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

FORM 10-Q

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

For the quarterly period ended September 30, 2023

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.)

377 Plantation Street
Worcester, MA 01605
(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 Capital 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 November 10, 2023**
Class A Common Stock, $0.0001 par value	845,385
Common Stock, $0.0001 par value	8,371,805

MUSTANG BIO, INC.
QUARTERLY REPORT ON FORM 10-Q
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SUMMARY OF RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in Item 1A, and the other reports and documents that we have filed with the Securities and Exchange Commission ("SEC").

Risks Related to our Finances and Capital Requirements

- We have incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future.
- There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional financing in upcoming periods, which may not be available on acceptable terms to the Company, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our commercial readiness efforts, activities to support a potential commercial launch following any approval of our product candidates, or other operations.
- Our short operating history makes it difficult to evaluate our business and prospects.
- Our success is contingent upon raising additional capital, which efforts may fail. Even if successful, our future capital raising activities may dilute our current stockholders, restrict our operations, or cause us to relinquish proprietary rights.

Risks Pertaining to our Business Strategy, Structure and Organization

- Our future growth and success depend on our ability to successfully develop and commercialize our product candidates, which we have yet to do.
- Our future success is highly dependent on the successful development of our chimeric antigen receptor ("CAR") engineered T cell ("CAR T") technology and gene therapy product candidates.

Risks Inherent in Drug Development and Commercialization

- Preclinical development is highly speculative and carries a high failure risk.
- We may not receive the required regulatory approvals for any of our product candidates on our projected timelines, if at all, which may result in increased costs and delay our ability to generate revenue.
- We may not obtain the desired labeling claims or intended uses for product promotion, or favorable scheduling classifications, to successfully promote our products.
- If a product candidate demonstrates adverse side effects, we may need to abandon or limit the development of such product candidate.
- Even if a product candidate is approved, it may be subject to various post-marketing requirements, including studies or clinical trials, and increased regulatory scrutiny.
- Our competitors may develop treatments for our products' target indications, which could limit our product candidates' commercial opportunity and profitability.
- If our products are not broadly accepted by the healthcare community, the revenues from any such product will likely be limited.
- Any successful products liability claim related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of such products.
- 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.

Risks Related to Reliance on Third Parties

- 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 contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and may also do so for commercialization, if and when our product candidates are approved.
- We rely on clinical data and results obtained by third parties, which may prove inaccurate or unreliable.
- 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.

Risks Relating to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

- We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations.
- We may be subject to 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.
- We are subject to numerous environmental, health and safety laws and regulations and could become subject to fines or penalties or incur costs that could harm our business.

Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof

- If we are unable to obtain and maintain sufficient patent protection for our technology and products, our competitors could develop and commercialize products similar or identical to ours and our ability to successfully commercialize our technology and products could be impaired.
- We depend on our licensors to maintain and enforce the intellectual property covering certain of our product candidates.
- We or our licensors may be subject to costly and time-consuming litigation for infringement of third-party intellectual property rights or to enforce our or our licensors' patents.
- Any dispute with our licensors may affect our ability to develop or commercialize our product candidates.

Risks Relating to Our Control by Fortress Biotech, Inc. ("Fortress")

- Fortress controls a voting majority of our common stock and has the right to receive significant share grants annually, which will result in dilution of our other stockholders and could reduce the value of our common stock.
- We have entered into certain agreements with Fortress and may have received better terms from unaffiliated third parties.

Risks Related to Conflicts of Interest

- We share certain directors with Fortress, which could create conflicts of interest between us and Fortress.

Risks Relating to the Sale of the Company's Manufacturing Facility

- We may be unable to complete the transaction as contemplated if the Committee on Foreign Investment in the United States determines to implement mitigation measures, including the potential divestment of some or all of the transferred assets by the buyer, which may limit our ability to realize the anticipated cost savings of the sale of the facility and may have a material adverse effect on our financial condition.
- Our receipt of the contingent portion of the consideration for the sale of the manufacturing facility is subject to receipt of the consent of the landlord of the facility to the transfer of such lease to the buyer and our ability to raise additional capital.

- If the landlord does not consent to the transfer of the lease within 120 days of the closing date of the transaction and the lease of the facility is not transferred to the buyer, we may be obligated to negotiate the repurchase of the facility from the buyer. The buyer may provide us with notice of its intentions to enter into negotiations for our repurchase of the facility if the lease of the facility is not transferred to the buyer within 120 days of the closing date, and we may be unable to successfully negotiate such repurchase.
- The landlord may object to certain aspects of the transaction which could result in expensive and time-consuming litigation and could prevent us from realizing the intended benefits of the transaction.
- If the sale of the facility is fully consummated, we will rely on the buyer for the manufacture of our lead product candidates which may subject us to additional manufacturing risks.
- We may incur substantial expenses related to the transaction and the consummation of the sale of the facility.
- Certain key personnel may depart the Company upon the completion of the sale of the facility which may adversely affect our ability to realize the anticipated benefits of the transaction.
- Our strategic pivot to our lead product candidate, MB-106, and our disposal of non-core assets, including our facility, may not result in the anticipated cost savings and could result in total costs and expenses that are greater than expected.

PART I. FINANCIAL INFORMATION
Item 1. Unaudited Financial Statements

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

	September 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,562	$ 75,656
Other receivables - related party	—	36
Prepaid expenses and other current assets	4,026	3,160
Total current assets	13,588	78,852
Property, plant and equipment, net	3,502	8,440
Fixed assets - construction in process	—	951
Restricted cash	750	1,000
Other assets	1,083	261
Operating lease right-of-use asset, net	1,644	2,918
Total Assets	**$ 20,567**	**$ 92,422**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 12,708	$ 13,731
Payables and accrued expenses - related party	1,005	766
Operating lease liabilities - short-term	453	612
Total current liabilities	**14,166**	**15,109**
Deferred income	270	270
Note payable, long-term, net	—	27,436
Operating lease liabilities - long-term	2,122	3,334
Total Liabilities	**16,558**	**46,149**
Commitments and Contingencies (Note 12)		
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 September 30, 2023 and December 31, 2022, respectively	—	—
Common stock ($0.0001 par value), 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively		
Class A common shares, 845,385 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Common shares, 7,451,015 and 7,100,111 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	1	11
Common stock issuable, 6,987 and 187,134 shares as of September 30, 2023 and December 31, 2022, respectively	4	1,109
Additional paid-in capital	376,359	374,522
Accumulated deficit	(372,355)	(329,369)
Total Stockholders' Equity	**4,009**	**46,273**
Total Liabilities and Stockholders' Equity	**$ 20,567**	**$ 92,422**

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

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 9,477	$ 15,419	$ 34,313	$ 46,872
Research and development – licenses acquired	50	40	50	40
Gain on the sale of property and equipment	(1,351)	—	(1,351)	—
General and administrative	2,131	3,389	7,507	9,815
Total operating expenses	10,307	18,848	40,519	56,727
Loss from operations	(10,307)	(18,848)	(40,519)	(56,727)
Other income (expense)				
Other income	138	669	918	669
Interest income	115	216	727	366
Interest expense	(4)	(1,034)	(4,112)	(2,199)
Total other income (expense)	249	(149)	(2,467)	(1,164)
Net Loss	**$ (10,058)**	**$ (18,997)**	**$ (42,986)**	**$ (57,891)**
Net loss per common share outstanding, basic and diluted	$ (1.23)	$ (2.42)	$ (5.29)	$ (7.61)
Weighted average number of common shares outstanding, basic and diluted	8,171,582	7,850,208	8,131,191	7,608,309

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

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

For the Three Months Ended September 30, 2023

	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 June 30, 2023	**250,000**	**$ —**	**845,385**	**$ —**	**7,320,444**	**$ 1**	**$ —**	**$ 376,009**	**$ (362,297)**	**$ 13,713**
Issuance of common shares under ESPP	—	—	—	—	34,869	—	—	90	—	90
Stock-based compensation expenses	—	—	—	—	43,822	—	—	100	—	100
Fractional share adjustment	—	—	—	—	—	—	—	—	—	—
Issuance of common shares, net of offering costs - At-the-Market Offering	—	—	—	—	51,880	—	—	160	—	160
Issuance of common shares, equity fee on At-the-Market Offering	—	—	—	—	—	—	4	—	—	4
Net loss	—	—	—	—	—	—	—	—	(10,058)	(10,058)
Balances at September 30, 2023	**250,000**	**$ —**	**845,385**	**$ —**	**7,451,015**	**$ 1**	**$ 4**	**$ 376,359**	**$ (372,355)**	**$ 4,009**

For the Nine Months Ended September 30, 2023

	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, 2022	**250,000**	**$ —**	**845,385**	**$ —**	**7,100,111**	**$ 11**	**$ 1,109**	**$ 374,522**	**$ (329,369)**	**$ 46,273**
Issuance of common shares - Founders Agreement	—	—	—	—	187,134	—	(1,109)	1,109	—	—
Issuance of common shares, net of offering costs - At-the-Market Offering	—	—	—	—	51,880	—	—	160	—	160
Issuance of common shares, equity fee on At-the-Market Offering	—	—	—	—	—	—	4	—	—	4
Issuance of common shares under ESPP	—	—	—	—	47,511	—	—	178	—	178
Stock-based compensation expenses	—	—	—	—	65,919	—	—	380	—	380
Exercise of warrants	—	—	—	—	93	—	—	—	—	—
Reverse Split (15:1)	—	—	—	—	—	(10)	—	10	—	—
Fractional share adjustment	—	—	—	—	(1,633)	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(42,986)	(42,986)
Balances at September 30, 2023	**250,000**	**$ —**	**845,385**	**$ —**	**7,451,015**	**$ 1**	**$ 4**	**$ 376,359**	**$ (372,355)**	**$ 4,009**

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

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

For the Three Months Ended September 30, 2022

	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 June 30, 2022	**250,000**	**$ —**	**845,385**	**$ —**	**6,967,413**	**$ 10**	**$ 28**	**$ 372,708**	**$ (290,738)**	**$ 82,008**
Issuance of common shares, net of offering shares -At-the-Market Offering	—	—	—	—	75,001	—	—	709	—	709
Issuance of common shares - Equity fee on At-the-Market Offering	—	—	—	—	4,179	1	(24)	42	—	19
Issuance of common shares under ESPP	—	—	—	—	11,570	—	—	90	—	90
Stock-based compensation expenses	—	—	—	—	37,022	—	—	496	—	496
Net loss	—	—	—	—	—	—	—	—	(18,997)	(18,997)
Balances at September 30, 2022	**250,000**	**$ —**	**845,385**	**$ —**	**7,095,185**	**$ 11**	**$ 4**	**$ 374,045**	**$ (309,735)**	**$ 64,325**

For the Nine Months Ended September 30, 2022

	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, 2021	**250,000**	**$ —**	**845,385**	**$ —**	**6,238,866**	**$ 9**	**$ 4,329**	**$ 359,906**	**$ (251,844)**	**$ 112,400**
Issuance of common shares - Founders Agreement	—	—	—	—	169,107	—	(4,212)	4,212	—	—
Issuance of common shares, net of offering shares -At-the-Market Offering	—	—	—	—	525,206	2	—	6,498	—	6,500
Issuance of common shares - Equity fee on At-the-Market Offering	—	—	—	—	16,084	—	(113)	279	—	166
Issuance of common shares under ESPP	—	—	—	—	22,056	—	—	206	—	206
Stock-based compensation expenses	—	—	—	—	60,204	—	—	1,810	—	1,810
Issuance of common shares - Equity fee on RWG debt	—	—	—	—	63,662	—	—	750	—	750
Issuance of warrants for RWG debt	—	—	—	—	—	—	—	384	—	384
Net loss	—	—	—	—	—	—	—	—	(57,891)	(57,891)
Balances at September 30, 2022	**250,000**	**$ —**	**845,385**	**$ —**	**7,095,185**	**$ 11**	**$ 4**	**$ 374,045**	**$ (309,735)**	**$ 64,325**

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

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

	For the nine months ended September 30,	
	2023	**2022**
Cash Flows from Operating Activities:		
Net loss	$ (42,986)	$ (57,891)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common shares - Equity fee on at-the-market offering to Fortress Biotech	—	165
Common shares issuable - Equity fee on at-the-market offering to Fortress Biotech	4	—
Issuance of common shares - Equity fee on note payable to Fortress Biotech	—	750
Research and development - licenses acquired	50	40
Stock-based compensation expenses	380	1,810
Depreciation expense	1,576	1,995
Amortization of debt discount	118	328
Reduction in the carrying amount of operating lease right-of-use assets	286	202
Loss on disposal of property and equipment	—	255
Gain on sale of property and equipment	(1,351)	—
Loss on extinguishment of debt	2,796	—
Gain on lease modification	(220)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,688)	(970)
Other receivables - related party	36	17
Accounts payable and accrued expenses	(1,299)	4,316
Payable and accrued expenses - related party	239	(571)
Lease liabilities	(163)	(223)
Net cash used in operating activities	(42,223)	(49,777)
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(50)	(40)
Proceeds from the sale of property and equipment	6,000	127
Purchase of fixed assets	(34)	(2,619)
Net cash provided by (used in) investing activities	5,916	(2,532)
Cash Flows from Financing Activities:		
Payment of debt	(30,375)	—
Proceeds from issuance of common shares - at-the-market offering	163	6,622
Offering costs for the issuance of common shares -at-the-market offering	(3)	(123)
Proceeds from debt issuance	—	30,000
Fees paid on the issuance of debt	—	(2,650)
Proceeds from issuance of common shares under ESPP	178	206
Net cash (used in) provided by financing activities	(30,037)	34,055
Net change in cash, cash equivalents and restricted cash	(66,344)	(18,254)
Cash, cash equivalents and restricted cash, beginning of the period	76,656	110,618
Cash, cash equivalents and restricted cash, end of the period	**$ 10,312**	**$ 92,364**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,340	$ 1,803
Supplemental disclosure of noncash activities:		
Fixed assets (acquired but not paid)	$ —	$ 21
Issuance of common shares - Founders Agreement	$ 1,109	$ 4,212
Note payable final payment fee (incurred but not paid)	$ —	$ 1,050
Issuance of warrants - note payable	$ —	$ 384
Lease liabilities arising from obtaining right-of-use assets	$ —	$ 2,176

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

MUSTANG BIO, INC.
Notes to Unaudited Financial Statements

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 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 Capital Market and trades under the symbol "MBIO."

Reverse Stock Split

On March 3, 2023, the Board of Directors of the Company (the "Board") unanimously adopted resolutions to approve and recommend stockholder approval of a form amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our issued and outstanding Common Stock within a range of between 5-for-1 and 20-for-1 (with our Board being authorized to determine the exact ratio), with such reverse stock split to be effected at such time and date before January 31, 2024, if at all, as determined by the Board in its sole discretion (such reverse stock split, the "Reverse Stock Split" and such amendment, the "Amendment"). On March 3, 2023, the holders of a majority in voting power of issued and outstanding shares of our Common Stock and issued and outstanding shares of our Class A Preferred Stock, par value $0.0001 (together, the "Majority Holders") approved the Amendment by written consent in lieu of a meeting (the "Written Consent"). On March 15, 2023, the Board selected the 15-for-1 reverse stock split ratio.

Pursuant to rules adopted by the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, a Schedule 14C information statement was filed with the SEC and provided to the stockholders of the Company. The Reverse Stock Split became effective on April 3, 2023, or twenty (20) days from the mailing of the information statement to the common stockholders of record.

All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock and warrants outstanding at April 3, 2023, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants.

No fractional shares were issued in connection with the Reverse Stock Split and stockholders who would otherwise be entitled to a fraction of one share received a proportional cash payment.

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 September 30, 2023, the Company had an accumulated deficit of $372.4 million.

The Company has funded its operations to date primarily through the sale of equity and via debt raises, which included its loan and financing agreement with Runway Growth Finance Corporation (the "Lender"), herein referred to as the "Term Loan." On April 11, 2023, the Company repaid the Term Loan, see Note 8. The Company expects to continue to use the proceeds from its other 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.

On May 18, 2023, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with uBriGene (Boston) Biosciences, Inc. ("uBriGene"), pursuant to which the Company agreed to sell its leasehold interest in its cell processing facility located in Worcester, MA (the "Facility") and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene. The Company and uBriGene subsequently entered into Amendment No. 1, dated as of June 29, 2023, and Amendment No. 2, dated as of July 28, 2023, to the Asset Purchase Agreement (the Asset Purchase Agreement, as so amended, the "Amended Asset Purchase Agreement"). On July 28, 2023, pursuant to the terms and conditions of the Amended Asset Purchase Agreement, the Company completed the sale of all of the Company's assets primarily relating to the Company's operations primarily relating to the manufacturing and production of cell and gene therapies to uBriGene for a base consideration of $6.0 million. uBriGene will be obligated to pay to the Company a contingent amount of $5.0 million less certain severance obligations and payments payable in connection with the transfer of certain contracts related to the transferred assets, if the Company, within two years of the closing date, (i) completes an issuance of equity securities in an amount equal to or greater than $10.0 million after the closing and (ii) obtains consent of the landlord to the proposed lease transfer within two years of the closing date. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments."

