Table of Contents

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, 2026

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.)

95 Sawyer Road, Suite 110
Waltham, MA 02453
(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 3, 2026**
Class A Common Stock, $0.0001 par value	845,385
Common Stock, $0.0001 par value	6,738,693

MUSTANG BIO, INC.
QUARTERLY REPORT ON FORM 10-Q
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION		5
Item 1.	Unaudited Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3.	Quantitative and Qualitative Disclosures About Market Risks	23
Item 4.	Controls and Procedures	24
PART II. OTHER INFORMATION		24
Item 1.	Legal Proceedings	24
Item 1A.	Risk Factors	24
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	62
Item 3.	Defaults Upon Senior Securities	62
Item 4.	Mine Safety Disclosures	62
Item 5.	Other Information	62
Item 6.	Exhibits	63
SIGNATURES		64

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 Part II, Item 1A of this Quarterly Report on Form 10-Q (this "Form 10-Q"), and the other reports and documents that we have filed with the Securities and Exchange Commission.

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.
- We may in the future need to raise additional funding, which may not be available on acceptable terms to us, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our potential product candidates.
- 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 short operating history makes it difficult to evaluate our business and prospects.
- Our success is contingent on raising additional capital, and our efforts to do so 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, if approved, 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 engineered T cell ("CAR T") technology and oncolytic virus product candidates.

Risks Inherent in Drug Development and Commercialization

- Preclinical and clinical development are both highly speculative and carry 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 product candidates, if approved.
- If a product candidate demonstrates adverse events, 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 product candidates' target indications, which could limit our product candidates' commercial opportunity and profitability, if approved.
- If our product candidates, if approved, are not broadly accepted by the healthcare community, the revenues from any such product will likely be limited.
- Any successful products' liability claims related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of any such product candidates, if approved.

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 Industry 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 therefore be impaired.
- We depend on our licensors to maintain and enforce the intellectual property rights 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' intellectual property rights against third-party infringers.
- 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.
- We share certain directors with Fortress, which could create conflicts of interest between us and Fortress.

General Risks and Risks Associated with Ownership of Our Common Stock

- We may become involved in securities class action litigation that could divert management's attention and harm our business.
- The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future.
- 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 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.
- 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 may not be able to manage our business effectively if we are unable to attract and retain key personnel.
- Our growth is subject to economic and geopolitical conditions.
- Our business could be adversely affected by the effects of health pandemics or epidemics, which could cause significant disruptions in our operations.
- 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 currently not in compliance with certain continued listing rules of The Nasdaq Stock Market LLC ("Nasdaq"), and if we are unable to meet the continued listing requirements and/or regain compliance with such rules, our common stock may be subject to delisting from the Nasdaq Capital Market. The delisting of our securities from Nasdaq may decrease the market liquidity and market price of our common stock.

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, 2026	December 31, 2025
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 14,276	$ 17,266
Other receivables	217	217
Prepaid expenses and other current assets	190	110
Total Assets	**$ 14,683**	**$ 17,593**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,416	$ 5,411
Payables and accrued expenses - related party	2,531	2,503
Total current liabilities	7,947	7,914
Deferred income	150	150
Total Liabilities	**8,097**	**8,064**
Commitments and Contingencies (Note 8)		
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, 2026 and December 31, 2025, respectively	—	—
Common stock ($0.0001 par value), 200,000,000 shares authorized as of September 30, 2026 and December 31, 2025, respectively		
Class A common shares, 845,385 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	—
Common shares, 6,738,693 and 6,453,701 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	1	1
Common stock issuable, zero and 278,385 shares as of September 30, 2026 and December 31, 2025, respectively	—	273
Additional paid-in capital	408,220	407,899
Accumulated deficit	(401,635)	(398,644)
Total Stockholders' Equity	**6,586**	**9,529**
Total Liabilities and Stockholders' Equity	**$ 14,683**	**$ 17,593**

