelina Mamcarz at St. Jude, and of Dr. James M. Markert at UAB. We have limited control over the nature or timing of their research and limited visibility into their day-to-day activities, and as a result can provide little assurance that their efforts will be successful.

CAR T is a new approach to cancer treatment that presents significant challenges.

We have concentrated our research and development efforts on CAR T technology, and our future success is highly dependent on the successful development of T cell immunotherapies in general and our CAR T technology and product candidates in particular. Because CAR T is a new approach to cancer immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of challenges, including, but not necessarily limited to:

- obtaining regulatory approval from the FDA and other regulatory authorities that may have very limited experience with the commercial development of genetically modified T cell therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a patient's T cells *ex vivo* and infusing the engineered T cells back into the patient;
- conditioning patients with chemotherapy in conjunction with delivering each of our products, which may increase the risk of adverse side effects of our products;

- educating medical personnel regarding the potential side effect profile of each of our products;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive our product candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for types of cancers beyond those addressed by our current product candidates.

Product candidates, even if successfully developed and commercialized, may be effective only in combating certain specific types of cancer, and the market for drugs designed to combat such cancer type(s) may be small and unprofitable.

There are many different types of cancer, and a treatment that is effective against one type of cancer may not be effective against another. CAR T or other technologies we pursue may only be effective in combating specific types of cancer but not others. Even if one or more of our products proves to be an effective treatment against a given type of cancer, the number of patients suffering from such cancer may be small, in which case potential sales from a drug designed to combat such cancer would be limited.

Our gene therapy product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.

We have concentrated a portion of our therapeutic product research and development efforts on our gene therapy platform, and our future success depends, in part, on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience in the future related to our gene therapy platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and commercial-scale manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Currently, a limited number of gene therapy products, including CAR T therapies, have been approved by the FDA, the EMA and the European Commission. Given the few precedents of approved gene therapy products, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the EU or other jurisdictions. Approvals by the EMA and the European Commission may not be indicative of what the FDA may require for approval.

Regulatory requirements governing the development of gene therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Tissues and Advanced Therapies within the Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and to advise the CBER on its review. The FDA can put an investigational new drug application, or IND, on clinical hold if the information in an IND is not sufficient to assess the risks in pediatric patients. Before a clinical study can begin at any institution, that institution's IRB and its Institutional Biosafety Committee will have to review the proposed clinical study to assess the safety of the study. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates.

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

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, the success of our gene therapy platform will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. Concern about environmental spread of our product, whether real or anticipated, may hinder the commercialization of our products.

Collaborative relationships with third parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return.

Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. In addition, there has been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we successfully establish new collaborations, these relationships may never result in the successful development or commercialization of product candidates or the generation of sales revenue. To the extent that we enter into collaborative arrangements, the related product revenues are likely to be lower than if we directly marketed and sold products. Such collaborators 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 any future product candidate.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the US and other countries with respect to our product candidates or any future product candidate that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them in the market they are being used or developed.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the US. The patent situation outside the US is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the US, and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than US law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we or our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a US patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the PTO to determine priority of invention in the US. We might also become involved in derivation proceedings in an event that a third party misappropriates one or more of our inventions and files their own patent application directed to such one or more inventions. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention (or that a third party derived an invention from us) would be unsuccessful, resulting in a material adverse effect on our US patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the US and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the US have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the US. Accordingly, we cannot predict the breadth of claims that may be allowed and remain enforceable in our patents or in those licensed from a third party.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include changes to transition from a “first-to-invent” system to a “first inventor-to-file” system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a less burdensome, quicker and less expensive process for challenging issued patents. The PTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the PTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention (or that another derived an invention from us or one of our licensors) would be unsuccessful, resulting in a material adverse effect on our US patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will 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 owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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 products similar or identical to ours.

We depend on our licensors for the maintenance and enforcement of intellectual property covering certain of our product candidates and have limited control, if any, over the amount or timing of resources that our licensors devote on our behalf, or whether any financial difficulties experienced by our licensors could result in their unwillingness or inability to secure, maintain and enforce patents protecting certain of our product candidates.

We depend on our licensors to protect the proprietary rights covering our product candidates and we have limited, if any, control over the amount or timing of resources that they devote on our behalf, or the priority they place on, maintaining patent rights and prosecuting patent applications to our advantage. Moreover, we have limited, if any, control over the strategies and arguments employed in the maintenance of patent rights and the prosecution of patent applications to our advantage. Our licensors might become involved in disputes with one of their other licensees, and we or a portion of our licensed patent rights might become embroiled in such disputes.

Our licensors, depending on the patent or application, are responsible for maintaining issued patents and prosecuting patent applications. We cannot be sure that they will perform as required. Should they decide they no longer want to maintain any of the patents licensed to us, they are required to afford us the opportunity to do so at our expense. If our licensors do not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. Moreover, and possibly unbeknownst to us, our licensors may experience serious difficulties related to their overall business or financial stability, and they may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors to protect a substantial portion of our proprietary rights and to inform us of the status of those protections and efforts thereto.

Our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. We may have limited, if any, control or involvement over the defense of these claims, and our licensors could be subject to injunctions and temporary or permanent exclusionary orders in the US or other countries. Our licensors are not obligated to defend or assist in our defense against third-party claims of infringement. We have limited, if any, control over the amount or timing of resources, if any, that our licensors devote on our behalf or the priority they place on defense of such third-party claims of infringement.

Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we or our licensors may not be successful in defending claims of intellectual property infringement alleged by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, in addition to being costly and time consuming to undertake. For example:

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate our product candidates or any future product candidate technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the scope of our issued patents may not extend to competitive products developed or produced by others;
- the issued patents covering our product candidates or any future product candidate may not provide a basis for market exclusivity for active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- intellectual property rights of others may have an adverse effect on our business.

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 issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file one or more actions for patent infringement, which can be expensive and time consuming. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents; or provoke those parties to petition the PTO to institute *inter partes* review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question or as a matter of public policy. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly. Furthermore, adverse results on US patents may affect related patents in our global portfolio.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell one or more of our product candidates or any future product candidate that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous US and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of fully human immuno-oncology targeted antibodies and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims asserted by third parties, which could have a material adverse effect on our results or operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications that are unknown to us, which may later result in issued patents that one or more of our product candidates may infringe. There could also be existing patents of which we are not aware that one or more of our product candidates may infringe, even if only inadvertently.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third-party claims that we infringe their patents or misappropriated their technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;

- substantial damages for past infringement which we may have to pay if a court decides that our product infringes a competitor's patent;

- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;

- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and

- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds, time, and may result in an inferior or less-desirable process or product.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties, who may or may not be interested in granting such a license, to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are currently a party to license agreements with St. Jude, the City of Hope, the Fred Hutchinson Cancer Research Center, the Regents of the University of California, Nationwide and other institutions. In the future, we may become party to licenses that are important for product development and commercialization. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Even if frivolous or unsubstantiated in nature, litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and the implicated employee(s).

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

In addition to seeking patent protection for our product candidates or any future product candidate, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We limit disclosure of such trade secrets where possible but we also seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who do have access to them, such as our employees, our licensors, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, 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 any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Because we in-license intellectual property pertaining to certain product candidates from third parties, any dispute with the licensors or the non-performance of such license agreements may adversely affect our ability to develop and commercialize the applicable product candidates.

The types of disputes which may arise between us and the third parties from whom we license intellectual property include, but are not limited to:

- the scope of rights granted under such license agreements and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to such license agreements;
- the sublicensing of patent and other rights under our license agreements and/or collaborative development relationships, and the rights and obligations associated with such sublicensing;

- the diligence and development obligations under license agreements (which may include specific diligence milestones) and what activities or achievements satisfy those diligence obligations;
- whether or not the milestones associated with certain milestone payment obligations have been achieved or satisfied;
- the applicability or scope of indemnification claims or obligations under such license agreements;
- the permissibility and advisability of, and strategy regarding, the pursuit of potential third-party infringers of the intellectual property that is the subject of such license agreements;
- the calculation of royalty, sublicense revenue and other payment obligations under such license agreements;
- the extent to which license rights, if any, are retained by licensors under such license agreements;
- whether or not a material breach has occurred under such license agreements and the extent to which such breach, if deemed to have occurred, is or can be cured within applicable cure periods, if any;
- disputes regarding patent filing and prosecution decisions, as well as payment obligations regarding past and ongoing patent expenses;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, 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 or may conflict in such a way that puts us in breach of one or more agreements, which would make us susceptible to lengthy and expensive disputes with one or more of such third-party licensing partners. 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 agreements, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Risks Related to Our Finances and Capital Requirements

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are an emerging growth company with a limited operating history. We have focused primarily on in-licensing and developing our product candidates, with the goal of supporting regulatory approval for these product candidates. We have incurred losses since our inception in March 2015 and have an accumulated deficit of $99.1 million as of June 30, 2019. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- one or more of our product candidates are approved for commercial sale, due to our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- we are required by the FDA or foreign regulatory authorities, to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;

- there are variations in the level of expenses related to our future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved;
- there are any regulatory developments affecting product candidates of our competitors; and
- one or more of our product candidates receives regulatory approval.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for one or more of our product candidates, or any future product candidate that we may license or acquire;
- manufacture commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

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

Our short operating history makes it difficult to evaluate our business and prospects.

We have only been conducting operations since our incorporation in March 2015. Our operations to date have been limited to preclinical operations and the in-licensing of our product candidates. We have not yet demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a clinical scale or commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly period as an indication of future operating performance.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

We have not generated any product related revenues to date, and do not expect to generate any such revenues for at least the next several years, if at all. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. As of June 30, 2019, we had $83.1 million in cash and restricted cash. We cannot provide any assurance that we will be able to raise funds to complete the development of our product candidates. Additionally, we may have to delay or terminate the development of certain product candidates if we are unable to secure additional funding; any such delay or termination, or the announcement of any such delay or termination, may impact our potential growth and have a material adverse effect on the value of our debt and equity securities.

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. We may also 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. Any of these events could significantly harm our business, financial condition and prospects.

Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, design and conduct of, and results from, preclinical and clinical trials for our product candidates;
- the potential for delays in our efforts to seek regulatory approval for our product candidates, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute our product candidates;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of our product candidates from our contract manufacturers for clinical trials and in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates; and
- the success of the commercialization of one or more of our product candidates.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidates or marketing territories.

Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock value to decline or require that we wind down our operations altogether.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and license and development agreements in connection with any collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a 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 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 when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

On August 22, 2017, we became a listed and traded public company. As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and the rules of the Nasdaq Stock Exchange. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations 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 persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

Compliance with the Sarbanes-Oxley Act of 2002 will require substantial financial and management resources and may increase the time and costs of completing an acquisition.