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. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations.

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. In performing its evaluation, management excluded certain elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future equity or debt issuances, and the potential sale of priority review vouchers cannot be considered probable at this time because these plans are not entirely within the Company's control nor have been approved by the Board of Directors as of the date of these financial statements.

The Company's expectation to generate operating losses and negative operating cash flows in the future, and the need for additional funding to support its planned operations raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that these unaudited consolidated financial statements are issued. The Company continues to monitor its spending by reducing 2023 expenses, which may include projected savings through delaying the development timelines of certain programs, or termination of such programs and the pursuit of additional cash resources through public or private equity or debt financings. The Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these unaudited financial statements.

The accompanying unaudited financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that may be necessary if the Company is unable to continue as a going concern.

Note 2 - Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited 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 interim unaudited 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 do 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, 2022, which were included in the Company's Form 10-K and filed with the SEC on March 30, 2023. 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 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.

Cash, Cash Equivalents and Restricted Cash

The Company records cash held in an escrow account as a security deposit for the manufacturing facility in Worcester, Massachusetts, as restricted cash.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash from the Unaudited Balance Sheets to the Unaudited Statements of Cash Flows for the nine months ended September 30, 2023, and 2022:

	September 30,	
($ in thousands)	**2023**	**2022**
Cash and cash equivalents	$ 9,562	$ 91,364
Restricted cash	750	1,000
Total cash, cash equivalents and restricted cash	$ 10,312	$ 92,364

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 30, 2023.

Recently Issued Accounting Standards

As of September 30, 2023, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "2022 Form 10-K") that affect the Company's present or future results of operations, overall financial condition, liquidity, or disclosures upon adoption.

Note 3 - Clinical Trial and Sponsored Research Agreements

Research and Development Expenses - Sponsored Research and Clinical Trial Agreements

For the three and nine months ended September 30, 2023 and 2022, the Company recorded the following expense in research and development for sponsored research and clinical trial agreements in the Unaudited Statements of Operations pursuant to the terms of this agreement:

($ in thousands)	For the three months ended September 30, 2023	2022	For the nine months ended September 30, 2023	2022
City of Hope National Medical Center				
CD123	$ 23	$ 63	$ 23	$ 165
IL13Rα2	180	192	817	654
CS1	—	187	188	287
HER2	—	691	—	1,233
PSCA	—	27	44	77
Fred Hutchinson Cancer Center - CD20	142	132	1,239	978
St. Jude Children's Research Hospital - XSCID	(106)	184	528	402
LUMC - RAG1 SCID	125	92	349	357
Mayo Clinic	—	269	551	731
Total	$ 364	$ 1,836	$ 3,739	$ 4,884

CD123 (MB-102) Clinical Research Support Agreement

Beginning in February 2017, the Company was party to a clinical research support agreement for the CD123-directed CAR T program (the "CD123 CRA") with City of Hope National Medical Center ("COH" or "City of Hope") whereby, the Company has agreed to contribute approximately $0.1 million per patient in connection with the ongoing investigator-initiated study. In May 2023, the Company determined to discontinue development of its MB-102 program and terminated the associated CRA and license.

IL13Rα2 (MB-101) Clinical Research Support Agreements

Since February 2017, the Company has been party to a clinical research support agreement for the IL13Rα2-directed CAR T program (the "IL13Rα2 CRA") with COH, whereby, the Company has agreed to contribute $0.1 million related to patient costs in connection with the on-going investigator-initiated study.

Since October 2020, the Company has been party to a clinical research support agreement for the IL13Rα2-directed CAR T program for adult patients with leptomeningeal glioblastoma, ependymoma or medulloblastoma (the "IL13Rα2 Leptomeningeal CRA") with COH whereby, the Company has agreed to contribute $0.1 million per patient in connection with the ongoing investigator-initiated study. Further, the Company agreed to fund approximately $0.2 million annually pertaining to the clinical development of the IL13Rα2-directed CAR T program for this patient population.

Since October 2020, the Company has been party to a Sponsored Research Agreement ("SRA") with COH to conduct combination studies of a potential IL13Rα2 CAR (MB-101) and herpes simplex-1 oncolytic virus therapy (MB-108). Pursuant to the SRA, the Company funded research in the amount of $0.3 million for the program. In November 2022, the SRA was amended to include additional funding of $0.6 million.

Since March 2021, the Company has been party to a clinical research support agreement for an Institutional Review Board-approved, investigator-initiated protocol entitled: "Single Patient Treatment with Intraventricular Infusions of IL13Rα2-targeting and HER2-targeting Chimeric Antigen Receptor (CAR)-T cells for a Single Patient (UPN 181) with Recurrent Multifocal Malignant Glioma." Pursuant to the terms of this agreement, the Company will contribute up to $0.2 million in connection with the ongoing investigator-initiated study.

CS1 (MB-104) Clinical Research Support Agreement

Beginning in June 2020, the Company was party to a clinical research and support agreement with COH in connection with an investigator-sponsored study conducted under an Institutional Review Board-approved for MB-104, whereby the Company has agreed to reimburse COH for costs associated with this trial, when incurred, not to exceed $2.4 million. The agreement will expire upon the delivery of a final study report or earlier. Since inception, the Company has reimbursed COH $2.2 million. In May 2023, the Company determined to discontinue development of its MB-104 program and terminated the associated CRA and license.

HER2 (MB-103) Clinical Research Support Agreement

Beginning in September 2020, the Company was party to a clinical research support agreement with COH in connection with an investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "Phase I Study of Cellular Immunotherapy using Memory-Enriched T Cells Lentivirally Transduced to Express a HER2-Specific, Hinge-Optimized, 41BB-Costimulatory Chimeric Receptor and a Truncated CD19 for Patients with Recurrent/Refractory Malignant Glioma" for MB-103. Under the terms of the agreement the Company will reimburse COH for costs associated with this trial not to exceed $3.0 million. The agreement will expire upon the delivery of a final study report or earlier. Since inception, the Company has reimbursed COH $3.0 million. In May 2023, the Company determined to discontinue development of its MB-103 program and terminated the associated CRA and license.

PSCA (MB-105) Clinical Research Support Agreement

Beginning in October 2020, the Company was party to a clinical research support agreement with COH in connection with an investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "A Phase 1 Study to Evaluate PSCA-Specific Chimeric Antigen Receptor (CAR)-T Cells for Patients with Metastatic Castration Resistant Prostate Cancer" for MB-105. The Company has agreed to reimburse COH for costs associated with this trial not to exceed $2.3 million. The agreement will expire upon the delivery of a final study report or earlier. Since inception, the Company has reimbursed COH $0.5 million. In May 2023, the Company determined to discontinue development of its MB-105 program and terminated the associated CRA and license.

CD20 (MB-106) Clinical Trial Agreement with Fred Hutchinson Cancer Research Center

Since July 3, 2017, in conjunction with the CD20 Technology License from Fred Hutchinson Cancer Center ("Fred Hutch"), the Company has been party to an investigator-initiated clinical trial agreement (the "CD20 CTA") to provide partial funding for a Phase 1/2 clinical trial at Fred Hutch evaluating the safety and efficacy of the CD20 Technology in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. In connection with the CD20 CTA, the Company agreed to fund up to $5.3 million of costs associated with the clinical trial, which commenced during the fourth quarter of 2017. In November 2020, the CD20 CTA was amended to include additional funding of approximately $1.8 million, which includes $0.8 million for the treatment of five patients with chronic lymphocytic leukemia. In January 2022, the CD20 CTA was amended to include additional funding of $2.2 million increasing the total payment obligation of the Company in connection with the CD20 CTA not to exceed $9.3 million. Since inception, the Company has reimbursed Fred Hutch $8.4 million.

XSCID (MB-107) Data Transfer Agreement with St. Jude Children's Research Hospital

Since June 2020, the Company has been party to a Data Transfer Agreement with St. Jude Children's Research Hospital ("St. Jude") under which Mustang will reimburse St. Jude for costs associated with St. Jude's clinical trial for the treatment of infants with X-linked severe combined immunodeficiency ("XSCID"), whereby the Company will continue to reimburse St. Jude for costs incurred in connection with this trial. Since inception, the Company has reimbursed St. Jude $3.5 million.

RAG1-SCID (MB-110) Sponsored Research Support Agreement ("SRA") with Leiden University Medical Centre

Since September 8, 2021, in connection with the Leiden License, the Company has been party to a Sponsored Research Support Agreement ("SRA") with Leiden University Medical Centre ("LUMC") under which the Company will fund

research in the amount of approximately $0.5 million annually over a period of 5 years. The research performed pursuant to this agreement will support technology the Company has licensed from Leiden for the use of a gene therapy under development for the treatment of severe immunodeficiency caused by mutations in the *RAG1* gene.

Sponsored Research Support Agreement with Mayo Clinic

Since June 2021, the Company has been party to an SRA with the Mayo Clinic under which the Company will fund research in the amount of $2.1 million over a period of two years. In October 2022, the SRA was amended to include additional funding of approximately $0.1 million. The research performed pursuant to this agreement will support technology the Company has licensed from Mayo Clinic for a novel technology that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy. Since inception, the Company has funded $2.2 million.

Note 4 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

In connection with the Company's Management Services Agreement (the "Management Services Agreement") with Fortress for the three and nine months ended September 30, 2023 and 2022, respectively, expenses related to the MSA are recorded 50% in research and development expenses and 50% in general and administrative expenses in the Unaudited Statements of Operations. For the three months ended September 30, 2023 and 2022, the Company recorded expense of $0.1 million and $0.2 million, respectively, related to the MSA. For the nine months ended September 30, 2023 and 2022, the Company recorded expense of $0.4 million and $0.8 million, respectively, related to this agreement.

Under the terms of the Second Amended and Restated Founders Agreement (the "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. For the nine months ended September 30, 2023, the Company recorded approximately $4,000 of common stock issuable to Fortress under the Founders Agreement. For the three months ended September 30, 2023 and 2022, the Company recorded expense of approximately $4,000 and $18,000, respectively, in general and administrative expenses related to these shares. For the nine months ended September 30, 2023 and 2022, the Company recorded expense of approximately $4,000 and $0.9 million, respectively, in general and administrative expenses related to these shares.

Annual Stock Dividend

Pursuant to the Amended and Restated Articles of Incorporation, the Company issued 187,134 shares of common stock to Fortress for the Annual Stock Dividend, representing 2.5% of the fully-diluted outstanding equity of Mustang on January 6, 2023. This was shown in the Statement of Stockholders' Equity at December 31, 2022, as Common stock issuable – Founders Agreement. The Company recorded an expense of approximately $1.1 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2022.

Payables 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 payables and accrued expenses - related party and are reimbursed to Fortress in the normal course of business.

Note 5 – Sale of Property and Equipment

On May 18, 2023, the Company entered into an Asset Purchase Agreement with uBriGene (Boston) Biosciences, Inc. ("uBriGene"), as amended by a first amendment thereto, dated as of June 29, 2023, and further amended by a second amendment thereto, dated as of July 28, 2023, pursuant to which the Company has agreed, subject to the terms and conditions therein, to sell its leasehold interest in its cell processing facility located in Worcester, Massachusetts (the "Facility") and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene. As a result of this agreement, the Company classified the related equipment as assets held for sale in our

unaudited balance sheet at June 30, 2023. On July 28, 2023, the Company completed the sale of the assets relating to the manufacturing and production of cell and gene therapies at the Facility.

In connection with the sale of such assets, the Company received base proceeds of $6.0 million for the assets and lab supplies on-hand as of the transaction date. Based on the fair value of the consideration received and the relative fair value allocation of the consideration, the Company recorded a gain of $1.4 million in the Unaudited Statements of Operations, for the three and nine months ended September 30, 2023. The Company recorded approximately $0.3 million of the consideration as deferred income, which will be recognized upon the transfer of the lease. The Company will record adjustments to the fair value of the potential future consideration each reporting period, prospectively.

Note 6 – Property, Plant and Equipment

At September 30, 2023, and December 31, 2022, property, plant and equipment consisted of the following:

($ in thousands)	Estimated Useful Life (in years)	September 30, 2023	December 31, 2022
Computer equipment	3	$ —	$ 145
Furniture and fixtures	5	—	370
Machinery and equipment	5	—	8,632
Leasehold improvements	9	7,694	7,694
Construction in process	N/A	—	951
Total property, plant and equipment		7,694	17,792
Less: accumulated depreciation		(4,192)	(8,401)
Property, plant and equipment, net		$ 3,502	$ 9,391

Depreciation expense for the three months ended September 30, 2023, and 2022, was approximately $0.3 million and $0.7 million, respectively, and was recorded in research and development expense in the Unaudited Statements of Operations.
Depreciation expense for the nine months ended September 30, 2023, and 2022, was approximately $1.6 million and $2.0 million, respectively, and was recorded in research and development expense in the Unaudited Statements of Operations.

Note 7 - Accounts Payable and Accrued Expenses

At September 30, 2023, and December 31, 2022, accounts payable and accrued expenses consisted of the following:

($ in thousands)	September 30, 2023	December 31, 2022
Accounts payable	$ 5,498	$ 6,833
Accrued research and development	3,671	2,782
Accrued compensation	2,641	3,468
Other	898	648
Total accounts payable and accrued expenses	$ 12,708	$ 13,731

Note 8 – Notes Payable

On April 11, 2023, the Company's long-term debt facility with Runway Growth Finance Corp. (the "Term Loan") was terminated upon receipt by Runway of a payoff amount of $30.7 million from the Company comprised of principal, interest and the applicable final payment amount. The loss on extinguishment was recorded in interest expense in the Unaudited Statements of Operations. For the three and nine months ended September 30, 2023 and 2022, the Company recorded the following components in interest expense:

	For the three months ended September 30,		For the nine months ended September 30,	
($ in thousands)	2023	2022	2023	2022
Interest expense	$ —	$ 887	$ 1,188	$ 1,883
Amortization of Debt Discount	—	143	118	304
Loss on Extinguishment	—	—	2,794	—
Other	4	4	12	12
Total Interest Expense	$ 4	$ 1,034	$ 4,112	$ 2,199

The Company entered into the Term Loan on March 4, 2022. Under the Term Loan, $30.0 million of the $75.0 million loan was funded on the Closing Date, with the remaining $45.0 million fundable if the Company achieved certain predetermined milestones.

The Term Loan accrued interest at a variable annual rate equal to 8.75% plus the greater of (i) 0.50% and (ii) the three month LIBOR Rate for U.S. dollar deposits or the rate otherwise reasonably determined by the Lender to be the rate at which U.S. dollar deposits with a term of three months would be offered by banks in London, England to major banks in the London or other offshore interbank market (the "Applicable Rate"); provided that the Applicable Rate would not be less than 9.25%. On December 7, 2022, the Company entered into the First Amendment (the "First Amendment") to the Loan Agreement by and between the Company and Runway. The First Amendment amended certain definitions and other provisions of the Loan Agreement to replace LIBOR-based benchmark rates applicable to loans outstanding under the Loan Agreement with SOFR-based rates, subject to adjustments as specified in the First Amendment. The Applicable Rate at September 30, 2022 was 11.69%. For the three and nine months ended September 30, 2023, the Company made interest payments of zero and $1.3 million, respectively, recorded in interest expense in the Unaudited Statements of Operations. For the three and nine months ended September 30, 2022, the Company made interest payments of $0.8 million and $1.8 million, respectively, recorded in interest expense in the Unaudited Statements of Operations.

($ in thousands)	September 30, 2023	December 31, 2022
Note payable [1]	$ —	$ 31,050
Discount on note payable	—	(3,614)
Long-term note payable	$ —	$ 27,436

[1] Balance includes $1.1 million final payment fee.

Amortization of the debt discount associated with the Term Loan was approximately $0.1 million for the nine months ended September 30, 2023, and was recorded in interest expense in the Unaudited Statements of Operations. Amortization of the debt discount associated with the Term Loan was approximately $0.1 million and $0.3 million for the three and nine months ended September 30, 2022, respectively, and was recorded in interest expense in the Unaudited Statements of Operations.

In addition, the Term Loan was secured by a lien on substantially all of our assets other than certain intellectual property assets and certain other excluded collateral, and it contained a minimum liquidity covenant and other covenants that included among other items: (i) limits on indebtedness, repurchase of stock from employees, officers and directors. The Company was not subject to the covenants of the Term Loan as of September 30, 2023. The Company was in compliance with all applicable covenants as of December 31, 2022.