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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 208	$ (333)	$ 610	$ (1,199)
General and administrative	850	957	2,676	2,961
Total operating expenses	1,058	624	3,286	1,762
Loss from operations	(1,058)	(624)	(3,286)	(1,762)
Other income:				
Interest income, net	94	156	295	379
Total other income	94	156	295	379
Net Loss	**$ (964)**	**$ (468)**	**$ (2,991)**	**$ (1,383)**
Net loss per Class A common and common shares outstanding, basic and diluted	$ (0.14)	$ (0.07)	$ (0.44)	$ (0.32)
Weighted average number of Class A common and common shares outstanding, basic and diluted	6,735,810	6,241,658	6,732,900	4,387,035

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

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

	For the Three Months Ended September 30, 2026									
	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, 2026	**250,000**	**$ —**	**845,385**	**$ —**	**6,732,120**	**$ 1**	**$ —**	**$ 408,215**	**$ (400,671)**	**$ 7,545**
Issuance of common shares under ESPP	—	—	—	—	6,571	—	—	3	—	3
Stock-based compensation expense	—	—	—	—	2	—	—	2	—	2
Net loss	—	—	—	—	—	—	—	—	(964)	(964)
Balances at September 30, 2026	**250,000**	**$ —**	**845,385**	**$ —**	**6,738,693**	**$ 1**	**$ —**	**$ 408,220**	**$ (401,635)**	**$ 6,586**

	For the Nine Months Ended September 30, 2026									
	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, 2025	**250,000**	**$ —**	**845,385**	**$ —**	**6,453,701**	**$ 1**	**$ 273**	**$ 407,899**	**$ (398,644)**	**$ 9,529**
Issuance of common shares - Annual Stock Dividend	—	—	—	—	278,385	—	(273)	273	—	—
Issuance of common shares under ESPP	—	—	—	—	6,571	—	—	3	—	3
Stock-based compensation expense	—	—	—	—	36	—	—	45	—	45
Net loss	—	—	—	—	—	—	—	—	(2,991)	(2,991)
Balances at September 30, 2026	**250,000**	**$ —**	**845,385**	**$ —**	**6,738,693**	**$ 1**	**$ —**	**$ 408,220**	**$ (401,635)**	**$ 6,586**

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

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

	For the Three Months Ended September 30, 2025									
	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, 2025	**250,000**	**$ —**	**845,385**	**$ —**	**3,532,452**	**$ —**	**$ —**	**$ 400,530**	**$ (397,638)**	**$ 2,892**
Issuance of common shares, equity fee on At-the-Market and equity offerings	—	—	—	—	59,334	—	—	179	—	179
Issuance of common shares under ESPP	—	—	—	—	100	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	8	—	—	23	—	23
Exercise of warrants	—	—	—	—	2,861,807	1	—	7,144	—	7,145
Net loss	—	—	—	—	—	—	—	—	(468)	(468)
Balances at September 30, 2025	**250,000**	**$ —**	**845,385**	**$ —**	**6,453,701**	**$ 1**	**$ —**	**$ 407,876**	**$ (398,106)**	**$ 9,771**

	For the Nine Months Ended September 30, 2025									
	Class A Preferred Stock		Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2024	**250,000**	**$ —**	**845,385**	**$ —**	**985,972**	**$ 5**	**$ 611**	**$ 392,234**	**$ (396,723)**	**$ (3,873)**
Issuance of common shares - Annual Stock Dividend	—	—	—	—	69,046	—	(611)	611	—	—
Issuance of common shares, equity fee on At-the-Market and equity offerings	—	—	—	—	127,140	—	—	395	—	395
Issuance of common shares, net of offering costs - Equity Offerings	—	—	—	—	495,000	—	—	6,782	—	6,782
Issuance of common shares, net of offering costs - At-the-Market Offering	—	—	—	—	54,440	—	—	599	—	599
Issuance of common shares under ESPP	—	—	—	—	200	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	68	—	—	106	—	106
Abeyance shares released	—	—	—	—	185,880	—	—	—	—	—
Exercise of warrants	—	—	—	—	4,536,162	1	—	7,144	—	7,145
Reverse Split (1-for-50) adjustment	—	—	—	—	(207)	(5)	—	5	—	—
Net loss	—	—	—	—	—	—	—	—	(1,383)	(1,383)
Balances at September 30, 2025	**250,000**	**$ —**	**845,385**	**$ —**	**6,453,701**	**$ 1**	**$ —**	**$ 407,876**	**$ (398,106)**	**$ 9,771**