A business that we identify as a potential acquisition target may not be in compliance with the provisions of the Sarbanes-Oxley Act regarding the adequacy of internal controls. The development of the internal controls of any such entity to achieve compliance with the Sarbanes-Oxley Act may increase the time and costs necessary to complete any such acquisition. Furthermore, any failure to implement required new or improved controls, or difficulties encountered in the implementation of adequate controls over our financial processes and reporting in the future, could harm our operating results or cause us to fail to meet our reporting obligations. 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 securities.

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

We are an "emerging growth company" as that term is used in the JOBS Act, and may remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the initial public offering of our common stock, (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 means the market value of our outstanding common stock that are held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in our Annual Report on Form 10-K;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected 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, as an emerging growth company, will adopt the new or revised standard. This may make comparison of our financial statements with another public company which has opted into using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We have elected to take advantage of certain of the reduced reporting obligations available to us. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

We may, from time to time, carry net operating loss carryforwards (“NOLs”) as deferred tax assets on our balance sheet. 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-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which changes are outside our control. As a result, our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

Raising funds through lending arrangements may restrict our operations or produce other adverse results.

Our current Loan Agreement with Horizon, which we entered into in March 2019, contains a variety of affirmative and negative covenants, including required financial reporting, limitations on certain dispositions of assets, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under this Loan Agreement, we granted a security interest in substantially all of our assets, other than certain intellectual property assets, to Horizon. Our failure to comply with the covenants in the Loan Agreement, the occurrence of a material impairment in our prospect of repayment or in the perfection or priority of Horizon’s lien on our assets, as determined by Horizon, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, potential foreclosure on our assets and other adverse results. Additionally, we are bound by certain negative covenants setting forth actions that are not permitted to be taken during the term of the Loan Agreement without consent of Horizon, including, without limitation, incurring certain additional indebtedness, making certain asset dispositions, entering into certain mergers, acquisitions or other business combination transactions or incurring any non-permitted lien or other encumbrance on our assets. The foregoing prohibitions and constraints on our operations could result in our inability to: (i) acquire promising intellectual property or other assets on desired timelines or terms; (ii) reduce costs by disposing of assets or business segments no longer deemed advantageous to retain; (iii) stimulate further corporate growth or development through the assumption of additional debt; or (iv) enter into other arrangements that necessitate the imposition of a lien on corporate assets.

Risks Relating to Securities Markets and Investment in Our Stock

Our stock may be subject to substantial price and volume fluctuations due to a number of factors, many of which are beyond our control and may prevent our stockholders from reselling our common stock at a profit.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize our product candidates or any future product candidate, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching these product candidates, if approved;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of one or more of our product candidates or any future product candidate, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

Fortress controls a voting majority of our common stock.

Pursuant to the terms of the Class A Preferred Stock held by Fortress, Fortress is entitled to cast, for each share of Class A Preferred held by Fortress, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding common stock and (B) the whole shares of common stock into which the shares of outstanding Class A common shares and the Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Accordingly, Fortress is able to control or significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of Fortress may not always coincide with the interests of other stockholders, and Fortress may take actions that advance its own interests and are contrary to the desires of our other stockholders. Moreover, this concentration of voting power may delay, prevent or deter a change in control of us even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of Mustang or our assets, and might affect the prevailing market price of our common stock.

Fortress has the right to receive a significant grant of shares of our common stock annually which will result in the dilution of your holdings of common stock upon each grant, which could reduce their value.

Under the terms of the Second Amended and Restated Founders Agreement, which became effective July 22, 2016, Fortress will receive a grant of shares of our common stock equal to two and one-half percent (2.5%) of the gross amount of any equity or debt financing. Additionally, the Class A Preferred Stock, as a class, will receive an annual dividend on January 1st, payable in shares of common stock in an amount equal to two and one-half percent (2.5%) of our fully-diluted outstanding capital stock as of the business day immediately prior to January 1st of such year. Fortress currently owns all outstanding shares of Class A Preferred Stock. These share issuances to Fortress and any other holder of Class A Preferred Stock will dilute your holdings in our common stock and, if the value of Mustang has not grown proportionately over the prior year, would result in a reduction in the value of your shares. The Second Amended and Restated Founders Agreement has a term of 15 years and renews automatically for subsequent one-year periods unless terminated by Fortress or upon a Change in Control (as defined in the Second Amended and Restated Founders Agreement).

We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with Fortress.

The agreements we have entered into with Fortress include a Management Services Agreement and the Founders Agreement. While we believe the terms of these agreements are reasonable, they might not reflect terms that would have resulted from arm's-length negotiations between unaffiliated third parties. The terms of the agreements relate to, among other things, payment of a royalty on product sales and the provision of employment and transition services. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business.

The dual roles of our directors who also serve in similar roles with Fortress could create a conflict of interest and will require careful monitoring by our independent directors.

We share some directors with Fortress. This could create conflicts of interest between the two companies in the future. While we believe that the Founders Agreement and the Management Services Agreement were negotiated by independent parties on both sides on arm's length terms, and the fiduciary duties of both parties were thereby satisfied, in the future situations may arise under the operation of both agreements that may create a conflict of interest. We will have to be diligent to ensure that any such situation is resolved by independent parties. In particular, under the Management Services Agreement, Fortress and its affiliates are free to pursue opportunities which could potentially be of interest to Mustang, and they are not required to notify Mustang prior to pursuing such opportunities. Any such conflict of interest or pursuit by Fortress of a corporate opportunity independent of Mustang could expose us to claims by our investors and creditors and could harm our results of operations.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. 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 us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits listed on the Exhibit Index are either filed or furnished with this report or incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
10.1	2019 Employee Stock Purchase Plan
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Senior Vice President of Finance & Corporate Controller (Principal Financial Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.2	Certification of Senior Vice President of Finance & Corporate Controller (Principal Financial Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statement of Stockholders' Equity, (iv) the Condensed Statements of Cash Flows, and (v) Notes to the Condensed Financial Statements (filed 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.