Note 9 - Stockholders' Equity

Reverse Stock Split

On March 3, 2023, the Board of Directors of the Company (the "Board") unanimously adopted resolutions to approve and recommend stockholder approval of a form amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, to effect a reverse stock split of our issued and outstanding Common Stock within a range of between 5-for-1 and 20-for-1 (with our Board being authorized to determine the exact ratio), with such reverse stock split to be effected at such time and date before January 31, 2024, if at all, as determined by the Board in its sole discretion (such reverse stock split, the "Reverse Stock Split" and such amendment, the "Amendment"). On March 3, 2023, the holders of a majority in voting power of issued and outstanding shares of our Common Stock and issued and outstanding shares of our Class A Preferred Stock, par value $0.0001 (together, the "Majority Holders") approved the Amendment by written consent in lieu of a meeting (the "Written Consent"). On March 15, 2023, the Board selected the 15-for-1 reverse stock split ratio.

Pursuant to rules adopted by the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, a Schedule 14C information statement was filed with the SEC and provided to the stockholders of the Company. The Reverse Stock Split became effective on April 3, 2023, or twenty (20) days from the mailing of the information statement to the common stockholders of record.

All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock and warrants outstanding at April 3, 2023, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants.

No fractional shares were issued in connection with the Reverse Stock Split and stockholders who would otherwise be entitled to a fraction of one share received a proportional cash payment.

Registration Statements

On October 23, 2020, the Company filed a shelf registration statement No. 333-249657 on Form S-3 (the "2020 S-3"), which was declared effective on December 4, 2020. Under the 2020 S-3, the Company may sell up to a total of $100.0 million of its securities. As of September 30, 2023, approximately $7.8 million of the 2020 S-3 remained available for sales of securities.

On April 23, 2021, the Company filed a shelf registration statement No. 333-255476 on Form S-3 (the "2021 S-3"), which was declared effective on May 24, 2021. Under the 2021 S-3, the Company may sell up to a total of $200.0 million of its securities. As of September 30, 2023, there have been no sales of securities under the 2021 S-3. On October 30, 2023, the Company closed a registered direct offering pursuant to which it issued and sold approximately $4.4 million of securities under the 2021 S-3, see Note 13.

As of the filing of this Quarterly Report on Form 10-Q, the Company is subject to the general instructions on Form S-3 known as the "baby shelf rules," which limit the amount of securities we can sell under our registration statements. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources," and "Risk Factors – 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."

At-the-Market Offering

In July 2018, the Company entered into an At-the-Market Issuance Sales Agreement (the "Mustang ATM") with B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.), Cantor Fitzgerald & Co., National Securities Corporation (now B. Riley

FBR, Inc.), and Oppenheimer & Co. Inc. (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock pursuant to the 2020 S-3. 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. On December 31, 2020, the Mustang ATM was amended to add H.C. Wainwright & Co., LLC as an Agent. On April 14, 2023, the Mustang ATM was amended to add the limitations imposed by General Instruction I.B.6 to Form S-3 and remove Oppenheimer & Co., Inc. as an Agent.

During the nine months ended September 30, 2023, the Company issued approximately 52,000 shares of common stock at an average price of $3.15 for gross proceeds of $0.2 million under the Mustang ATM. In connection with these sales, the Company paid aggregate fees of approximately $3,000. During the nine months ended September 30, 2022, the Company issued approximately 525,000 shares of common stock at an average price of $12.61 per share for gross proceeds of $6.6 million under the Mustang ATM. In connection with these sales, the Company paid aggregate fees of approximately $0.1 million.

Pursuant to the Founders Agreement, the Company issued zero shares of common stock to Fortress for the nine months ended September 30, 2023 and recorded 1,297 shares issuable to Fortress under the Mustang ATM. Pursuant to the Founders Agreement, Mustang issued 13,131 shares of common stock to Fortress at a weighted average price of $13.56 per share for the nine months ended September 30, 2022, under the Mustang ATM.

Equity Incentive Plan

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 133,333 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 200,000 shares, for a total of 333,333 shares. In June 2021, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 533,333 shares. In June 2022, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 733,333 shares.

As of September 30, 2023, 287,606 shares are available for issuance under the Incentive Plan.

Stock Options

The following table summarizes stock option activities for the nine months ended September 30, 2023:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding at December 31, 2022	76,112	$ 59.09	4.31
Outstanding at September 30, 2023	76,112	$ 59.09	3.56
Options vested and exercisable at September 30, 2023	47,570	$ 59.09	3.56

As of September 30, 2023, the Company had no unrecognized stock-based compensation expense related to options. The Company accounts for forfeited awards as they occur as permitted.

Restricted Stock

The following table summarizes restricted stock award activities for the nine months ended September 30, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2022	34,016	$ 22.20
Granted	36,230	6.90
Vested	(5,540)	46.20
Nonvested at September 30, 2023	64,706	$ 11.59

As of September 30, 2023, the Company had unrecognized stock-based compensation expense related to restricted stock of $0.4 million, which is expected to be recognized over the remaining weighted average vesting period of approximately 2.4 years.

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 nine months ended September 30, 2023:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2022	165,912	$ 27.60
Granted	29,732	5.13
Forfeited	(46,172)	27.93
Vested	(43,372)	32.82
Nonvested at September 30, 2023	106,100	$ 19.03

As of September 30, 2023, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately $0.7 million, which is expected to be recognized over the remaining weighted average vesting period of approximately 2.4 years.

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
General and administrative	$ 119	$ 194	$ 381	$ 549
Research and development [1]	(19)	302	(1)	1,261
Total stock-based compensation expense	$ 100	$ 496	$ 380	$ 1,810

[1] The credit in research and development stock-based compensation expense reflects the reversal of expense related to Restricted Stock Unit forfeitures during the three and nine months ended September 30, 2023.

Employee Stock Purchase Plan

Eligible employees can purchase the Company's Common Stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period. The Employee Stock Purchase Plan ("ESPP") is compensatory and results in stock-based compensation expense. The ESPP was initially authorized in 2019 to sell up to 26,667 shares of authorized but unissued common stock. In June 2021, the Company's stockholders approved an amendment to the ESPP to increase the number of authorized shares issuable by 40,000 shares. In addition, in June 2023, the Company's stockholders approved an amendment to the ESPP to increase the number of authorized shares issuable thereunder by 400,000 for a total of 466,667 shares.

As of September 30, 2023, 86,578 shares have been purchased and 380,089 shares are available for future sale under the Company's ESPP.

Warrants

A summary of warrant activities for the nine months ended September 30, 2023, is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2022	70,195	$ 22.80	8.29
Exercised	(93)	—	—
Outstanding as of September 30, 2023	70,102	$ 22.80	7.55

Upon the cashless exercise of warrants, the Company will issue new shares of common stock. In connection with the Term Loan, on March 4, 2022, the Company issued a warrant to the Lender to purchase 49,869 shares of the Company's common stock with an exercise price of $12.03, see Note 8.

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 options and warrants, outstanding Class A preferred shares, and unvested restricted stock and restricted stock units, 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 nine months ended September 30,	
	2023	2022
Warrants	70,102	70,195
Options	76,112	76,112
Class A Preferred Shares	250,000	250,000
Unvested restricted stock awards	64,706	34,016
Unvested restricted stock units	106,100	164,600
Total	567,020	594,923

Note 11 – Income Taxes

The Company incurred net operating losses and recorded a full valuation allowance against net deferred tax assets for all periods presented. Accordingly, the Company has not recorded a provision for federal or state income taxes.

The Company is subject to US federal and state income taxes. Income tax expense is the total of the current year income tax due or refundable and the change in deferred tax assets and liabilities. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in the opinion of Management, it is more likely than not that some portion, or all, of the deferred tax asset will not be realized.

Note 12 – Commitments and Contingencies

Indemnification

In accordance with its certificate of incorporation, bylaws and indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. The Company has director and officer insurance to address such claims. The Company also provides indemnification of contractual counterparties in certain situations, including without limitation to clinical sites, service providers and licensors.

Leases

On June 14, 2022, the Company entered into a sublease agreement with The Paul Revere Life Insurance Company. Pursuant to the terms of the sublease lease agreement, the Company agreed to lease 26,503 square feet, located at One Mercantile Street, Worcester, MA (the "Mercantile Center"), through January 2030. The Company recorded a right of use asset and related operating lease liability of $2.2 million on the Unaudited Balance Sheet at the lease inception.

On July 18, 2023, the Company executed, with a retroactive Effective Date of June 15, 2023, a Third Amendment to Sublease (the "Third Amendment"), with the Paul Revere Life Insurance Company, pursuant to which the Company relocated from the 26,503 square feet of rentable space on the fourth floor of the Mercantile Center to 11,916 square feet of rentable space on the second floor of the Mercantile Center. As a result of the modification, the Company recorded an adjustment to its right of use asset and related operating lease liability of $1.0 million and $1.2 million, respectively, and $0.2 million gain on the modification of the sublease, which is recorded in Other Income in the Unaudited Statements of Operations.

The Company also leases office space and copiers under agreements classified as operating leases that expire on various dates through 2026. The Company's lease liabilities result from the lease of its Plantation Street Facility in Massachusetts, which expires in 2026, and its copiers, which expire in 2024. 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 September 30, 2023, the Company had operating lease liabilities of $2.6 million and right of use assets of $1.6 million, which were included in the Unaudited Balance Sheet. At December 31, 2022, the Company had operating lease liabilities of $3.9 million and right of use assets of $2.9 million, which were included in the Unaudited Balance Sheet.

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

	For the Nine Months Ended	
($ in thousands)	**September 30, 2023**	**September 30, 2022**
Lease cost		
Operating lease cost	$ 592	$ 414
Variable lease cost	544	293
Total	$ 1,136	$ 707

	For the Nine Months Ended	
($ in thousands)	**September 30, 2023**	**September 30, 2022**
Operating cash flows from operating leases	$ 395	$ 362
Gain on lease modification	$ 220	$ —
Weighted-average remaining lease term – operating leases	4.7	6.3
Weighted-average discount rate – operating leases	9.1 %	9.1 %

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

($ in thousands)		
Six months ended December 31, 2023	$	134
Year ended December 31, 2024		722
Year ended December 31, 2025		774
Year ended December 31, 2026		702
Year ended December 31, 2027		269
Thereafter		578
Total		3,179
Less present value discount		(604)
Operating lease liabilities	$	2,575

Note 13 – Subsequent Events

On October 26, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with a single institutional accredited investor (the "Investor") pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market (the "Registered Offering"), (i) 920,000 shares of its common stock, $0.0001 par value per share, at a price per share of $1.70 and (ii) pre-funded warrants (the "Pre-funded Warrants") to purchase up to 1,668,236 shares of its common stock, at a price per Pre-funded Warrant equal to $1.699, the price per Share, less $0.001. The Pre-funded Warrants have an exercise price of $0.001 per share, became exercisable upon issuance and remain exercisable until exercised in full.

The Pre-funded Warrants were sold, in lieu of shares of Common Stock, to the Investor whose purchase of shares of Common Stok in the Registered Offering would otherwise result in such Investor, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at such Investor's option upon issuance 9.99%) of the Company's outstanding common stock immediately following the consumption of the Registered Offering. The Pre-funded Warrants have an exercise price of $0.001 per share, became exercisable upon issuance and remain exercisable until exercised in full.

The Registered Offering closed on October 30, 2023. The Company intends to use the net proceeds from the Registered Offering for general corporate purposes and working capital requirements, which may include, among other things, the advancement of its product candidates to obtain regulatory approval from the FDA.

In a concurrent private placement, pursuant to the terms of the Purchase Agreement, the Company also agreed to issue and sell unregistered warrants (the "Warrants") to purchase up to 2,588,236 shares of its common stock, at an offering price of $0.125 per Warrant to purchase one share of common stock (the "Private Placement" and, together with the Registered Offering, the "Offerings") (which offering price is included in the purchase price per Share or Pre-funded warrant). The Warrants have an exercise price of $1.58 per share (subject to customary adjustments as set forth in the Warrants), are exercisable upon issuance and will expire five and one-half years from the date of issuance. The Warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions.

The Private Placement also closed on October 30, 2023, concurrently with the Registered Offering. The Company received approximately $4.4 million in gross proceeds from the Offerings, before deducting placement agency fees and offering expenses of approximately $0.5 million.

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 financial statements and the related notes included elsewhere in this Form 10-Q. Our 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 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions, include, but are not limited to, any statements relating to our growth strategy and product development programs, including the Company's expectations with respect to the consummation of the sale of its manufacturing facility, the timing of and our ability to make regulatory filings such as INDs and other applications and to obtain regulatory approvals for our product candidates, statements concerning the potential of therapies and product candidates, and any other statements that are not historical facts. 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: CAR T therapies for hematologic malignancies, CAR T therapies for solid tumors and gene therapies for rare genetic disorders. For each therapy we have partnered with world class research institutions. For our CAR T therapies we have partnered with COH, Fred Hutch, Nationwide and Mayo Clinic. For our gene therapies, we have partnered with St. Jude in the development of a first-in-class *ex vivo* lentiviral ("LV") treatment of XSCID and with LUMC in the development of a first-in-class *ex* vivo LV treatment of RAG1-SCID.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of its potential products. However, there can be no assurance that the Company will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all. Therefore, there exists substantial doubt about the Company's ability to continue as a going concern. The unaudited financial statements do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

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 academic partners and transfer the underlying technology to our or our contract manufacturer's cell processing facility, in order to conduct our own clinical trials.

We are developing a CAR T therapy for hematologic malignancies in partnership with Fred Hutch targeting CD20 (MB-106). On May 18, 2023, the Company announced a series of changes resulting from a review of its portfolio of product candidates to determine the future strategy of its programs and the proper allocation of its resources. Following this review, the Company determined to discontinue development of its MB-102 (CD123), MB-103 (HER2), MB-104 (CS1) and MB-105 (PSCA) programs (such programs, the "Discontinued Programs"), comprising a portion of the Company's portfolio of CAR T therapies being developed by the Company in partnership with City of Hope.

MB-106 (CD20-targeted CAR T cell therapy for Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia)

In August 2023, Mustang Bio announced the first data from the indolent lymphoma cohort of its company-sponsored multicenter clinical trial, demonstrating clinical responses as well as safety and efficacy consistent with the ongoing Phase 1/2 Fred Hutch-sponsored clinical trial. The multicenter study data showed substantial clinical benefit in four of four patients with relapsed or refractory indolent non-Hodgkin lymphoma ("NHL") at the starting dose of 3.3 x 10^6 CAR-T cells/kg, a dose comparable to that employed for the majority of the indolent lymphoma patients in the Fred Hutch trial. The multicenter data also showed persistence of CAR-T cells at 6+ months and favorable safety data, with only Grade 1 cytokine release syndrome reported to date in each of the 4 patients and no immune effector cell-associated neurotoxicity syndrome of any grade reported in any patient. Two patients with follicular lymphoma had complete response by both PET-CT and bone marrow, one of whom had been previously treated with a CD19-directed CAR-T. A third patient, with a diagnosis of Waldenstrom macroglobulinemia ("WM"), who had nine prior treatments and high disease burden, achieved a very good partial response characterized by complete metabolic response by PET-CT, morphologic clearance of lymphoma in bone marrow, and resolution of the IgM monoclonal protein. The fourth patient, with a diagnosis of hairy cell leukemia variant, who had been heavily transfusion dependent, continued to have stable disease with decreased disease in his bone marrow and achieved complete transfusion independence, which was ongoing at six plus months. Following treatment of these four indolent NHL patients, the Safety Review Committee unanimously approved dose escalation in the indolent lymphoma cohort to the second and final dose level of 1.0 x 10^7 CAR-T cells/kg.

On November 2, 2023, the Company announced that interim Phase 1/2 data from its multicenter clinical trial have been selected for presentation at the 65th American Society of Hematology Annual Meeting taking place December 8 through 12, 2023. This presentation will summarize results from all patients enrolled in the indolent lymphoma cohort treated at the starting dose level, as well as all patients in that cohort treated at the second and final dose level who have had their initial 28-day follow-up evaluation for safety and efficacy.

In the first quarter of 2024, the Company expects to receive FDA feedback in and End-of-Phase 1 Meeting on its strategy to conduct a non-randomized registrational multicenter trial in relapsed or refractory WM. In mid-2024, the Company expects to treat the first patient in that trial, with top-line data anticipated in 2026. In 2025, the Company expects to initiate a non-randomized registrational multicenter trial in patients with diffuse large B-cell lymphoma who have relapsed from previous treatment with a CD19-directed CAR-T.

MB-109 (Combination of MB-101 CAR T Therapy with MB-108 Oncolytic Virus Therapy for Malignant Brain Tumors)

In April 2022, Mustang announced interim data from two ongoing investigator-sponsored Phase 1 clinical trials evaluating two clinical candidates, MB-101 (IL13Rα2-targeted CAR T cell therapy licensed from City of Hope) and MB-108 (herpes simplex virus type 1 oncolytic virus licensed from Nationwide Children's Hospital) for the treatment of recurrent glioblastoma.

On October 26, 2023, the Company announced that the FDA accepted its IND application for MB-109 for the treatment of recurrent glioblastoma ("GBM") and high-grade astrocytoma. The Company plans to initiate a Phase 1 multicenter clinical trial at City of Hope and the University of Alabama at Birmingham ("UAB") to assess the safety, tolerability and efficacy of MB-109 in adult patients with recurrent GBM and high-grade astrocytomas that express IL13Rα2 on the surface of the tumor cells in 2024.

In Vivo CAR T Platform Technology

Mustang is collaborating with the Mayo Clinic to develop a novel technology that may be able to transform the administration of CAR T therapies and potentially be used as an off-the-shelf therapy. In 2024, the Mayo Clinic expects

to publish *in vivo* proof-of-concept data in a mouse model of cancer in a major scientific journal, and Mustang plans to file an IND application for a multicenter Phase 1 clinical trial once a lead construct has been identified.

Gene Therapies

MB-117 (Ex vivo LV Gene Therapy for Newly Diagnosed X-linked Severe Combined Immunodeficiency (XSCID)) and MB-217 (Ex vivo LV Gene Therapy for Previously Transplanted XSCID)

In partnership with St. Jude, our XSCID gene therapy programs (MB-117 and MB-217) are 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. St. Jude's first-in-class *ex vivo* LV gene therapy has been utilized in two Phase 1/2 clinical trials involving two different autologous cell products produced via transduction of patients' hematopoietic stem cells using a predecessor LV vector. These cell products were designated MB-107 and MB-207, and the respective Phase 1/2 clinical trials were: a multicenter trial of the MB-107 product in newly diagnosed infants sponsored by St. Jude (LVXSCID-ND) and a single-center trial of the MB-207 product in previously transplanted patients sponsored by the National Institutes of Health ("NIH") (LVXSCID-OC).

Going forward, this predecessor LV vector will be replaced by a modified LV vector which will be used to produce the MB-117 and MB-217 cell products. St Jude has informed the Company that it intends to initiate a new Phase 1 trial in newly diagnosed infants using MB-117, and the NIH has informed the Company that it intends to initiate a new Phase 1 trial in previously transplanted patients using MB-217, each in 2024.

LUMC License

MB-110, a first-in-class *ex vivo* treatment for RAG1 SCID, is currently being evaluated at LUMC in a Phase 1/2 multicenter clinical trial in Europe. In 2022 the first patient was treated without any complications, after which the patient developed a functioning immune system which responded well to the standard vaccinations for newborns. In 2024 we expect that additional centers will be added and that additional patients will be enrolled.

Recent Developments

Sale of Manufacturing Facility – Overview of Transaction

As previously disclosed, on May 18, 2023, the Company entered into an Asset Purchase Agreement (the "Original Asset Purchase Agreement") with uBriGene (Boston) Biosciences, Inc., a Delaware corporation ("uBriGene"), pursuant to which the Company agreed to sell its leasehold interest in its cell processing facility located in Worcester, Massachusetts (the "Facility"), and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene (the "Transaction"). The Company and uBriGene subsequently entered into Amendment No. 1, dated as of June 29, 2023, and Amendment No. 2, dated as of July 28, 2023, to the Original Asset Purchase Agreement (the Original Asset Purchase Agreement, as so amended, the "Asset Purchase Agreement").

On July 28, 2023 (the "Closing Date"), pursuant to the Asset Purchase Agreement, the Company completed the sale of all of the Company's assets relating to the Company's operations primarily relating to the manufacturing and production of cell and gene therapies at the Facility (such operations, the "Transferred Operations" and such assets, the "Transferred Assets") to uBriGene for upfront consideration of $6 million cash (the "Base Amount"). The Transferred Assets that were transferred to uBriGene on the Closing Date include, but are not limited to: (i) the Company's leases of equipment and other personal property and all other property, equipment, machinery, tools, supplies, inventory, fixtures and all other personal property primarily related to the Transferred Operations, (ii) the data, information, methods, quality management systems, and intellectual property primarily used for the purposes of the Transferred Operations, (iii) the records and filings, including customer and vendor lists, production data, standard operating procedures and business records relating to, used in or arising under the Transferred Operations and (iv) all transferrable business license, permits and approvals necessary to operate the Transferred Operations. As described in greater detail below, certain Transferred Assets, including the Company's lease of the Facility and contracts that are primarily used in the Transferred Operations (the "Transferred Contracts") did not transfer to uBriGene on the Closing Date.

Under the terms of the Asset Purchase Agreement, in addition to the Base Amount, uBriGene will be obligated to pay the Company a contingent amount (the "Contingent Amount") if the Company, within two years from the Closing Date: (i) completes an issuance of equity securities in an amount equal to or greater than $10,000,000 after the closing (the "Contingent Capital Raise") and (ii) obtains the consent of the landlord of the Facility to transfer the lease of the Facility to uBriGene (as discussed under "—Transfer of Lease of the Facility" below). As of November 14, 2023, the Company has completed issuances of equity securities for proceeds totaling approximately $4.6 million following the Closing Date. If the Company is unable to close the full amount of the Contingent Capital Raise and/or does not receive the Landlord's consent to the transfer the lease of the Facility to uBriGene within two years from the Closing Date, uBriGene will not be obligated to pay the Contingent Amount to the Company. The Contingent Amount to be paid to the Company upon the satisfaction of the conditions listed above will be an amount equal to $5,000,000 less (i) any severance payments or other monetary obligations to Company employees who support the Transferred Operations and who have accepted offers of employment with uBriGene that arise between the Closing Date and the date the lease transfers to uBriGene and (ii) any payments payable by the Company under Transferred Contracts in connection with the consummation of the Transaction, including any payments necessary to obtain third party consents.

Voluntary Notice to U.S. Committee on Foreign Investment in the United States

uBriGene is an indirect, wholly owned subsidiary of UBrigene (Jiangsu) Biosciences Co., Ltd., a Chinese contract development and manufacturing organization. Under the Asset Purchase Agreement, the Company and uBriGene agreed to use their reasonable best efforts to obtain clearance for the Transaction from the U.S. Committee on Foreign Investment in the United States ("CFIUS"), although obtaining such clearance was not a condition to closing the Transaction. In accordance with the Asset Purchase Agreement, the Company and uBriGene previously submitted a voluntary notice to CFIUS.

Following an initial 45-day review period and subsequent 45-day investigation period, on November 13, 2023, CFIUS requested Mustang and uBriGene to withdraw and re-file their joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction, and whether and to what extent mitigation of risk would be feasible. Upon CFIUS's request, Mustang and uBriGene submitted a request to withdraw and re-file their joint voluntary notice to CFIUS, and on November 13, 2023, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period commencing on November 14, 2023, which may be followed by a further 45-day investigation period.

At the completion of its review and, if applicable, investigation, if CFIUS determines there are no unresolved national security concerns, CFIUS will apprise the parties of its determination and conclude all action on the matter. Alternatively, CFIUS may identify and impose mitigation measures. Depending on the nature and severity of perceived national security risks identified, CFIUS may, among other mitigation measures, require suspension of the Transaction, require uBriGene to divest the Facility or other assets relating thereto, forfeit contracts that CFIUS deems to be sensitive, or require appointment of special compliance personnel or a proxy board consisting of U.S. persons. If CFIUS determines to require mitigating measures with respect to the Transaction, then uBriGene must comply with such measures although the Closing Date has already occurred.

Mustang and uBriGene have been and will continue to be actively engaged with CFIUS, and they remain fully committed to obtaining clearance from CFIUS and completing the full transfer of the Facility to uBriGene. There can be no assurance, however, that CFIUS will ultimately provide clearance with respect to the Transaction, or what mitigating measures may be required in order to obtain such clearance.

Transfer of Lease of the Facility

The Asset Purchase Agreement contemplates that Mustang will seek to procure the consent and approval of the landlord of the Facility, WCS-377 Plantation Street, Inc. (the "Landlord"), of either (i) an assignment and assumption agreement to be executed by the Company and uBriGene pursuant to which uBriGene would assume the Company's lease of the Facility or (ii) a new lease agreement by and between uBriGene and the Landlord with respect to the Facility on terms and conditions acceptable to uBriGene (the "Proposed Lease Transfer"). Because the Landlord had not consented to the

Proposed Lease Transfer as of the Closing Date, the Company's lease of the Facility did not transfer to uBriGene on the Closing Date.

The Landlord has informed the Company that it will not consider the Company's request for the Proposed Lease Transfer until the Company receives the final determination letter from CFIUS (the "CFIUS Letter") with respect to the Transaction and provides the Landlord with a reasonably detailed summary of the Company and uBriGene's reaction to such final determination (the "Reaction Summary"). Upon the Landlord's receipt of the CFIUS Letter and the Reaction Summary, the Landlord will have an additional thirty business days to make its determination on the Proposed Lease Transfer. Assuming CFIUS concludes its action with respect to the Transaction at the completion of the initial 45-day review period, and the Company and uBriGene deliver the CFIUS Letter and Reaction Summary to the landlord the following day, then the landlord would be expected to deliver its decision regarding the Proposed Lease Transfer by February 12, 2024. If CFIUS does not conclude its action with respect to the Transaction until the end of its 45-day review followed by a 45-day investigation, and the Company and uBriGene deliver the CFIUS letter and Reaction Summary to the landlord the following day, then the landlord would be expected to deliver its decision regarding the Proposed Lease Transfer by March 26, 2024.

Under the Asset Purchase Agreement, the lease of the Facility is to be transferred to uBriGene within three business days following receipt of the Landlord's consent to the Proposed Lease Transfer, if such consent is received. Unless and until the lease is transferred to uBriGene, Mustang will retain its facility lease and facility personnel, and will continue to occupy the leasehold premises and manufacture there its lead product candidates, including MB-106, pursuant to the arrangements described below under "Manufacturing Services Agreement and Sub-Contracting CDMO Agreement".

uBriGene's Right to Deliver a Repurchase Notice with Respect to the Transferred Assets

If the lease of the Facility is not assigned to uBriGene within 120 days following the Closing Date, and for so long as the lease has not been so assigned, uBriGene may deliver a notice to the Company indicating its intention to enter into good faith negotiations (the "Repurchase Notice") to provide for the Company to repurchase the Transferred Assets, re-assume the transferred liabilities and resume all Transferred Operations for a repurchase price equal to the purchase price of the Transaction actually paid by uBriGene as of the repurchase date ("Repurchase Transaction"). Upon receipt of such Repurchase Notice, the Company and uBriGene have agreed to use their best commercial efforts to negotiate in good faith the terms of any such Repurchase Transaction.

Based on the expected timeline for CFIUS to complete its review and investigation of the Transaction, and the Landlord's stated timeline to make a determination with respect to the Proposed Lease Transfer, the Company anticipates that the Proposed Lease transfer will not be completed by November 25, 2023, which is the date falling 120 days after the Closing Date. As a result, it is expected that, commencing on November 26, 2023, and for so long as the lease has not been transferred, uBriGene may deliver the Repurchase Notice to the Company.

Transferred Employees and Transferred Contracts

Under the Asset Purchase Agreement, uBriGene has agreed to (or cause one of its affiliates to) offer employment to no less than forty Company employees who support operations at the Facility on terms with base salary or hourly wages, target bonus opportunities (excluding equity-based compensation) and retirement and welfare benefits that are no less favorable than those provided by the Company immediately prior to the closing of the Transaction. Employees who receive and accept offers of employment from uBriGene are the "Transferred Employees."

Because the lease of the Facility did not transfer to uBriGene on the Closing Date, the Transferred Employees and the Company's rights in, to and under the Transferred Contracts also did not transfer to uBriGene on the Closing Date. Under the terms of the Asset Purchase Agreement, the Transferred Employees will become employees of uBriGene effective on the date that is 30 days following the completion of the Proposed Lease Transfer, and the Transferred Contracts will transfer to uBriGene on the date on which the Company and uBriGene confirm in writing that the Landlord has notified the Company or uBriGene of its consent to the Proposed Lease Transfer.

Manufacturing Services Agreement and Sub-Contracting CDMO Agreement

As contemplated by the Asset Purchase Agreement, on the Closing Date, the Company and uBriGene entered into a Manufacturing Services Agreement (the "Manufacturing Services Agreement"). Under the Manufacturing Services Agreement, the Company contracted uBriGene to manufacture the Company's lead product candidates, including MB-106, and the Company committed to spend at least $8,000,000 over a period of two years after the closing of the Transaction to purchase manufacturing and related services (the "Manufacturing Services") from uBriGene (the "Minimum Commitment"). The Company paid uBriGene 25% of the Minimum Commitment at the time of signing of the Manufacturing Services Agreement and will pay the remainder of the Minimum Commitment over the following two years. Subject to the Company's payment of its Minimum Commitment, uBriGene will provide to the Company a manufacturing rebate, payable in cash at the end of the second year of the Manufacturing Services Agreement term, for any amounts paid for Manufacturing Services in excess of the Minimum Commitment (but in no event will such rebate exceed $3,000,000). In connection with the Manufacturing Services Agreement, the Company will provide uBriGene with the customary licenses to use intellectual property rights specific to the Company's cell and gene therapies to the extent reasonably necessary for uBriGene's performance under the Manufacturing Services Agreement.

In addition, as contemplated by the Asset Purchase Agreement, on the Closing Date, the Company and uBriGene entered into a sub-contracting Manufacturing Services Agreement (the "Sub-Contracting CDMO Agreement"), pursuant to which uBriGene contracted the Company to perform the Manufacturing Services to be performed by uBriGene under the Manufacturing Services Agreement and granted the Company a revocable, non-exclusive, royalty-free license to use the Transferred Assets in connection with the performance of such services. Under the terms of the Sub-Contracting CDMO Agreement, the Company will manufacture its lead product candidates, including MB-106 (the "Company CDMO Manufacturing Services"), and may from time to time manufacture other products as requested by uBriGene. Pursuant to the Sub-Contracting CDMO Agreement, the price to be paid by uBriGene in exchange for the Company CDMO Manufacturing Services will be an amount equal to the sum of: (i) the base salary and hourly wages for the Transferred Employees for time spent performing the Company CDMO Manufacturing Services, (ii) the fees, payments, costs and expenses payable by the Company to third parties under any of the Transferred Contracts used to perform the CDMO Manufacturing Services (so long as such amounts are generally consistent with amounts paid by the Company under such Transferred Contracts immediately prior to the Closing Date and such amounts did not become payable as a result of a breach of, a default under, a termination, a cancellation or an acceleration of any right or obligation under the Transferred Contracts), and (iii) any other amounts approved in advance in writing by uBriGene. As of the date hereof, uBriGene has not informed the Company of any plans to request any manufacturing services under the Sub-Contracting CDMO Agreement, other than the Company CDMO Manufacturing Services. In addition, under the Sub-Contracting CDMO Agreement, the Company and uBriGene agreed to establish a joint steering committee comprising two representatives from each of the Company and uBriGene to review, discuss and decide on operational matters relating to the services to be performed by the Company under such agreement, including matters relating to expenses. In addition, the Company has agreed to permit uBriGene to locate up to three of uBriGene's personnel at the Facility so as to participate in meetings of the joint steering committee and allow for in-person feedback and decision-marking regarding the services to be performed by the Company.

In addition to other customary termination events, in the event uBriGene delivers the Repurchase Notice, the Manufacturing Services Agreement and the Sub-Contracting CDMO Agreement will terminate upon the earlier of (i) the closing of the Repurchase Transaction or (ii) 60 days after the delivery of the Repurchase Notice.

The Company intends to expense manufacturing costs under the MSA and Sub-Contracting CDMO Agreement and account for reimbursed costs associated with the agreements as an offset to such expense. For the three and nine months ended September 30, 2023, the Company expensed $1.7 million of manufacturing costs under the MSA and received $2.5 million for reimbursed costs associated with the Sub-Contracting CDMO agreement.

Transition Services Agreement and Quality Services Agreement

On the Closing Date, the parties also entered into a Quality Services Agreement, pursuant to which the Company and uBriGene agreed to specified duties for each party with respect to the contract manufacture by uBriGene of the Company's product candidates. The Quality Services Agreement sets forth the quality activities associated with the production,

analysis, and release of such products and assigns responsibility for each activity to the Company and/or uBriGene. The Quality Services Agreement terminates upon the earlier of: (i) the date of expiration of the MSA or (ii) the date of termination of the MSA.

In addition, as contemplated by the Amended Asset Purchase Agreement, on the Closing Date, the Company and uBriGene entered into a Transition Services Agreement, which will become effective upon completion of the Proposed Lease Transfer (if such Proposed Lease Transfer is completed). Pursuant to the Transition Services Agreement, the Company will provide certain transitional services to uBriGene to ensure the smooth transition of operations and continuity of business for a period of six months after the effective date of the Transition Services Agreement, unless otherwise extended upon the mutual agreement of the Company and uBriGene.