MUSTANG BIO, INC.

August 8, 2019

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

By: /s/ Brian Achenbach
Brian Achenbach
Senior Vice President of Finance & Corporate Controller
(Principal Financial Officer)

EXHIBIT 10.1

Mustang Bio, Inc.

2019 EMPLOYEE STOCK PURCHASE PLAN

1. Purpose. The Mustang Bio, Inc. 2019 Employee Stock Purchase Plan (the "Plan") is established to provide eligible employees of Mustang Bio, Inc., a Delaware corporation, and any successor corporation thereto (collectively, "Mustang"), and any current or future parent corporation or subsidiary corporations of Mustang as the Board of Directors of Mustang (the "Board") shall from time to time designate (collectively referred to as the "Company" and individually referred to as a "Participating Company"), with an opportunity to acquire a proprietary interest in the Company by the purchase of common stock of Mustang. For purposes of the Plan, the terms "parent corporation" and "subsidiary corporation" shall have the meanings as defined in sections 424(e) and 424(f), respectively, of the Internal Revenue Code of 1986, as amended (the "Code").

Mustang intends that the Plan shall qualify as an "employee stock purchase plan" under section 423 of the Code (including any amendments or replacements of such section), and the Plan shall be so construed. Any term not expressly defined in the Plan but defined for purposes of section 423 of the Code shall have the same definition herein.

An employee participating in the Plan (a "Participant") may withdraw such Participant's accumulated payroll deductions (if any) and terminate participation in the Plan or any Offering (as defined below) therein at any time during a Purchase Period (as defined below). Accordingly, each Participant is, in effect, granted an option pursuant to the Plan to purchase shares of common stock of Mustang (each a "Purchase Right", and collectively, the "Purchase Rights") which may or may not be exercised at the end of a Purchase Period.

2. Administration. The Plan shall be administered by the Board and/or by a duly appointed committee of the Board having such powers as shall be specified by the Board. Any subsequent references to the Board shall also mean the committee if a committee has been appointed. All questions of interpretation of the Plan or of any Purchase Right shall be determined by the Board and shall be final and binding upon all persons having an interest in the Plan and/or any Purchase Right. Subject to the provisions of the Plan, the Board shall determine all of the relevant terms and conditions of Purchase Rights granted pursuant to the Plan; provided, however, that all Participants granted Purchase Rights pursuant to the Plan shall have the same rights and privileges within the meaning of section 423(b)(5) of the Code. All expenses incurred in connection with the administration of the Plan shall be paid by the Company.

3. Share Reserve. The maximum number of shares which may be issued under the Plan shall be Four Hundred Thousand (400,000) shares of Mustang's authorized but unissued common stock, $0.0001 par value (the "Shares"). In the event that any Purchase Right for any reason expires or is canceled or terminated, the Shares allocable to the unexercised portion of such Purchase Right may again be subjected to a Purchase Right.

4. Eligibility. Any employee of a Participating Company is eligible to participate in the Plan except employees who:

(a) customarily work 20 hours or less per week for a Participating Company;

(b) customarily work not more than five months in any calendar year for a Participating Company; or

(c) as of the start of an Offering, own stock of Mustang (or any parent or subsidiary corporation of Mustang) and/or own or hold options to purchase or who, as a result of participation in the Plan, would own or hold options to purchase, stock of Mustang (or any parent or subsidiary corporation of Mustang), possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of Mustang (or any parent or subsidiary corporation of Mustang) within the meaning of section 423(b)(3) of the Code.

Notwithstanding anything herein contained to the contrary, any individual performing services for a Participating Company solely through a leasing agency or employment agency shall not be deemed an "employee" of such Participating Company.

5. Offering Dates.

(a) Offering Periods. Except as otherwise set forth below, the Plan shall be implemented by offerings (individually, an "Offering") of approximately six (6) months duration (an "Offering Period"). The "Initial Offering Date" is September 1, 2019. The initial Offering shall be of six (6) months duration, shall commence on the Initial Offering Date and shall end on February 29, 2020 (the "Initial Offering Period"). Thereafter, Offering Periods shall commence on September 1 and end on February 28 (or 29 in the case of a leap year) and then commence on March 1 and end on August 31. Notwithstanding the foregoing, the Board may establish a different term for one or more Offerings and/or different commencing and/or ending dates for such Offerings. An employee who becomes eligible to participate in the Plan after an Offering Period has commenced shall not be eligible to participate in such Offering but may participate in any subsequent Offering provided such employee is still eligible to participate in the Plan as of the commencement of any such subsequent Offering. Eligible employees may not participate in more than one Offering at a time. The first day of an Offering Period shall be the "Offering Date" for such Offering Period. In the event the first and/or last day of an Offering Period as set forth above is not a Trading Day (as defined below), such first and/or last day shall be deemed to be the last Trading Day before such day, respectively. For purposes of this Plan, "Trading Day" shall mean a day on which national stock exchanges are open for trading.

(b) Purchase Periods. Except for the Initial Offering Period, each Offering Period shall consist of one (1) purchase period of approximately six (6) months duration (individually, a "Purchase Period"). The last day of each Purchase Period shall be the "Purchase Date" for such Purchase Period. The Purchase Period commencing on the Initial Offering Date of September 1, 2019 (the "First Purchase Period") shall end on February 29, 2020. Each subsequent Purchase Period after the First Purchase Period will commence with the beginning of the respective Offering Period and end at the end of such respective Offering Period. Notwithstanding the foregoing, the Board may establish a different term for one or more Purchase Periods and/or different commencing dates and/or Purchase Dates for such Purchase Periods, upon providing reasonable notice. In the event the first and/or last day of a Purchase Period as set forth above is not a Trading Day, such first and/or last day shall be deemed to be the last Trading Day before such day, respectively.