Impact of Landlord Consent to the Proposed Lease Transfer on the Transaction

In the event the Landlord consents to the Proposed Lease Transfer, it is expected that the lease to the Facility and the Transferred Employees of the Facility will be transferred to uBriGene as described above, in accordance with the terms of the Asset Purchase Agreement. In addition, following receipt of the Landlord's consent to the Proposed Lease Transfer (if such consent is received), the Sub-Contracting CDMO Agreement will be terminated no later than 30 days following completion of the Proposed Lease Transfer, following which uBriGene will commence the Manufacturing Services in connection with the Company's lead product candidates, including MB-106, pursuant to the Manufacturing Services Agreement. If, however, the Landlord does not consent to the Proposed Lease Transfer the parties may mutually agree to extend the term of the Sub-Contracting CDMO Agreement indefinitely and uBriGene may continue to procure manufacturing services (including the Company CDMO Manufacturing Services) from the Company. In the event the Landlord does not consent to the Proposed Lease Transfer within 120 days of closing, uBriGene may deliver the Repurchase Notice to the Company, following which the parties will negotiate in good faith regarding the Repurchase Transaction. By their terms, the Manufacturing Services Agreement and the Sub-Contracting CDMO Agreement terminate upon the earlier of (i) the closing of the Repurchase Transaction or (ii) 60 days after the delivery of the Repurchase Notice.

Risks Relating to the Transaction

The Company is exposed to a number of risks and uncertainties relating to the Transaction. Please see "Risk Factors—Risks Relating to the Sale of the Company's Manufacturing Facility" for a discussion of these risks and uncertainties.

Financing Activities

Registered Direct Offering

On October 26, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with a single institutional accredited investor (the "Investor") pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market under the rules of The Nasdaq Stock Market (the "Registered Offering"), (i) 920,000 shares of common stock, $0.0001 par value per share, at a price per Share of $1.70 and (ii) pre-funded warrants (the "Pre-funded Warrants") to purchase up to 1,668,236 shares of its common stock, at a price per Pre-funded Warrant equal to $1.699, the price per Share, less $0.001.

The Pre-funded Warrants were sold, in lieu of shares of common stock, to the Investor whose purchase of shares of common stock in the Registered Offering would otherwise result in such Investor, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at such Investor's option upon issuance, 9.99%) of the Company's outstanding common stock immediately following the consumption of the Registered Offering. The Pre-funded Warrants have an exercise price of $0.001 per share, became exercisable upon issuance and remain exercisable until exercised in full.

The Registered Offering closed on October 30, 2023. The Company intends to use the net proceeds from the Registered Offering for general corporate purposes and working capital requirements, which may include, among other things, the advancement of its product candidates to obtain regulatory approval from the FDA.

In a concurrent private placement, pursuant to the terms of the Purchase Agreement, the Company also agreed to issue and sell unregistered warrants (the "Warrants") to purchase up to 2,588,236 shares of Common Stock, at an offering price of $0.125 per Warrant to purchase one share of common stock (the "Private Placement" and, together with the Registered Offering, the "Offerings") (which offering price is included in the purchase price per Share or Pre-funded warrant). The Warrants have an exercise price of $1.58 per share (subject to customary adjustments as set forth in the Warrants), are exercisable upon issuance and will expire five and one-half years from the date of issuance. The Warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions.

The Private Placement also closed on October 30, 2023, concurrently with the Registered Offering. The Company received approximately $4.4 million in gross proceeds from the Offerings, before deducting placement agency fees and offering expenses of approximately $0.5 million.

At-the-Market Offering

During the nine months ended September 30, 2023, the Company issued approximately 52,000 shares of common stock at an average price of $3.15 for gross proceeds of $0.2 million under the Mustang ATM. In connection with these sales, the Company paid aggregate fees of approximately $3,000.

The amount of securities we are able to sell pursuant to the registration statements on Form S-3 is limited. See "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. Applying these principles requires our judgment in determining the appropriateness of acceptable accounting principles and methods of application in diverse and complex economic activities. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of expenses, assets and liabilities, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and other assumptions that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our critical accounting estimates, see the MD&A in the 2022 Form 10-K. There were no material changes in our critical accounting estimates or accounting policies from December 31, 2022.

Accounting Pronouncements

During the nine months ended September 30, 2023, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2022 Form 10-K that are expected to materially affect the Company's present or future financial statements.

Smaller Reporting Company Status

We are a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K, have reduced disclosure obligations regarding executive compensation and certain other matters, and smaller reporting companies are permitted to delay adoption of certain recent accounting pronouncements discussed in Note 2 to our financial statements in this report on Form 10-Q.

Controlled Company Status

We are a majority-controlled subsidiary of 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.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

	For the three months ended September 30,		Change	
($ in thousands)	2023	2022	$	%
Operating expenses:				
Research and development	$ 9,477	$ 15,419	$ (5,942)	(39)%
Research and development – licenses acquired	50	40	10	25 %
Gain on sale of property and equipment	(1,351)	—	(1,351)	100 %
General and administrative	2,131	3,389	(1,258)	(37)%
Total operating expenses	10,307	18,848	(8,541)	(45)%
Loss from operations	(10,307)	(18,848)	8,541	(45)%
Other income (expense)				
Other income	138	669	(531)	(79)%
Interest income	115	216	(101)	(47)%
Interest expense	(4)	(1,034)	1,030	(100)%
Total other income (expense)	249	(149)	398	(267)%
Net Loss	**$ (10,058)**	**$ (18,997)**	**$ 8,939**	**(47)%**

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, sponsored research and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations ("CROs") 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 September 30, 2023 and 2022, research and development expenses were $9.5 million and $15.4 million, respectively. The decrease of approximately $5.9 million is primarily attributed to decreased expenses of $3.2 million for personnel related costs, which includes approximately $1.5 million of costs reimbursed through the subcontracting agreement with uBriGene, $1.2 million for lab supplies, which includes approximately $0.5 million of costs reimbursed through the subcontracting agreement with uBriGene, $3.1 million for program related expenses, primarily reflecting the Company's review of its portfolio of product candidates, $0.6 million for facility and deprecation expenses, which includes approximately $0.2 million of costs reimbursed through the subcontracting agreement with uBriGene, partially offset by higher expenses of $1.6 million for services provided by uBriGene and $0.6 million for other expenses.

For the three months ended September 30, 2023, and 2022, research and development expenses for licenses acquired were $50,000 and $40,000, respectively.

The following table provides a breakout of the components of research and development expenses for the three months ended September 30, 2023 and 2022:

($ in thousands)	For the three months ended September 30, 2023	2022
R&D program related expenses [1]		
MB-102	$ 394	$ 839
MB-106	92	225
MB-107/207	(389)	285
MB-109	356	249
MB-110	125	129
Mayo in situ CAR T	6	212
All others [2]	30	1,784
Total R&D development expense	614	3,723
R&D personnel related expenses	1,826	4,988
R&D facility and depreciation expense	398	1,034
R&D consulting expenses	819	889
R&D lab supplies	2,520	3,746
R&D other expense [3]	3,300	1,039
Total research and development expense	$ 9,477	$ 15,419

[1] Includes sponsored research, license and clinical trial related costs.
[2] Includes costs for long-term follow up and programs that were terminated.
[3] Includes services provided by uBriGene under the manufacturing services agreement.

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 September 30, 2023, and 2022, general and administrative expenses were $2.1 million and $3.4 million, respectively. The decrease of approximately $1.3 million is primarily attributed to a $0.3 million decrease in legal expenses, substantially all of which were transaction expenses related to the sale of property and equipment to uBriGene, a $0.4 million decrease in consulting and outside services, a $0.2 million decrease in personnel costs, and a $0.4 million decrease across various other general and administrative expenses.

Other Income or Expense

For the three months ended September 30, 2023, and 2022, other income (expense) was $0.2 million and $(0.1) million, respectively. The decrease of approximately $0.3 million in expense is primarily attributed to a $1.0 million decrease in interest expense, partially offset by a $0.5 million decrease in grant income and a $0.1 million decrease in interest income.

Comparison of the Nine Months Ended September 30, 2023 and 2022

($ in thousands)	For the nine months ended September 30, 2023	2022	Change $	Change %
Operating expenses:				
Research and development	$ 34,313	$ 46,872	$ (12,559)	(27)%
Research and development – licenses acquired	50	40	10	25 %
Gain on sale of property and equipment	(1,351)	—	(1,351)	100 %
General and administrative	7,507	9,815	(2,308)	(24)%
Total operating expenses	40,519	56,727	(16,208)	(29)%
Loss from operations	(40,519)	(56,727)	16,208	(29)%
Other income (expense)				
Other income	918	669	249	37 %
Interest income	727	366	361	99 %
Interest expense	(4,112)	(2,199)	(1,913)	87 %
Total other income (expense)	(2,467)	(1,164)	(1,303)	112 %
Net Loss	**$ (42,986)**	**$ (57,891)**	**$ 14,905**	**(26)%**

Research and Development Expenses

For the nine months ended September 30, 2023, and 2022, research and development expenses were $34.3 million and $46.9 million, respectively.

The decrease of approximately $12.6 million is primarily attributed to decreased expenses of $4.0 million for employee related costs, which includes approximately $1.5 million of costs reimbursed through the subcontracting agreement with uBriGene, $4.5 million for lab supplies, which includes approximately $0.5 million of costs reimbursed through the subcontracting agreement with uBriGene, $4.6 million for program related costs, primarily reflecting the Company's review of its portfolio of product candidates, $0.8 million for consulting and $0.3 million of other research and development expenses, partially offset by higher expenses of $1.6 million for services provided by uBriGene. Non-cash stock compensation expense included in research and development expense for the nine months ended September 30, 2023, and 2022 approximated $(1,000) and $1.3 million, respectively.

For the nine months ended September 30, 2023, and 2022, research and development expenses for licenses acquired were $50,000 and $40,000, respectively.

The following table breaks out the components of research and development expenses for the nine months ended September 30, 2023 and 2022:

($ in thousands)	For the nine months ended September 30, 2023	2022
R&D program related expenses [1]		
MB-102	$ 505	$ 1,106
MB-106	3,026	2,564
MB-107/207	(862)	976
MB-109	945	516
MB-110	309	395
Mayo in situ CAR T	588	712
All others [2]	648	3,492
Total R&D development expense	5,159	9,761
R&D personnel related expenses	11,541	15,517
R&D facility and depreciation expense	2,463	2,712
R&D consulting expenses	2,750	3,615
R&D lab supplies	7,573	12,116
R&D other expense [3]	4,827	3,151
Total research and development expense	$ 34,313	$ 46,872

[1] Includes sponsored research, license and clinical trial related costs.
[2] Includes costs for long-term follow up and programs that were terminated.
[3] Includes services provided by uBriGene under the manufacturing services agreement.

General and Administrative Expenses

For the nine months ended September 30, 2023, and 2022, general and administrative expenses were $7.5 million and $9.8 million, respectively. The decrease of approximately $2.3 million is primarily attributed to $0.9 million decrease for shares issued to Fortress, in connection with the equity fees paid on financings, $0.6 million for professional and outside services, $0.4 million for consulting, $0.3 million for personnel related costs, $0.2 million for Management Services Agreement fee and $0.2 million across various other expenses, partially offset by $0.3 million increase in legal expense, which includes approximately $1.0 million of transaction expenses related to the sale of property and equipment to uBriGene. Non-cash stock compensation included in general and administrative expense for the nine months ended September 30, 2023, and 2022 approximated $0.4 million and $1.5 million, respectively.

Other Income or Expense

For the nine months ended September 30, 2023, and 2022, other expense was $2.5 million and $1.2 million, respectively. The increase of approximately $1.3 million in expense is primarily attributed to the loss recognized for the extinguishment of debt of $2.8 million, partially offset by $0.9 million decrease in interest expense, $0.4 million increase in interest income, and $0.2 million gain recognized on the modification of the Mercantile Center lease.

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 September 30, 2023, the Company had an accumulated deficit of $372.4 million.

The Company has funded its operations to date primarily through the sale of equity and its Term Loan. On April 11, 2023, we repaid the Term Loan, see Note 8 to the Financial Statements. On October 30, 2023, the Company completed a registered direct offering of (i) 920,000 shares of its common stock, at a price per share of $1.70 and (ii) Pre-funded Warrants to purchase up to 1,668,236 shares of its common stock, at a price per Pre-funded Warrant equal to $1.699. In a concurrent private placement, the Company also issued and sold unregistered Warrants to purchase up to 2,588,236 shares of its common stock, at an offering price of $0.125 per Warrant (which offering price is included in the purchase price per

share or Pre-funded Warrant). The net proceeds to the Company of these offerings were approximately $3.9 million, after deducting placement agent fees and expenses.

As of September 30, 2023, the Company had cash and cash equivalents of $9.6 million. Based on the Company's current operating plan, the Company currently expects that such cash and cash equivalents, together with the approximately $3.9 million net proceeds received in October 2023 from the registered direct offering, will be sufficient to fund its operations and clinical trials through the first quarter of 2024. In the near term, the Company's liquidity and capital resources will be significantly affected by its ability to raise additional equity capital and receive the Contingent Payment pursuant to the Amended Asset Purchase Agreement in connection with the sale of its Facility, as described under "Recent Developments" above. The Company currently believes that, if it is able secure the Contingent Payment no later than the end of the second quarter of 2024—which is contingent upon its raising an additional $5.4 million through issuances of equity securities in order to complete the Contingent Capital Raise and obtaining the Landlord's consent to the Proposed Lease transfer—based on its current operating plan, it will have sufficient cash to fund its operations and clinical trials, through the third quarter of 2024, depending on the timing of certain expenses relating to clinical trials that are within the Company's control. If the Company is not able to secure the Contingent Payment by the end of the first quarter of 2024, the Company will continue to seek addition funding through corporate partnerships and capital markets fundraising and may face significant difficulty in funding its operations in the short term and will need to pursue other options to reduce expenses. See "Risk Factors—Risks Related to Our Finances and Capital Requirements."

The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of September 30, 2023, there is substantial doubt about the Company's ability to continue as a going concern for the next 12 months from the date of issuance of these financial statements. The financial statements included in this Quarterly Report on Form 10-Q do not include any adjustments that might be necessary should operations discontinue.

In addition, the amount of proceeds the Company may be able to raise pursuant to its existing shelf registration statements on Form S-3 may be limited. As of the filing of this Quarterly Report on Form 10-Q, the Company is subject to the general instructions on Form S-3 known as the "baby shelf rules." Under these instructions, the amount of funds we can raise through primary offerings of securities in any 12-month period using our registration statements on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by our affiliates. Therefore, we will be limited in the amount of proceeds we are able to raise by selling securities using our Form S-3 until such time as our public float exceeds $75 million.

Contractual Obligations

We enter into contracts in the normal course of business with licensors, CROs, contract manufacturing organizations (CMOs) and other third parties for the procurement of various products and services, including without limitation biopharmaceutical development, biologic assay development, commercialization, clinical and preclinical development, clinical trials management, pharmacovigilance and manufacturing and supply. These contracts typically do not contain minimum purchase commitments (although they may) and are generally terminable by us upon written notice. Payments due upon termination or cancelation/delay consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation; in certain cases, our contractual arrangements with CROs and CMOs include cancelation and/or delay fees and penalties.

During the nine months ended September 30, 2023, the Company amended the Mercantile Center lease, which resulted in a decrease to the right of use asset and corresponding lease liability, see Note 12. There were no other material changes in our contractual obligations and commitments, as described in our 2022 Form 10-K.

Cash Flows for the Nine Months Ended September 30, 2023 and 2022

($ in thousands)	For the nine months ended September 30, 2023	2022
Statement of cash flows data:		
Total cash (used in) provided by:		
Operating activities	$ (42,223)	$ (49,777)
Investing activities	5,916	(2,532)
Financing activities	(30,037)	34,055
Net change in cash, cash equivalents and restricted cash	$ (66,344)	$ (18,254)

Operating Activities

Net cash used in operating activities was $42.2 million for the nine months ended September 30, 2023, compared to $49.8 million for the nine months ended September 30, 2022.

Net cash used in operating activities for the nine months ended September 30, 2023, was primarily due to approximately $43.0 million in net loss, $2.9 million change in operating assets and liabilities and $1.4 million due to the gain on the sale of property and equipment to uBriGene, partially offset by $0.4 million of non-cash stock compensation expenses, $1.6 million of depreciation, $2.8 million due to the loss on extinguishment of debt, and $0.3 million from other operating activities.

Net cash used in operating activities for the nine months ended September 30, 2022, was primarily due to approximately $57.9 million in net loss, partially offset by $2.6 million change in operating assets and liabilities, $1.8 million of non-cash stock compensation expenses, $2.0 million of depreciation, $0.9 million of equity fee on issuance of common shares to Fortress for the Term Loan and at-the-market issuances, and $0.8 million from other operating activities.

Investing Activities

Net cash provided by investing activities was $5.9 million for the nine months ended September 30, 2023, primarily reflecting proceeds from the sale of property and equipment to uBriGene of $6.0 million. Net cash used in investing activities was $2.5 million for the nine months ended September 30, 2022, primarily representing purchases of fixed assets.

Financing Activities

Net cash used in financing activities was $30.0 million during the nine months ended September 30, 2023, driven by the repayment of the Term Loan, partially offset by $0.2 million raised from the issuance of the Company's common shares in connection with the ESPP, and $0.2 million of net proceeds from the Mustang ATM.