(c) Governmental Approval; Stockholder Approval. Notwithstanding any other provision of the Plan to the contrary, any Purchase Right granted pursuant to the Plan shall be subject to (i) obtaining all necessary governmental approvals and/or qualifications of the sale and/or issuance of the Purchase Rights and/or the Shares, and (ii) obtaining stockholder approval of the Plan as required pursuant to section 423(b)(2) of the Code. Notwithstanding the foregoing, such stockholder approval shall not be necessary in order to grant any Purchase Right granted in the Plan's Initial Offering Period; provided, however, that the exercise of any such Purchase Right shall be subject to obtaining such stockholder approval of the Plan. If such stockholder approval is not obtained before the end of the Initial Offering Period, this Plan shall be deemed null and void and all rights hereunder shall terminate and each Participant's accumulated payroll deductions shall be returned as soon as practicable after the termination, without the payment of any interest (unless the Board decides otherwise pursuant to paragraph 9(e) below), to the Participant, and the Participant's interest in the Offering and/or the Plan, as applicable, shall terminate.

6. Participation in the Plan. An eligible employee shall become a Participant on the Offering Date after satisfying the eligibility requirements and delivering to the Company not later than three (3) full business days before such Offering Date (the "Subscription Date") a fully-completed subscription agreement (utilizing a form provided by the Company for such purpose) indicating the employee's election to participate in the Plan and authorizing initial payroll deductions for the applicable Offering of 1% to 10% of the Participant's Compensation. An eligible employee who does not deliver such a subscription agreement to the Company on or before the Subscription Date shall not participate in the Plan for that Offering Period or for any subsequent Offering Period unless such employee subsequently enrolls in the Plan by filing such a subscription agreement with the Company by the Subscription Date for such subsequent Offering Period. The Company may, from time to time, change the Subscription Date as

deemed advisable by the Company in its sole discretion for proper administration of the Plan, upon providing reasonable notice. Each employee shall be required to comply with above participation requirements, as well as any other requirements set forth in this Plan, with respect to each Offering Period to be a Participant in such Offering Period.

7. Right to Purchase Shares. Except as set forth below, during an Offering Period each Participant in such Offering Period shall have a Purchase Right consisting of the right to purchase the lesser of:

(a) that number of whole Shares arrived at by dividing Twenty Five Thousand Dollars ($25,000.00) by the fair market value of a Share on the Offering Date of such Offering Period; and

(b) 5,000 Shares.

The "fair market value" of Shares shall be determined in accordance with paragraph 8 below. Shares may only be purchased under the Plan through a Participant's payroll withholding pursuant to paragraph 9 below. In no event shall a Participant's Purchase Right permit such Participant to acquire more Shares in any calendar year than is permitted under paragraph 10(a) hereof.

Notwithstanding anything herein to the contrary, each Purchase Right shall expire in accordance with paragraph 9(j) hereof.

8. Purchase Price. The purchase price at which Shares may be acquired in a given Purchase Period pursuant to the exercise of all or any portion of a Purchase Right granted under the Plan (the "Offering Exercise Price") shall be set by the Board; provided, however, that the Offering Exercise Price shall not be less than eighty-five percent (85%) of the lesser of (i) the fair market value of the Shares on the Offering Date of the Offering Period of which the Purchase Period is a part, or (ii) the fair market value of the Shares on the Purchase Date for such Purchase Period. Unless otherwise provided by the Board prior to the commencement of an Offering Period, the Offering Exercise Price for each Purchase Period in that Offering Period shall be eighty-five percent (85%) of the lesser of (i) the fair market value of the Shares on the Offering Date of such Offering Period or (ii) the fair market value of the Shares on the given Purchase Date. For purposes of the plan, the "fair market value" of the Shares on the applicable dates shall be the closing sales price on The Nasdaq Global Market (or the average of the closing bid and asked prices if the Shares are so quoted instead) or as reported on such other national or regional securities exchange or market system if the Shares are traded on such other exchange or system instead, or as determined by the Board if the Shares are not so reported. If the relevant date does not fall on a day on which the Shares are quoted on The Nasdaq Global Market or such other national or regional securities exchange or market, the date on which the fair market value per Share shall be established shall be the last day on which the Shares were so quoted to such relevant date.

9. Payment of Purchase Price. Shares which are acquired pursuant to the exercise of all or any portion of a Purchase Right may be paid for only by means of payroll deductions from the Participant's Compensation during the Offering Period. For purposes of the Plan, a Participant's "Compensation" with respect to an Offering (i) shall include the Participant's base salary before deduction for any contributions to any plan maintained by a Participating Company and described in section 401(k) or section 125 of the Code, commissions, overtime and bonuses and (ii) shall not include annual awards, other incentive payments, shift premiums, long-term disability, worker's compensation or any other payments not specifically referenced in (i). Except as set forth below, the amount of Compensation to be withheld from a Participant's Compensation during each pay period shall be determined by the Participant's subscription agreement.

(a) Election to Decrease or Stop Withholding. During an Offering Period, a Participant may elect to decrease the amount to be withheld as many times as desired, or to stop withholding (by reducing the Participant's withholding election to 0%), from his or her Compensation by filing an amended subscription agreement with the Company on or before the "Change Notice Date." The "Change Notice Date" shall initially be the seventh (7^{th}) day prior to the end of the first pay period for which such election is to be effective; however, the Company may change such Change Notice Date from time to time, upon reasonable notice.

(b) Limitations on Payroll Withholding. The amount of payroll withholding with respect to the Plan for any Participant during any pay period shall be no less than one percent (1%) of the Participant's Compensation (except where the Participant has elected under Section 9 (a) to decrease the amount of the Participant's withholding election to 0%) for such pay period, and, unless such 0% withholding is in effect, shall be in one percent (1%) increments not to exceed ten percent (10%) of the Participant's Compensation for such pay period. Notwithstanding the foregoing, the Board may change the limits on payroll withholding effective as of a future Offering Date, as determined by the Board, upon reasonable notice. Amounts withheld shall be reduced by any amounts contributed by the Participant and applied to the purchase of Company stock pursuant to any other employee stock purchase plan qualifying under section 423 of the Code.

(c) Payroll Withholding. Payroll deductions shall commence on the first payday following the Offering Date and shall continue to the end of the Offering Period unless sooner altered or terminated by the Participant or otherwise as provided in the Plan.

(d) Participant Accounts. An individual account shall be maintained under the Plan for each Participant. All payroll deductions from a Participant's Compensation shall be credited to such account and shall be deposited with the general funds of the Company. All payroll deductions received or held by the Company may be used by the Company for any corporate purpose.

(e) No Interest Paid. Interest shall not be paid on sums withheld from a Participant's Compensation, unless the Board elects to make such payments to all Participants on a non-discriminatory basis.

(f) Exercise of Purchase Right. On each Purchase Date of an Offering Period, each Participant who has not withdrawn from the Offering or whose participation in the Offering has not terminated on or before such Purchase Date shall automatically acquire pursuant to the exercise of the Participant's Purchase Right the number of whole Shares arrived at by dividing the total amount of the Participant's accumulated payroll deductions for the Purchase Period by the Offering Exercise Price; provided, however, in no event shall the number of Shares purchased by the Participant exceed the number of Shares subject to the Participant's Purchase Right or the limitations imposed by paragraph 10(a) hereof. No Shares shall be purchased on a Purchase Date on behalf of a Participant whose participation in the Offering or the Plan has terminated on or before such Purchase Date.

(g) Remaining Cash Balance. Any cash balance remaining in a Participant's account at the end of a Purchase Date shall be refunded to the Participant as soon as practicable after such Purchase Date. In the event the cash to be returned to a Participant pursuant to the preceding sentence is an amount less than the amount necessary to purchase a whole Share, the Company may establish procedures whereby such cash is maintained in the Participant's account and applied toward the purchase of Shares in the subsequent Offering Period.

(h) Tax Withholding. At the time a Purchase Right is exercised, in whole or in part, or at the time some or all of the Shares received pursuant to a Purchase Right are disposed of, the Participant shall make adequate provision for the foreign, federal and state tax withholding obligations of the Company, if any, which arise upon exercise of the Purchase Right and/or upon disposition of Shares, respectively. The Company may, but shall not be obligated to, withhold from the Participant's Compensation the amount necessary to meet such withholding obligations.

(i) Company Established Procedures. The Company may, from time to time, establish or change (i) a minimum required withholding amount for participation in an Offering, (ii) limitations on the frequency and/or number of changes in the amount withheld during an Offering, (iii) an exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, (iv) payroll withholding in excess of or less than the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of subscription agreements, and/or (v) such other limitations or procedures as deemed advisable by the Company in the Company's sole discretion which are consistent with the Plan and in accordance with the requirements of section 423 of the Code.

(j) Expiration of Purchase Right. Any portion of a Participant's Purchase Right remaining unexercised after the end of the Offering Period to which such Purchase Right relates shall expire immediately upon the end of such Offering Period.

10. Limitations on Purchase of Shares; Rights as a Stockholder.

(a) Fair Market Value Limitation. Notwithstanding any other provision of the Plan, no Participant shall be entitled to purchase Shares under the Plan (and under all other employee stock purchase plans which are intended to meet the requirements of section 423 of the Code sponsored by the Company or a parent or subsidiary corporation of the Company) at a rate which exceeds $25,000 in fair market value, which fair market value is determined for Shares purchased during a given Offering Period as of the Offering Date for such Offering Period (or such other limit as may be imposed by the Code), for each calendar year in which such Participant's Purchase Right with respect to such Offering Period remains outstanding under the Plan (and under all other employee stock purchase plans described in this sentence).

(b) Pro Rata Allocation. In the event the number of Shares which might be purchased by all Participants in the Plan exceeds the number of Shares available under the Plan (as set forth in paragraph 3), the Company shall make a pro rata allocation of the remaining Shares in as uniform a manner as shall be practicable and as the Company shall determine to be equitable.

(c) Rights as a Stockholder and Employee. A Participant shall have no rights as a stockholder by virtue of the Participant's participation in the Plan until the date of the issuance of a stock certificate(s) for the Shares being purchased pursuant to the exercise of the Participant's Purchase Right. No adjustment shall be made for cash dividends or distributions or other rights for which the record date is prior to the date such stock certificate(s) are issued. Nothing herein shall confer upon a Participant any right to continue in the employ of the Company, or any Participating Company or interfere in any way with any right of the Company, to terminate the Participant's employment at any time.