Net cash provided by financing activities was $34.1 million during the nine months ended September 30, 2022, driven by (i) proceeds from the issuance of the Term Loan of $30.0 million, net of financing costs of $2.7 million, (ii) gross proceeds of $6.6 million, net of offering costs of $0.1 million, from the Mustang ATM; and (iii) $0.2 million raised from the issuance of the Company's common shares in connection with the ESPP.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of September 30, 2023, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No change in internal control over financial reporting occurred during the most recent quarter with respect to our operations, which materially affected, or is reasonable likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None

Item 1A. Risk Factors

Investing in our Common Stock or any other type of equity or debt securities we may offer (together, our "Securities") involves a high degree of risk. 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 Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Form 10-Q, before making an investment decision. 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 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 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 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 $372.4 million as of September 30, 2023. 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 receive regulatory approval and are approved for commercial sale, due to our need to establish the necessary commercial infrastructure to launch and commercialize this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for manufacturing, testing, 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 that require us to make payments to collaborators or licensors;
- 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; and
- there are any regulatory developments affecting product candidates of our competitors.

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 or have manufactured 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 the 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 the Company could also cause you to lose all or part of your investment.

There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding (which may not be available on acceptable terms to the Company, or at all) and/or to delay, limit or terminate our product development efforts or other operations.

We are currently advancing our programs in hematologic cancers, solid tumors and rare genetic diseases through clinical development. Developing and commercializing CAR T and gene therapy products is expensive, and we do not expect to generate meaningful product revenues in the foreseeable future until we obtain marketing approval for products in the United States and following any potential commercial launch.

As of September 30, 2023, our cash and cash equivalents were $9.6 million. Based on our current business plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended September 30, 2023 are issued. Our fundraising efforts to raise additional funding may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our potential products following marketing approval if and when obtained. In addition, we cannot guarantee

that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. Potential indebtedness, if incurred, would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

In addition, in order to address our current funding constraints, we may be required to further revise our business plan and strategy, which may result in us (i) further curtailing, delaying or discontinuing more of our research or development programs or the commercialization of any product candidates, (ii) selling certain of our assets and/or (iii) may result in our being unable to expand our operations or otherwise capitalize on our business opportunities. Such actions measures may become necessary whether or not we are able to raise additional capital. As a result, our business, financial condition, and results of operations could be materially affected.

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. 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 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 will need 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 may receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and, if approved, commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. As of September 30, 2023, we had $10.3 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, if we are unable to secure additional funding, it is likely that we will need to delay or terminate the development of certain product candidates; 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. Additional funding may be more difficult to obtain, or may be more expensive, as a result of recent increases in inflation and interest rates in the U.S. economy generally. 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, if approved, 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 studies 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 a New Drug Application ("NDA") or Biologics License Application ("BLA") 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, if approved.

In order to carry out our business plan and implement our strategy, we will need to obtain additional financing 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.

Under current SEC regulations, if at the time we file our Annual Report on Form 10-K our public float is less than $75 million, and for so long as our public float remains less than $75 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float, which is referred to as the "baby shelf rules." SEC regulations permit us to use the highest closing sales price of our common stock (or the average of the last bid and last ask prices of our common stock) on any day within 60 days of sales under the registration statement to calculate our public float.

As of the date of our Annual Report on Form 10-K, filed with the SEC on March 30, 2023, our public float was less than $75 million. As a result, for sales following the date of our Annual Report on Form 10-K, and until we again have a public float with a value in excess of $75 million, if ever, we only have the capacity to sell shares up to one-third of our public

float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statements will also decrease.

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, including through lending arrangements, 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, including through lending arrangements, 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.

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. 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.

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.

Risks Related to Our Business Strategy, Structure, and Organization

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 commercialize such product candidates. Most of our product candidates are currently 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 have no drug products for sale, currently generate no revenues from sales of any drug products and may never be able to develop or commercialize a marketable product.

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

- developing our technology platform;
- identifying, developing, formulating, manufacturing and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- participating in regulatory approval processes, including ultimately gaining approval to market a drug product, which may not occur;
- obtaining sufficient quantities of our product candidates from our third-party manufacturers to meet clinical trial needs and, if approved, to meet 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 establish; and
- maintaining patent protection and regulatory exclusivity for our product candidates.

Our operations have been limited to organizing the 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 clinical development, management of clinical and manufacturing activities, regulatory approval in the jurisdictions in which we plan to market the product, obtaining manufacturing supply, building a commercial organization, and significant marketing efforts before we generate any revenues from product sales, which may not occur. We are not permitted to market or promote any of our product candidates in the U.S. or any other jurisdiction before we receive regulatory approval from the FDA or comparable foreign regulatory authority, respectively, and we may never receive such regulatory approval for any of our product candidates.

Our approach to the 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 develop into commercially viable therapies to treat human patients with cancer or other diseases. One of the reasons for the lack of commercial viability could be our inability to obtain regulatory approval for such technologies.

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

We have concentrated much of 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 relatively 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-ups 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.

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 the 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 and/or effectively 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.

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

We are 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. 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.

Risks Inherent in Drug Development and Commercialization

Delays in the commencement or conduct of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

The commencement or conduct of clinical trials can be delayed for a variety of reasons, including, but not necessarily limited to, delays in:

- obtaining regulatory approval to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching and preserving agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Institutional Review Board (“IRB”) or ethics committee approval to conduct a clinical trial at a prospective site;
- developing and validating companion diagnostics on a timely basis, if required;

- adding new clinical sites once a trial has begun;
- change in the principal investigator or other key staff overseeing the clinical trial at a given site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; or
- retaining (or replacing) patients who have initiated a clinical trial but who may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, personal issues, or other reasons.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Suspensions or delays in the completion of clinical testing could result in increased costs and delay or prevent our ability to complete development of that product or generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements and on a timely basis. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities, due to a number of factors, including, but not necessarily limited to:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- stopping rules contained in the protocol;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may in turn impact the costs and timing of, and the likelihood of successfully completing, a clinical trial. If we experience delays in the completion of, or if we must suspend or terminate, any clinical trial of any product candidate, our ability to obtain regulatory approval for that product candidate will be delayed, and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

Product candidates that we advance into clinical trials may not receive regulatory approval.

Pharmaceutical development has inherent risks. We will be required to demonstrate through well-controlled clinical trials that product candidates are effective with a favorable benefit-risk profile for use in their target indications before seeking regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful, as product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Also, we may need to conduct additional clinical trials that are not currently anticipated. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. As a result, product candidates that we advance into clinical trials may not receive regulatory approval.

In addition, even if our product candidates were to obtain approval, regulatory authorities may approve any such 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. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of the product. In addition, the Drug Enforcement Agency ("DEA") (or foreign equivalent) may classify one or more of our product candidates in scheduling under the Controlled Substances Act (or its foreign equivalent) that could impede such product's commercial viability. Any of these scenarios could impact the commercial prospects for one or more of our current or future product candidates.

Any product candidates we advance into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize product candidates.

The research and clinical development, testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of any product candidate, including our product candidates, is subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market a product candidate until such product candidate's BLA or NDA is approved by the FDA. The process of obtaining approval is uncertain, expensive, often spanning many years, and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to significant and expensive clinical testing requirements, our ability to obtain marketing approval for product candidates depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or equipment and facilities are inadequate to support approval. Approval policies or regulations may change, and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in the clinical development of product candidates, regulatory approval is never guaranteed.

The FDA and other regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

- the FDA or comparable foreign regulatory authorities may disagree with the trial design or implementation of our clinical trials, including proper use of clinical trial methods and methods of data analysis;
- an inability to establish sufficient data and information to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for an indication;
- the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from that of the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- the FDA may disagree with the interpretation of data from preclinical studies or clinical trials;
- the FDA may determine that our manufacturing processes or facilities or those of third-party manufacturers with which we or our respective collaborators currently contract for clinical supplies and plan to contract for commercial supplies do not satisfactorily comply with current good manufacturing practices ("cGMP") requirements; or
- the approval policies or interpretation of regulations of the FDA may significantly change in a manner rendering the clinical data insufficient for approval or the product characteristics or benefit-risk profile unfavorable for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, rapid drug and biological development during the COVID-19 pandemic has raised questions about the safety and efficacy of certain marketed pharmaceuticals and may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Regulatory approval for our product candidates by the FDA, or any similar regulatory authorities outside the United States, is limited to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to the indications for use and related treatment of those specific diseases and indications set forth in the approval for which a product is deemed to be safe and effective by the FDA, or other similar regulatory authorities outside the United States. In addition to the regulatory approval required for new drug products, new formulations or indications for an approved product also require regulatory approval. If we are not able to obtain regulatory 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 ("off-label uses"), our ability to promote the products is limited to those indications that are specifically approved by the FDA, or similar regulatory authorities outside the United States. Such off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in certain circumstances. Regulatory authorities in the U.S. generally do not regulate practice of medicine or the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the promotion of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to compliance or enforcement actions, including Warning Letters, by these authorities. In addition, our failure to follow FDA laws, regulations and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, request a recall or institute fines or penalties, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business.

If any of our product candidates are approved and we or our contract manufacturer(s) fail to produce the product, or components of 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, if approved, 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 establishment inspection program. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party suppliers and contract manufacturers, but 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, restrictions on imports and exports, 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 recalls, re-stocking costs, damage to our reputation and potential for product liability claims.

If the contract manufacturers upon whom we may rely to manufacture one or more of our product candidates, and any future product candidate we may in-license, fails 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.

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 the 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 or adverse events 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 adverse events, 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 adverse events that prevented further development of the compound. In the event that our clinical trials reveal a high or unacceptable severity and prevalence of adverse events, 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. Adverse events or 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 or in denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, which would, in turn, prevent us from commercializing and generating market acceptance and revenues from the sale of that product candidate. Adverse events or 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, including specific warnings, black box warnings, adverse reactions, precautions, and/or contraindications;
- regulatory authorities may suspend or withdraw their approval of the product, and/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, or any 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.

If one or more of our product candidates that we may license or acquire is approved, the approved product candidate will be subject to ongoing requirements and review by 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, or other regulatory authorities, 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 and other applicable regulatory authorities closely regulate 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 and other applicable regulatory authorities impose 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 Federal Food Drug and Cosmetic Act ("FDCA") relating to the promotion of prescription drugs may lead to investigations, civil claims, and/or criminal charges 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, untitled letters, import alerts, and/or inspection observations;
- 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, consent decrees, and/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, or negatively affect those products for which we may have already received regulatory approval, if any. 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 be subject to the various actions listed above, including losing 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 U.S. or other countries until we have completed a rigorous and extensive regulatory review process, 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 United States Patent and Trademark Office ("USPTO"). The FDA typically conducts a review of proposed product brand names, including an evaluation of the 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.

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 U.S. 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 ("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 that we are targeting for 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 candidates or future product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing.

If our competitors develop treatments for any of our product candidates' target indications and those competitor products are approved more quickly, marketed more successfully or demonstrated to be more effective, the commercial opportunity for our product candidate will be reduced or eliminated.

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, if approved, 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We will also face competition from these third parties in establishing clinical trial sites, in patient registration for clinical trials, and in identifying and in-licensing new product candidates.

Further, 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, including those that have lost or will lose their patent exclusivity. In the future, we may face additional competition from a generic form of our own candidates when the patents covering them 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.

If any of our product candidates are successfully developed but do not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that any such product candidates generate from sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of any approved products would depend 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 product is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the product as a safe and effective treatment;
- the safety of such product candidates seen in a broader patient group, (i.e., based on actual use);
- 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, including any contradictions, warnings, drug interactions, or other precautions;
- changes in the standard of care for the targeted indications for our product candidate or future product candidates, which could reduce the marketing impact of any labeling or marketing claims that we could make following FDA approval;
- 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.

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 U.S., the European Union ("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 a 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 be unsuccessful in commercializing our product candidates, if 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 approved product candidate, we would need to build marketing, sales, distribution, managerial and other non-technical capabilities or arrange for third parties to perform these services, and we may be unsuccessful in doing so. In the event of successful development and regulatory approval of any of our current or future product candidates, 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 our own sales and marketing organization.

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.

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 therapy 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 ("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 Therapeutic Products ("OTP") within the Center for Biologics Evaluation and Research ("CBER"), to consolidate the review of gene therapy and related products, and to advise the CBER on its review. The FDA can put an 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 Institutional Review Board ("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 the therapies that underpin many of our product candidates 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 one or more of the therapies underpinning our product candidates, including without limitation gene therapy, is unsafe, and such therapy may not gain the acceptance of the public or the medical community. In particular, the success of our gene therapy platforms 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 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 do obtain approval and/or a decrease in demand for any such product candidates. Concern about environmental spread of our products, whether real or anticipated, may also hinder the commercialization of our products.

Risks Related to Reliance on Third Parties

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 our licensors to conduct some of our preclinical studies and some of our clinical trials for our product candidates and for future product candidates, and we rely on third-party CROs and site management organizations to conduct most of the remainder of our preclinical studies and all the rest of our clinical trials. We expect to continue to rely on third parties, such as our licensors, CROs, 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 reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our preclinical studies and clinical trials is 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 practices ("GLPs") 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 CROs 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 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 and/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 CROs or site management organizations terminates, we may not be able to enter into arrangements with alternative CROs or site management organizations or to do so on commercially reasonable terms. Switching or adding additional CROs or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We are currently reliant on COH, Fred Hutch, St. Jude, the NIH, UAB, Mayo Clinic, and LUMC 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, UAB, Mayo Clinic and LUMC, 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 team at COH, of Drs. Brian Till and Mazyar Shadman and their team at Fred Hutch, of Drs. Stephen Gottschalk and Ewelina Mamcarz and their team at St. Jude, of Dr. James M. Markert and his team at UAB, of Dr. Larry R. Pease and his team at Mayo Clinic, and Dr. Frank Staal and his team at LUMC. 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.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and may also do so for commercialization, if and when our product candidates are approved. 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.

We may 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, while still being required by law to establish adequate oversight and control over products furnished by that third party;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers are unable to obtain raw materials due to supply chain disruptions, 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. Forces beyond our control, including the continuing effects of the COVID-19 pandemic, could disrupt the global supply chain and impact our or our third-party manufacturers' ability to obtain raw materials or other products necessary to manufacture our product candidates. 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 contract manufacturers to potentially manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our contract manufacturers, but we do not control the day-to-day manufacturing operations of, and are dependent on, the 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, restrictions on imports and exports, 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.

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 may 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, if approved, producing additional losses and depriving us of potential product revenue.

We rely on third parties to conduct all aspects of our LV vector production and these third parties may not perform satisfactorily.

We do not independently conduct our LV vector production and we currently rely, and expect to continue to rely, on third parties with respect to the manufacture of these items.

Our reliance on these third parties for manufacturing LV vector reduces our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For products that we develop and commercialize, we will remain responsible for ensuring that each of our IND-enabling studies and clinical studies is conducted in accordance with the study plan and protocols, and that our LV vectors are manufactured in accordance with GMP as applied in the relevant jurisdictions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, or manufacture our LV vectors in

accordance with GMP, we will not be able to complete, or may be delayed in completing, the preclinical and clinical studies and manufacturing process validation activities required to support future IND, market authorization application and BLA submissions and approval of our product candidates, or to support commercialization of our products, if approved. Many of our agreements with these third parties contain termination provisions that allow these third parties to terminate their relationships with us at any time. If we need to enter into alternative arrangements, our product development and commercialization activities could be delayed.

We may be forced to enter into an agreement with a different manufacturer, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills required to manufacture LV vector for our drug product candidates may be unique or proprietary to the original manufacturer, and we may have difficulty or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Any of these events could lead to clinical study delays or failure to obtain marketing approval or impact our ability to successfully commercialize our product or any future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

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 well-studied 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.

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.

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 Relating to Legislation and Regulation Affecting the Biopharmaceutical and Other Industries

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.

Legislative and regulatory changes to the healthcare systems of the United States and certain foreign countries could impact our ability to sell our products profitably. Several federal agencies including FDA, CMS and HHS, in addition to state and local governments regulate drug product development and marketing. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products by revising the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors.

Since 2003, there have been several other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act" or "ACA," was enacted in 2010 and made significant changes to the United States' healthcare system. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

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 biological products, 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 to enroll in the 340B Drug Pricing Program to include certain critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals, but exempting certain drugs from the ceiling price requirements for these covered entities;
- 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.

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.

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.

In the United States there is significant interest in containing healthcare costs and increasing scrutiny of pharmaceutical pricing practices. Congress has continually 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), regularly evaluate and hold hearings on legislation intended to address various elements of the prescription drug supply chain and prescription drug pricing. Proposals include a significant overhaul of the Medicare Part D benefit design, efforts to cap the increase in drug prices, create drug price transparency, and efforts to allow the Secretary of the Department of Health and Human Services to negotiate drug prices with prescription drug manufacturers. 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 former Trump administration took several regulatory steps and proposed numerous prescription drug cost control measures. Similarly, the Biden administration has identified promoting competition and lowering drug prices as a priority. State legislatures are similarly active in proposing and passing legislation and regulations aimed at controlling pharmaceutical and biological prices and drug cost transparency. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services, including prescription drugs. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and prescription drugs may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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 and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. 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 U.S. 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.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business or the business of our partners.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, ability to accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business or the business of our partners. The U.S. government has shut down several times, including for 35 days beginning in December 2018, and certain regulatory agencies, such as the FDA, have had to furlough nonessential FDA employees and stop routine activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If the timing of FDA's review and approval of new products is delayed, the timing of our or our partners' development process may be delayed, which could result in delayed milestone revenues and materially harm our operations or business.