11. Withdrawal.

(a) Withdrawal From an Offering. A Participant may withdraw from an Offering by signing and delivering to the Company a written notice of withdrawal on a form provided by the Company for such purpose (a "Withdrawal Notice"). Such withdrawal may be elected at any time up to three (3) full business days (or such other number of business days as deemed advisable by the Company in its sole discretion for proper administration of the Plan, upon reasonable notice) prior to the end of an Offering. Unless otherwise indicated, withdrawal from an Offering shall not result in such Participant's withdrawal from the Plan or any succeeding Offering therein. By withdrawing from an Offering effective as of the close of a given Offering, a Participant may immediately commence participation in the next offering commencing immediately thereafter by again satisfying the requirements of paragraphs 4 and 6 above. A Participant is prohibited from again participating in an Offering at any time upon withdrawal from such Offering. The Company may impose, from time to time, a requirement that the notice of withdrawal be on file with the Company for a reasonable period prior to the effectiveness of the Participant's withdrawal from an Offering.

(b) Return of Payroll Deductions. Upon withdrawal from an Offering pursuant to paragraph 11(a), the withdrawn Participant's accumulated payroll deductions which have not been applied toward the purchase of Shares under the Plan shall be returned as soon as practicable after the withdrawal, without the payment of any interest (unless the Board decides otherwise pursuant to paragraph 9(e) above), to the Participant, and the Participant's interest in the Offering shall terminate. Such accumulated payroll deductions may not be applied to any other Offering under the Plan.

12. Termination of Employment. Termination of a Participant's employment with the Company for any reason, including retirement, disability or death or the failure of a Participant to remain an employee eligible to participate in the Plan, shall terminate the Participant's participation in the Plan immediately. In such event, the payroll deductions credited to the Participant's account since the last Purchase Date shall, as soon as practicable, be returned to the Participant or, in the case of the Participant's death, to the Participant's legal representative, and all of the Participant's right under the Plan shall terminate. Interest

shall not be paid on sums returned to a Participant pursuant to this paragraph 12 unless the Board elects otherwise pursuant to paragraph 9(e) above. A Participant whose participation has been so terminated may again become eligible to participate in the Plan by again satisfying the requirements of paragraphs 4 and 6 above.

13. Transfer of Control. A "Transfer of Control" shall be deemed to have occurred in the event any of the following occurs with respect to Mustang:

(a) a merger or consolidation in which Mustang is not the surviving corporation;

(b) a merger or consolidation in which Mustang is the surviving corporation where the stockholders of Mustang before such merger or consolidation do not retain, directly or indirectly, at least a majority of the beneficial interest in the voting stock of Mustang;

(c) the sale, exchange, or transfer of all or substantially all of Mustang's assets other than a sale, exchange, or transfer to one (1) or more subsidiary corporations (as defined in paragraph 1, above) of Mustang;

(d) the direct or indirect sale or exchange by the stockholders of Mustang of all or substantially all of the stock of Mustang where the stockholders of Mustang before such sale or exchange do not retain, directly or indirectly, at least a majority of the beneficial interest in the voting stock of Mustang after such sale or exchange; or

(e) the liquidation or dissolution of Mustang.

In the event of a Transfer of Control, the Board, in its sole discretion, may shorten the Purchase Period then in progress by setting a new Purchase Date, which shall be before the date of the proposed transaction giving rise to the Transfer of Control, or may arrange with the surviving, continuing, successor, or purchasing corporation, as the case may be (the "Acquiring Corporation"), for the Acquiring Corporation to assume Mustang's rights and obligations under the Plan. All Purchase Rights shall terminate effective as of the date of the Transfer of Control to the extent that the Purchase Right is neither exercised as of the date of the Transfer of Control nor assumed by the Acquiring Corporation. In the event of such termination, the payroll deductions credited to a Participant's account since the last Purchase Date prior to such termination shall, as soon as practicable, be returned to the Participant. Interest shall not be paid on such sums returned to a Participant pursuant to this paragraph 13 unless the Board elects otherwise pursuant to paragraph 9(e) above.

14. Capital Changes. In the event of changes in the common stock of Mustang due to a stock split, reverse stock split, stock dividend, recapitalization, combination, reclassification, or like change in Mustang capitalization, or in the event of any merger (including a merger effected for the purpose of changing Mustang's domicile), sale or other reorganization, appropriate adjustments shall be made by Mustang in the securities subject to purchase under a Purchase Right, the Plan's share reserve, the number of Shares subject to a Purchase Right, and in the purchase price per Share.

15. Transferability. A Purchase Right may not be transferred in any manner otherwise than by will or the laws of descent and distribution and shall be exercisable during the lifetime of the Participant only by the Participant. Mustang, in its absolute discretion, may impose such restrictions on the transferability of the Shares purchasable upon the exercise of a Purchase Right as it deems appropriate, and any such restriction shall be set forth in the respective subscription agreement and may be referred to on the certificates evidencing such Shares.

16. Reports. Each Participant who exercised all or part of his or her Purchase Right for an Offering shall receive, as soon as practicable after the Purchase Date of such Purchase Period, a report of such Participant's account setting forth the total payroll deductions accumulated, the number of Shares purchased, the fair market value of such Shares, the date of purchase and the remaining cash balance to be refunded or retained in the Participant's account pursuant to paragraph 9(g) above, if any. In addition, each Participant shall be provided information concerning Mustang equivalent to that information generally made available to Mustang's common stockholders.

17. Plan Term. This Plan shall continue until terminated by the Board.

18. Restriction on Issuance of Shares. The issuance of Shares under the Plan shall be subject to compliance with all applicable requirements of foreign, federal or state law with respect to the Shares. A Purchase Right may not be exercised if the issuance of Shares upon such exercise would constitute a violation of any applicable foreign, federal or state securities laws or other law or regulations. In addition, no Purchase Right may be exercised unless (i) a registration statement under the Securities Act of 1933, as amended, shall at the time of exercise of the Purchase Right be in effect with respect to the Shares issuable upon exercise of the Purchase Right, or (ii) in the opinion of legal counsel to Mustang, the Shares issuable upon exercise of the Purchase Right may be issued in accordance with the terms of an applicable exemption from the registration requirements of said Act. As a condition to the exercise of a Purchase Right, Mustang may require a Participant to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation, and to make any representation or warranty with respect thereto as may be requested by the Company.

19. Legends. The Company may at any time place legends or other identifying symbols referencing any applicable foreign, federal and/or state securities restrictions or any provision convenient in the administration of the Plan on some or all of the certificates representing Shares issued under the Plan. A Participant shall, at the request of Mustang, promptly present to Mustang any and all certificates representing Shares acquired pursuant to a Purchase Right in the possession of the Participant in order to carry out the provisions of this paragraph 19. Unless otherwise specified by Mustang, legends placed on such certificates may include but shall not be limited to the following:

"THE SHARES EVIDENCED BY THIS CERTIFICATE WERE ISSUED BY THE CORPORATION TO THE REGISTERED HOLDER UPON THE PURCHASE OF SHARES UNDER THE EMPLOYEE STOCK PURCHASE PLAN AS DEFINED IN SECTION 423 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED, THE TRANSFER AGENT FOR THE SHARES EVIDENCED HEREBY SHALL NOTIFY THE CORPORATION IMMEDIATELY OF ANY TRANSFER OF THE SHARES BY THE REGISTERED HOLDER HEREOF MADE ON OR BEFORE . THE REGISTERED HOLDER SHALL HOLD ALL SHARES PURCHASED UNDER THE PLAN IN THE REGISTERED HOLDER'S NAME (AND NOT IN THE NAME OF ANY NOMINEE) PRIOR TO THIS DATE."

20. Notification of Sale of Shares. Mustang may require a Participant to give Mustang prompt notice of any disposition of Shares acquired by exercise of a Purchase Right within two (2) years from the date of granting such Purchase Right or one year from the date of exercise of such Purchase Right. Mustang may require that until such time as a Participant disposes of Shares acquired upon exercise of a Purchase Right, the Participant shall hold all such Shares in the Participant's name (and not in the name of any nominee) until the lapse of the time periods with respect to such Purchase Right referred to in the preceding sentence. Mustang may direct that the certificates evidencing Shares acquired by exercise of a Purchase Right refer to such requirement to give prompt notice of disposition.

21. Amendment or Termination of the Plan. The Board may at any time amend or terminate the Plan, except that such termination shall not affect Purchase Rights previously granted under the Plan, nor may any amendment make any change in a Purchase Right previously granted under the Plan which would adversely affect the right of any Participant (except to the extent permitted by the Plan or as may be necessary to qualify the Plan as an employee stock purchase plan pursuant to section 423 of the Code or to obtain qualification or registration of the Shares under applicable foreign, federal or state securities laws). In addition, an amendment to the Plan must be approved by the stockholders of the Company within twelve (12) months of the adoption of such amendment if such amendment would change the number of Shares authorized for issuance under the Plan or would change the definition of the employees (or class of employees) eligible to participate in the Plan, including the corporations that may be designated by the Board as Participating Companies.

22. Section 409A. The Purchase Rights under the Plan are not intended to constitute “nonqualified deferred compensation” within the meaning of section 409A of the Code. However, if at any time the Board or other administrator determines that the Purchase Rights may be subject to section 409A of the Code, the Board or other administrator shall have the right, in its sole discretion, to amend the Plan and any outstanding Purchase Rights as it may determine is necessary or desirable either to (a) exempt the Purchase Rights from section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Purchase Rights, or (b) comply with the requirements of section 409A of the Code and related Department of Treasury guidance and thereby avoid the application of any penalty taxes under such Section.

The foregoing Mustang Bio, Inc. 2019 Employee Stock Purchase Plan was duly adopted by the Board of Directors of the Company on the 27th day of March, 2019.

Exhibit 31.1

MUSTANG BIO, INC.
CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Manuel Litchman, M.D., President and Chief Executive Officer (Principal Executive Officer), certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Mustang Bio, Inc. (the "Registrant");

(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(s) 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. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of 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 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(s) 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 controls over financial reporting.

August 8, 2019

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

Exhibit 31.2

MUSTANG BIO, INC.
CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Achenbach, Senior Vice President of Finance & Corporate Controller (Principal Financial Officer), certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Mustang Bio, Inc. (the “Registrant”);

(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(s) 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. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of 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 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(s) 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 controls over financial reporting.

August 8, 2019

By: /s/ Brian Achenbach
Brian Achenbach
Senior Vice President of Finance & Corporate Controller
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Mustang Bio, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Manuel Litchman, M.D., President and Chief Executive Officer (Principal Executive Officer), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(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, as of, and for, the periods presented in the Report.

August 8, 2019	By:	/s/ Manuel Litchman
		Manuel Litchman, M.D., President and Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Mustang Bio, Inc. (the “Company”) on Form 10-Q for the quarterly period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Brian Achenbach, Senior Vice President of Finance & Corporate Controller (Principal Financial Officer), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(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, as of, and for, the periods presented in the Report.

August 8, 2019	By:	/s/ Brian Achenbach
		Brian Achenbach
		Senior Vice President of Finance & Corporate Controller
		(Principal Financial Officer)