The COVID-19 pandemic caused considerable disruptions at the FDA, namely with respect to diverting the FDA's attention and resources to facilitate vaccine development and ensure rapid review and emergency use authorization of vaccines intended to prevent COVID-19. Continued focus on COVID-19 countermeasures, and the reorganization and rededication of critical resources, both at the FDA and within similar governmental authorities across the world, may impact the ability of new products and services from being developed or commercialized in a timely manner.

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 U.S. 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 ("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 ("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 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 June 30, 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.

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.

Risks Related to Intellectual Property and Potential Disputes Thereof

If we are unable to obtain and maintain sufficient patent protection for our technology and products, 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 success depends, in large part, on our ability to obtain patent protection for product candidates and their formulations and uses. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in obtaining patents or what the scope of an issued patent may ultimately be. These risks and uncertainties include, but are not necessarily limited to, the following:

- patent applications may not result in any patents being issued, or the scope of issued patents may not extend to competitive product candidates and their formulations and uses developed or produced by others;
- our competitors, many of which have substantially greater resources than us or our partners, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that may limit or interfere with our abilities to make, use, and sell potential product candidates, file new patent applications, or may affect any pending patent applications that we may have;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

In addition, patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, 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 would be unsuccessful, resulting in a material adverse effect on our U.S. patent positions. 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 technologies 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. Third parties are often responsible for maintaining patent protection for our product candidates, at our and their expense. If that party fails to appropriately prosecute and maintain patent protection for a product candidate, our abilities to develop and commercialize products may be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Such a failure to properly protect intellectual property rights relating to any of our product candidates could have a material adverse effect on our financial condition and results of operations. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents.

We and our licensors also rely on trade secrets and proprietary know-how to protect product candidates. Although we have taken steps to protect our and their trade secrets and unpatented know-how, including entering into confidentiality and non-use agreements with third parties, and proprietary information and invention assignment agreements with employees, consultants and advisers, third parties may still come upon this same or similar information independently. Despite these efforts, any of these parties may also breach the agreements and may unintentionally or willfully disclose our or our licensors' proprietary information, including our trade secrets, and we may not be able to identify such breaches or obtain adequate remedies. 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 or our licensors' trade secrets were to be lawfully obtained or independently developed by a competitor, we and our licensors 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 or our licensors' trade secrets were to be disclosed to or independently developed by a competitor, our competitive positions would be harmed.

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 U.S. The patent situation outside the U.S. is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S., 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 U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. 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 U.S. 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 USPTO to determine priority of invention in the U.S. 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 U.S. 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 U.S. 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 U.S. 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 the 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 U.S. 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.

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.

We also may rely on the regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is generally 12 years from the date of marketing approval (depending on the nature of the specific product), there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect our business.

We depend on our licensors to maintain and enforce the intellectual property covering certain of our product candidates. We have limited, if any, control over the resources that our licensors can or will devote to securing, maintaining, and enforcing patents protecting 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 U.S. 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.

Protecting our proprietary rights is difficult and costly, and we may be unable 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, and an unfavorable outcome in any litigation would harm our business.

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 USPTO 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 U.S. patents may affect related patents in our global portfolio.

If we or our licensors are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends on our ability, and the abilities of any of our respective current or future collaborators, to develop, manufacture, market and sell product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our or our licensors' intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we or our licensors are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. 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 such licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we and our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. 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 USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain.

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 or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to, among other things:

- obtain additional licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign products or processes to avoid infringement, which may demand substantial funds, time and resources and which may result in inferior or less desirable processes and/or products;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross-licenses to our product candidates; and/or
- defend litigation or administrative proceedings which may be costly regardless of outcome, and which could result in a substantial diversion of financial and management resources.

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.

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

We are currently a party to license agreements with St. Jude, COH, Fred Hutch, University of California at Los Angeles ("UCLA"), 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 and/or consultants have wrongfully used or disclosed to us alleged trade secrets of their former employers or other clients.

As is common in the biopharmaceutical industry, we rely on employees and consultants to assist in the development of product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biopharmaceutical companies, including our competitors or potential competitors. We may become subject to claims related to whether these individuals have inadvertently or otherwise used, disclosed or misappropriated trade secrets or other proprietary information of their former employers or their former or current clients. Litigation may be necessary to defend against these claims. Even if we are successful in defending these claims, litigation could result in substantial costs and be a distraction to management and/or the employees or consultants that are implicated.

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.

We in-license intellectual property pertaining to certain product candidates from third parties. As such, 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 scope and interpretation of the representations and warranties made to us by our licensors, including those pertaining to the licensors' right title and interest in the licensed technology and the licensors' right to grant the licenses contemplated by such 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, including whether or not a given transaction constitutes a sublicense under such license agreement;
- 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;
- intellectual property rights resulting from the joint creation or use of intellectual property (including improvements made to licensed intellectual property) by our and our partners' 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 Relating to Our Control by Fortress

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 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 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 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 which 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.

General Risks

Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties' cybersecurity.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such confidential information in a manner that preserves its confidentiality and integrity. Furthermore, we have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk.

We are in the process of implementing our internal security and business continuity measures and developing our information technology infrastructure. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, data center facilities, lab equipment, and connection to the internet, face the risk of breakdown or other damage or interruption from service interruptions, system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), each of which could compromise our system infrastructure or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, and could result in financial, legal, business, and reputational harm to us.

In addition, the loss or corruption of, or other damage to, clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidates or any future drug candidates and to conduct clinical trials, and similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Sophisticated cyber attackers (including foreign adversaries engaged in industrial espionage) are skilled at adapting to existing security technology and developing new methods of gaining access to organizations' sensitive business data, which could result in the loss of proprietary information, including trade secrets. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

Any security breach or other event leading to the loss or damage to, or unauthorized access, use, alteration, disclosure, or dissemination of, personal information, including personal information regarding clinical trial subjects, contractors, directors, or employees, our intellectual property, proprietary business information, or other confidential or proprietary information, could directly harm our reputation, enable competitors to compete with us more effectively, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Each of the foregoing could result in significant legal and financial exposure and reputational damage that could adversely affect our business. Notifications and follow-up actions related to a security incident could impact our reputation or cause us to incur substantial costs, including legal and remediation costs, in connection with these measures and otherwise in connection with any actual or suspected security breach. We expect to incur significant costs in an effort

to detect and prevent security incidents and otherwise implement our internal security and business continuity measures, and actual, potential, or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third-party experts and consultants.

The costs related to significant security breaches or disruptions could be material, and our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored or processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Furthermore, if the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Major public health issues, and specifically the pandemic caused by the spread of COVID-19, could have an adverse impact on our financial condition and results of operations and other aspects of our business.

In December 2019, a novel strain of coronavirus, COVID-19, was first detected in Wuhan, China, and has since spread around the world. On March 11, 2020, the World Health Organization declared that the rapidly spreading COVID-19 outbreak had evolved into a pandemic. In response to the pandemic, many governments around the world are implementing a variety of measures to reduce the spread of COVID-19, including travel restrictions and bans, instructions to residents to practice social distancing, quarantine advisories, shelter-in-place orders and required closures of non-essential businesses.

The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. Although COVID-19 has not had a material adverse effect on our business to date, no assurance can be given that it will not in the future if the situation persists or worsens. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Should the coronavirus continue to spread, our business operations could be delayed or interrupted. For instance, our preclinical research and clinical trials have been affected in the past by the pandemic, and they may be affected again in the future should the pandemic return to previous levels of severity. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Infections and deaths related to the pandemic may disrupt the United States' and other countries' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA or other regulatory review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently rely on third parties, such as contract laboratories, CROs, medical institutions and clinical investigators to conduct these studies and clinical trials. If these third parties themselves are adversely impacted by restrictions resulting from the coronavirus outbreak, we will likely experience delays and/or realize additional costs. We also rely on third parties for the manufacture of our product candidates for preclinical and clinical testing. Disruptions to the global supply chain have impacted our and our third-party manufacturers' ability to obtain raw materials or other products necessary to manufacture and distribute our product candidates. As a result, our efforts to develop our products have been delayed, and recurrence of such disruptions could delay or disrupt our ability to obtain regulatory approvals for, and to commercialize, our product candidates. Finally, we have incurred considerable expense to warehouse sufficient supplies in anticipation of future unexpected supply chain disruptions, and we may need to increase these expenses as we increase our cell processing.

The potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, however it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and will depend on future developments that cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19, and the effectiveness of actions to contain and treat for COVID-19. Although, as of the date of this Quarterly Report on Form 10-Q, we do not expect any material impact on our long-term activity, we do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole, which could have a material adverse effect on our business, financial condition and results of operations and cash flows. The Company has experienced some delays in clinical trial accrual and in the availability and delivery of certain consumables and raw materials used in its laboratory and manufacturing operations due to the impact of COVID-19 on the global supply chain.

The ability of the Company's employees and consultants to work may be significantly impacted by the coronavirus.

The Company's employees and consultants are being affected by the COVID-19 pandemic. The Company may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the coronavirus. COVID-19 may also compromise the ability of independent contractors who perform consulting services for us to deliver services or deliverables in a satisfactory or timely manner. Further, our management team is focused on mitigating the adverse effects of the COVID-19 pandemic, which continues to require a large investment of time and resources, thereby diverting their attention from other priorities that existed prior to the outbreak of the pandemic. If these conditions worsen, or last for an extended period of time, the Company's ability to manage its business may be impaired, and operational risks, cybersecurity risks and other risks facing the Company even prior to the pandemic may be elevated.

Our growth is subject to economic and political conditions.

Our business is affected by global and local economic and political conditions as well as the state of the financial markets, inflation, recession, financial liquidity, currency volatility, growth, and policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our consolidated cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Political changes, including war or other conflicts, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location.

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, consultants, or third-party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of 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, consultants, or third-party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with cGMPs, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, comply with internal procedures, policies or agreements to which such employees, consultants or partners are subject, 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, consultant, or third-party 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, as well as civil and criminal liability. 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 civil and/or criminal sanctions.

We receive a large amount of proprietary information from potential or existing licensors of intellectual property and potential acquisition target companies, all pursuant to confidentiality agreements. The confidentiality and proprietary invention assignment agreements that we have in place with each of our employees and consultants prohibit the unauthorized disclosure of such information, but such employees or consultants may nonetheless disclose such information through negligence or willful misconduct. Any such unauthorized disclosures could subject us to monetary damages and/or injunctive or equitable relief. The notes, analyses and memoranda that we have generated based on such information are also valuable to our businesses, and the unauthorized disclosure or misappropriation of such materials by our employees and consultants could significantly harm our strategic initiatives – especially if such disclosures are made to our competitors.

We rely on information technology, and any internet or internal computer system failures, inadequacies, interruptions or compromises of our systems or the security of confidential information could damage our reputation and harm our business.

Although a significant portion of our business is conducted using traditional methods of contact and communications such as face-to-face meetings, our business is increasingly dependent on critical, complex and interdependent information technology systems, including internet-based systems, to support business processes as well as internal and external communications. We could experience system failures and degradations in the future. We cannot assure you that we will be able to prevent an extended and/or material system failure if any of the following or similar events occurs:

- human error;
- subsystem, component, or software failure;
- a power or telecommunications failure;
- hacker attacks, cyber-attacks, software viruses, security breaches, unauthorized access or intentional acts of vandalism; or
- terrorist acts or war.

If any of the foregoing events were to occur, our business operations could be disrupted in ways that would require the incurrence of substantial expenditures to remedy. 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 were to result in a loss of, or damage to, our data and applications, or inappropriate/unauthorized disclosure of confidential or proprietary information (including trade secrets), we could incur liability and our business and financial condition could be harmed.

The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits, or we could lose key data which could cause us to curtail or cease operations.

We are vulnerable to damage and/or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, health epidemics and pandemics, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our businesses could be seriously impaired. We have property, liability and business interruption insurance that may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects. Any of the aforementioned circumstances, including without limitation the resurgence of COVID-19 virus, may also impede our employees' and consultants' abilities to provide services in-person and/or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of "force majeure" clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such "force majeure" clauses, or the enforceability of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time-consuming.

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.

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.

Risks Relating to Sale of the Company's Manufacturing Facility

As discussed in the Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments, on May 18, 2023, the Company entered into an Asset Purchase Agreement, as amended on June 29, 2023, and July 28, 2023, and certain related agreements with uBriGene relating to the Transaction. The following discussion of risks relating to the Transaction uses certain capitalized terms that are defined in Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments, and the following discussion of risks should be read together with such discussion of the Transaction.

We may be unable to complete the Transaction as anticipated if the Committee on Foreign Investment in the United States ("CFIUS") determines to implement mitigating measures, including the potential divestment of some or all of the Transferred Assets by uBriGene; any such mitigating measures may limit our ability to realize the anticipated cost savings of the sale of the Facility and may have a material adverse effect on our financial condition.

Pursuant to the Amended Asset Purchase Agreement, uBriGene and the Company agreed to cause their respective affiliates to use their reasonable best efforts to obtain clearance for the Transaction from CFIUS, although obtaining such clearance was not a condition to closing the Transaction. In accordance with the Amended Asset Purchase Agreement, the Company and uBriGene submitted a joint notice to CFIUS.

Following an initial 45-day review period and subsequent 45-day investigation period, on November 13, 2023, CFIUS requested Mustang and uBriGene withdraw and re-file their joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction, and whether and to what extent mitigation of risk would be feasible. Upon CFIUS's request, Mustang and uBriGene submitted a request to withdraw and re-file their joint voluntary notice to CFIUS, and on November 13, 2023, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period commencing on November 14, 2023, which may be followed by a further 45-day investigation period.

At the completion of its review and, if applicable, investigation, if CFIUS determines there are no unresolved national security concerns, it will apprise the parties of its determination and conclude all action on the matter. Alternatively, CFIUS may identify and impose mitigation measures. Depending on the nature and severity of perceived national security risks identified during its investigation, CFIUS may, among other mitigation measures, require suspension of the Transaction,

require uBriGene to divest some or all of the Transferred Assets, forfeit contracts CFIUS deems to be sensitive, or require appointment of special compliance personnel or a proxy board consisting of U.S. persons. If CFIUS determines to require mitigating measures with respect to the Transaction, then uBriGene must comply with such measures although the Closing Date has already occurred.

If CFIUS requires uBriGene to divest the Transferred Assets, uBriGene is not required to sell the Transferred Assets back to us, and uBriGene could elect to sell the Transferred Assets to a third-party purchaser. If uBriGene sells the Transferred Assets to a third-party purchaser, the manufacturing and production of the Company's lead product candidate may be disrupted. Under the terms of the MSA, uBriGene will manufacture the Company's lead product candidate, including MB-106, upon the completion of the sale of the Facility. Pursuant to the Sub-Contracting CDMO Agreement, the Company will perform the manufacturing services to be performed by uBriGene under the MSA until the sale of the Facility is completed in exchange for an amount equal to the Company's operating costs associated with the Company CDMO Manufacturing Services.

If uBriGene sells the Transferred Assets to a third-party purchaser, there can be no assurance that such third-party purchaser will continue to contract with the Company for the Company CDMO Manufacturing Services. Any third-party purchaser of the Transferred Assets may not be willing to contract with the Company to provide Company CDMO Manufacturing Services. In addition, a third-party purchaser may not be able to comply with cGMP or similar regulatory requirements related to the production of our lead product candidates or otherwise may not be able to provide manufacturing services on quality and timeliness standards that are acceptable to us. In either such case, the manufacturing of the Company's lead product candidate may need to be transferred to an unknown CDMO and may be at risk of delays, disruptions or quality issues, any of which could significantly and adversely affect supplies of our lead product candidate and our ability to conduct clinical trials and receive regulatory approval.

If CFIUS requires uBriGene to divest the Transferred Assets and uBriGene sells the Transferred Assets back to the Company, the Company will incur significant costs associated with the repurchase and continued operation of the Facility. In addition to the payment of the repurchase price of the Facility, the Company will cease to be reimbursed by uBriGene for the Company CDMO Manufacturing Services and, as a result, will experience substantially increased expenses in connection with operating the Facility and manufacturing its lead product candidate, which could materially adversely affect the Company's results of operations, financial condition, prospects and ability to operate as a going concern.

The Company's ability to receive the Contingent Amount from uBriGene is subject to receipt of the Landlord's consent to the Proposed Lease Transfer and its ability to raise additional capital; if we do not receive such consent from the Landlord and/or are unable to raise the requisite amount of capital, we will not receive the full purchase price for the Transaction which may have a material adverse effect on our financial condition.

Pursuant to the Asset Purchase Agreement, in addition to the base purchase price paid to the Company upon closing of the Transaction, uBriGene will also pay a Contingent Amount to the Company as consideration of the Transaction once the Company (i) completes an issuance of equity securities in an amount equal to or greater than $10,000,000 (the "Contingent Capital Raise") and (ii) obtains the consent of the Landlord to the Proposed Lease Transfer. As of November 14, 2023, the Company had completed issuances of equity securities for proceeds totaling approximately $4.6 million following the Closing Date. If the Company is unable to close the full amount of the Contingent Capital Raise and/or does not receive the Landlord's consent to the Proposed Lease Transfer within two years from the Closing Date, uBriGene will no longer be obligated to pay the Contingent Amount to the Company.

If we do not receive the Contingent Amount our business, prospects, financial condition, results of operation and ability to operate as a going concern will be materially and adversely affected, and we may be required to implement further cost reduction strategies.

If the Landlord does not consent to the Proposed Lease Transfer and the lease of the Facility is not transferred to uBriGene within 120 days of the Closing Date, we may be obligated to negotiate the Company's repurchase of the Facility from uBriGene in good faith; if the Company negotiates and completes the Repurchase Transaction with respect to the Transferred Assets, it will incur significant costs associated with the continued operation of the Facility and the production of its lead product candidates, which will limit our ability to realize the anticipated cost savings of the Transaction and may have a material adverse effect on the Company's financial condition.

The Landlord has informed the Company that it will not consider the Proposed Lease Transfer until the Company receives a final determination letter regarding clearance for the Transaction from CFIUS and provides the Landlord with the Reaction Summary. The Landlord will have an additional thirty business days to make its determination on the Proposed Lease Transfer following its receipt of the CFIUS Letter and the Reaction Summary. Assuming CFIUS concludes its action with respect to the Transaction at the completion of the initial 45-day review period, and the Company and uBriGene deliver the CFIUS Letter and Reaction Summary to the landlord the following day, then the landlord would be expected to deliver its decision regarding the Proposed Lease Transfer by February 12, 2024. If CFIUS does not conclude its action with respect to the Transaction until the end of its 45-day review followed by a 45-day investigation, and the Company and uBriGene deliver the CFIUS letter and Reaction Summary to the landlord the following day, then the landlord would be expected to deliver its decision regarding the Proposed Lease Transfer by March 26, 2024.

There can be no assurance that the Landlord will consent to the Proposed Lease Transfer, regardless of CFIUS's final determination with respect to the Transaction. If the Landlord does not consent to the Proposed Lease Transfer, (i) uBriGene may provide the Company with the Repurchase Notice, obligating the Company to enter into good faith negotiations for the Repurchase Transaction, and (ii) the Company will not receive the Contingent Amount from uBriGene in connection with the Transaction.

Based on the expected timeline for CFIUS to complete its review and investigation of the Transaction, and the Landlord's stated timeline to make a determination with respect to the Proposed Lease Transfer, the Company anticipates that the Proposed Lease transfer will not be completed by November 25, 2023, which is the date falling 120 days after the Closing Date. As a result, it is expected that, commencing on November 26, 2023, and for so long as the lease has not been transferred, uBriGene may opt to deliver the Repurchase Notice to the Company, indicating its intention to enter into good faith negotiations to provide for the Company to repurchase the Transferred Assets, re-assume the transferred liabilities and resume all Transferred Operations. The repurchase price for the Repurchase Transaction is equal to the purchase price of the Transaction actually paid by uBriGene as of the repurchase date. Upon receipt of such notice, uBriGene and the Company have agreed to use their best commercial efforts to negotiate in good faith the terms of any such Repurchase Transaction.

uBriGene may decide to deliver the Repurchase Notice for a variety of reasons, including, if it determines it cannot effectively market its services as a CDMO on a sub-contracted basis through the Company, or if it decides for any other reason to sell the Transferred Assets. If uBriGene delivers the Repurchase Notice and the parties negotiate and complete the Repurchase Transaction, the Company will be unable to recover any of the expenses incurred in connection with the negotiation and execution of the Repurchase Transaction. In addition, the MSA and the Sub-Contracting CDMO Agreement terminate upon the earlier of (i) the closing of the Repurchase Transaction or (ii) 60 days after the delivery of the Repurchase Notice. Upon the termination of the MSA and the Sub-Contracting CDMO Agreement, the Company will experience significantly increased operating expenses in connection with the operation of the Facility and the manufacture of its lead product candidates which would materially adversely affect the Company's results of operations, financial condition, prospects and ability to operate as a going concern.

Any negotiations in connection with the Repurchase Transaction may also divert the attention of the management of the Company instead of enabling it to more fully pursue other opportunities that could be beneficial to the Company without realizing any of the benefits, and cost-savings, of having completed the Transaction as originally contemplated.

Despite their agreement to use their best commercial efforts to negotiate in good faith, the parties may be unable to successfully negotiate the Repurchase Transaction if uBriGene provides the Company with the Repurchase Notice, and the manufacture of the Company's lead product candidates may be disrupted or delayed.

Despite the parties' agreement to use their best commercial efforts to negotiate in good faith the terms of the Repurchase Transaction, if uBriGene provides the Company with the Repurchase Notice, there can be no assurances as to the outcome of these negotiations. If we are unable to complete such negotiations to our satisfaction or the satisfaction of uBriGene, our financial condition may be adversely affected. The MSA and the Sub-contracting CDMO Agreement terminate upon the earlier of (i) the closing of the Repurchase Transaction or (ii) 60 days after the delivery of the Repurchase Notice. If the parties are unable to successfully negotiate and close the Repurchase Transaction within 60 days of delivery of the Repurchase Notice, the Company will not have access to the Transferred Assets and may be unable to produce its lead product candidates, which could adversely impact the Company's future clinical trials.

The Landlord may object to the sale of the Transferred Assets to uBriGene and/or our performance under the Sub-Contracting CDMO Agreement and could initiate a lawsuit to enjoin our sale of the Transferred Assets to uBriGene or our performance under the Sub-Contracting CDMO Agreement, which could be expensive and time-consuming and may prevent us from realizing the intended benefits of the Transaction.

Although we believe we are entitled, under the terms of the lease of the Facility, to sell manufacturing equipment, operate as a CDMO and provide manufacturing services related to the Company's lead product candidate pursuant to terms of the Sub-Contracting CDMO Agreement, there can be no assurances that the Landlord will not object to the sale of the Transferred Assets to uBriGene and use of the Facility under the Sub-Contracting CDMO Agreement. The Landlord could file a lawsuit to enjoin the sale of the Transferred Assets or our performance under the Sub-Contracting CDMO Agreement.

Even if resolved in our favor, any such litigation (or actions preceding or in anticipation of litigation) relating to the sale of the Transferred Assets to uBriGene or the Sub-Contracting CDMO Agreement may cause us to incur significant expenses and could distract our management from their normal responsibilities. In addition, if we are unsuccessful in any such litigation, we may not be able to complete the Transaction, or we may be enjoined from performing under the Sub-Contracting CDMO Agreement, which could jeopardize the manufacturing and production of our lead product candidate and result in delays or quality issues that could adversely impact future clinical trials. Any such litigation could also significantly increase our operating losses and we may not have sufficient financial or other resources to conduct such litigation adequately.

If the members of the Joint Steering Committee are unable to agree on matters pertaining to the Company CDMO Manufacturing Services, the manufacture and supply of the Company's lead product candidate may be adversely impacted.

Pursuant to the Sub-Contracting CDMO Agreement, during the term of the Sub-Contracting CDMO Agreement, the Company and uBriGene have agreed to establish a joint steering committee comprising of two representatives from each of the Company and uBriGene (the "Joint Steering Committee"). The Joint Steering Committee will review, discuss and decide on operational matters relating to the Company CDMO Manufacturing Services to be performed by the Company.

If the Joint Steering Committee is unable to reach agreement and is deadlocked with regards to matters within its oversight of the Company CDMO Manufacturing Services, the Company may experience difficulties meeting quality standards and production timelines for its Company CDMO Manufacturing Services. If the Joint Steering Committee is deadlocked, the Company may incur additional costs and uncertainties until any such impasse is resolved, which may have an adverse effect on the Company's operations. Any clinical trial, regulatory approval or development progress could be significantly delayed or halted, or the deadlock could result in time-consuming litigation or arbitration and could have a negative impact on our business. Any of the above discussed scenarios could adversely affect the timing and extent of the development activities related to our lead product candidate, which could negatively impact our business.

In addition, pursuant to the Sub-Contracting Agreement, the Company has agreed to permit uBriGene to locate up to three of uBriGene's personnel at the Facility (each a "Person-in-Plant" and together, the "Persons-in-Plant") so as to participate in meetings of the Joint Steering Committee and allow for in-person feedback and decision-making regarding the Company

CDMO Manufacturing Services. The presence of the Persons-in-Plant at the Facility may distract our technical personnel from their normal responsibilities and ongoing business operations. Any production delays or disruptions or quality issues that result from such distraction could adversely affect our clinical trials and regulatory approvals.

If the sale of the Facility is fully consummated, we will rely on uBriGene for the manufacture of our lead product candidates, which may subject us to additional manufacturing risks, any of which could substantially increase our costs and limit the supply of our lead product candidates and any future products.

If we obtain a favorable determination from CFIUS and the Landlord approves the transfer of the lease, then the lease of the Facility and the Transferred Employees will transfer to uBriGene, the Sub-Contracting CDMO Agreement will terminate, and uBriGene will provide all manufacturing services related to the manufacture of the Company's lead product candidates, including MB-106, pursuant to the Manufacturing Services Agreement. As a result, if the sale of the Facility is fully consummated, the Company will rely entirely on uBriGene for the manufacture and production of its lead product candidates, which exposes the Company to risks to which it would not be subject if the Company manufactured its product candidates itself, including risks related to the reliance on third parties for the availability of drug product to use in our clinical trials and for regulatory compliance and quality assurance, the possibility of breach of the Manufacturing Services Agreement by uBriGene because of factors beyond our control (including a failure to manufacture our product candidates in accordance with our specifications) and the possibility of termination or nonrenewal of the Manufacturing Services Agreement by uBriGene, based on its own business priorities, at a time that is costly or damaging to us. Under this arrangement, the eventual success or commercial viability of our lead product candidate will depend in large part on uBriGene's performance under the Manufacturing Services Agreement.

The manufacture of our product candidates is complex, highly regulated and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. As a result, our reliance on uBriGene as a third-party manufacturer exposes us to the following risks:

- uBriGene has little to no experience with manufacturing our product candidates and, therefore may experience production delays, quality issues or require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates;
- uBriGene may be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical needs;
- uBriGene may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- uBriGene may not perform as agreed, may not devote sufficient resources to our product candidates, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by uBriGene in the manufacturing process for our product candidates;
- Raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- uBriGene may have unacceptable or inconsistent product quality success rate and yields; and
- uBriGene may experience supply chain difficulties or other business continuity issues beyond its control such as fires, floods, earthquakes, hurricanes, epidemics, quarantines, wars, civil unrest, strikes or other governmental action.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA or other regulatory authorities, result in higher costs or adversely impact development of our lead product candidate.

The Company may incur substantial expenses related to the Transaction and the completion of the sale of the Facility.

The Company may incur substantial expenses, in addition to the legal, financial advisory, accounting and other costs the Company has already incurred, in completing the Transaction and the sale of the Facility. While the Company has assumed that a certain level of expenses would be incurred, there are a number of factors beyond its control that could affect the

total amount or the timing of the expenses relating to the completion of the Transaction and the sale of the Facility. Many of the expenses that will be incurred, by their nature, are difficult to estimate accurately at the present time. As a result, the expenses associated with the Transaction could, particularly in the near term, reduce the savings that the Company expects to achieve from the reduction in expenses following the sale of the Facility and could impact the Company's business and operations. In addition, any significant diversion of our management's attention away from our ongoing business and day-to-day operations due to the pending completion of the sale of the Facility may adversely affect our financial condition and results of operations.

Certain key personnel may choose to depart the Company upon the completion of or shortly after the completion of the sale of the Facility, and any loss of key personnel may materially adversely affect the future business and operations of the Company and the Company's ability to realize the anticipated benefits of the Transaction.

The Company's ability to maintain its competitive position depends on the efforts and abilities of its senior executives and key employees. Finding suitable replacements for senior executives and key employees can be difficult, expensive and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. The risk of departure of such key personnel may be heightened in the event the Joint Steering Committee experiences any deadlock. If, despite efforts to retain key personnel at the Company, any key personnel depart or fail to continue employment as a result of the Transaction, the loss of the services of such personnel and their experience and knowledge could adversely affect the Company's business, results of operations, strategic relationships, financial condition and prospects and the successful ongoing operation of its business.

Our strategic pivot to focus on our lead product candidate, MB-106, and our disposal of non-core assets, including the Facility, may not result in the anticipated cost savings, could result in total costs and expenses that are greater than expected, could make it more difficult to retain qualified personnel and may significantly disrupt our operations, each of which could have a material adverse effect on our business.

In May of 2023, we conducted a review of our portfolio products to refine the strategy of our programs and the proper allocation of the Company's resources. In connection with this portfolio review, we (i) discontinued development of our MB-102 (CD123), MB-103 (HER2), MB-104 (CS1) and MB-105 (PSCA) programs and terminated the associated license agreements; (ii) reduced our workforce by approximately 14%; and (iii) entered into the Transaction with uBriGene regarding the sale of the Facility and further reduction of our workforce for a cumulative reduction of approximately 82%. The reprioritization of our portfolio products and the actions described above have been disruptive to our daily operating activities and resulted in a shift in focus of our business.

There can be no assurance that our divesture of these programs and assets, including the Facility, will be successful or that the cost savings realized from the Transaction and the other arrangements described above will result in sufficient savings for us to continue our business. We may not realize in full the anticipated benefits, savings and improvements in our reallocation of resources due to unforeseen difficulties, delays, disruptions or unexpected costs. The costs of disposing of the assets may exceed the cost savings we generate. Any cost-savings measures we implement, including further workforce reductions, may distract remaining employees from our business, cause unplanned employee attrition, reduce employee morale and productivity, disrupt our disclosure controls and procedures and internal control over financing reporting, yield other unanticipated consequences and damage our reputation.

There can be no assurance that our focus on MB-106 will be successful, result in advance of a proprietary drug product or yield any revenue in the future. The drug development process is expensive and can take many years to complete, and its outcome is inherently uncertain. We may suffer significant additional setbacks in focusing on our MB-106 program and may never become profitable. Any of these factors could have a material adverse effect on our business.

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

Not applicable.

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
2.1	Second Amendment to Asset Purchase Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc. (incorporated by reference to Exhibit 2.3 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on July 31, 2023).
3.1	Amended and Restated Certificate of Incorporation of Mustang Bio, Inc. (formerly Mustang Therapeutics, Inc.), dated July 26, 2016 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 1012G (file No. 000-5568) filed with SEC on July 28, 2016).
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated June 14, 2018 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 10-Q (file No. 001-38191) filed with SEC on August 13, 2018).
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated September 30, 2019 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-38191) filed with SEC on September 30, 2019).
3.4	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated December 4, 2020 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-38191) filed with SEC on December 4, 2020).
3.5	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated June 17, 2021 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-38191) filed with SEC on June 22, 2021).
3.6	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated July 5, 2022 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-38191) filed with SEC on July 7, 2022).
3.7	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated April 3, 2023 (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (file No. 001-38191) filed with SEC on April 3, 2023).
3.8	Amended and Restated Bylaws of Mustang Bio, Inc. (incorporated by reference to Exhibit 3.2 of the Registrant's Form 8-K (file No. 001-38191) filed with SEC on April 3, 2023).
10.1	Manufacturing Services Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on July 31, 2023).
10.2	Sub-Contracting Manufacturing Services Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on July 31, 2023).
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 Interim Chief Financial Officer (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 Interim Chief Financial Officer (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 September 30, 2023, formatted as Inline Extensible Business Reporting Language (iXBRL): (i) the Balance Sheets, (ii) the Unaudited Statements of Operations, (iii) the Unaudited Statement of Stockholders' Equity, (iv) the Unaudited Statements of Cash Flows, and (v) Notes to the Unaudited Financial Statements (filed herewith).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in exhibit 101)

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.

November 14, 2023

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

By: /s/ Eliot Lurier
Eliot Lurier
Interim Chief Financial Officer
(Principal Financial Officer)

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.

November 14, 2023

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, Eliot Lurier, Interim Chief Financial Officer (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.

November 14, 2023

By: /s/ Eliot Lurier
Eliot Lurier
Interim Chief Financial Officer
(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 September 30, 2023, 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.

November 14, 2023

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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eliot Lurier, Interim Chief Financial Officer (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.

November 14, 2023

By: /s/ Eliot Lurier
Eliot Lurier
Interim Chief Financial Officer
(Principal Financial Officer)