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,	
	2026	**2025**
Cash Flows from Operating Activities:		
Net loss	$ (2,991)	$ (1,383)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common shares - equity fee on equity offerings to Fortress Biotech	—	395
Stock-based compensation expenses	45	106
Depreciation expense	—	34
Amortization of operating lease right-of-use assets	—	7
Settlement of payables	(109)	(1,373)
Gain on lease termination	—	(394)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	62	40
Other receivables	—	435
Accounts payable and accrued expenses	114	(1,202)
Payable and accrued expenses - related party	28	(138)
Lease liabilities	—	(73)
Net cash used in operating activities	(2,851)	(3,546)
Cash Flows from Investing Activities:		
Proceeds from the sale of property and equipment	—	1,165
Net cash from investing activities	—	1,165
Cash Flows from Financing Activities:		
Proceeds from issuance of common shares, net of offering costs - equity offering	—	6,782
Proceeds from issuance of common shares, net of offering costs - At-the-Market offering	(142)	599
Proceeds from warrant exercises	—	7,145
Proceeds from issuance of common shares under ESPP	3	—
Net cash (used in) provided by financing activities	(139)	14,526
Net change in cash and cash equivalents	(2,990)	12,145
Cash and cash equivalents, beginning of the period	17,266	6,839
Cash and cash equivalents, end of the period	**$ 14,276**	**$ 18,984**
Supplemental disclosure of noncash activities:		
Issuance of common shares - Founders Agreement and equity fee to Fortress	$ 273	$ 611

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 medical breakthroughs into potential cures for difficult-to-treat cancers. 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").

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. To date, the Company has funded its operations primarily with the proceeds from offerings of equity securities. As of September 30, 2026, the Company had an accumulated deficit of $401.6 million, and cash and cash equivalents of $14.3 million.

The Company expects to incur substantial expenses for the foreseeable future relating to research, development and commercialization of our potential products and may never achieve profitability. The Company does not have any products that are approved for commercial sale and, therefore, it does not expect to generate any revenues from product sales in the foreseeable future, if ever. Additionally, there can be no assurance that it will be successful in securing additional resources when needed, on terms acceptable to the Company, if at all.

The Company is currently not in compliance with certain standards for continued listing on the Nasdaq Capital Market, namely, Nasdaq Listing Rule 5550(a)(2), which sets forth the minimum bid price requirement. There can be no assurance that the Company will be able to regain compliance with the continued listing rules of The Nasdaq Stock Market LLC ("Nasdaq"), which could adversely affect the value and liquidity of its common stock.

The Company expects to continue generating operating losses and negative operating cash flows as it develops its products to potential approval. As of September 30, 2026, the Company believes it has sufficient cash and cash equivalents to fund its operations for at least twelve months from the issuance date of these financial statements.

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 under the Securities Exchange Act of 1934, as amended (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. 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, 2025, which were included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 19, 2026 (the "2025 Form 10-K"). 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.

Segment Reporting

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment, which reflects the research and development of potential cures for difficult-to-treat cancers. The Company's chief operating decision maker ("CODM") is its chief executive officer.

The CODM assesses performance and decides how to allocate resources based on net loss, which is reported on the Unaudited Statements of Operations. The CODM uses net loss to assess performance, make operating decisions, allocate resources, and plan and forecast for future periods. The measure of segment assets is reported on the unaudited balance sheet as total assets. The accounting policies of the segment are the same as those described in this Note 2.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies previously disclosed in the 2025 Form 10-K.

Recently Issued Accounting Standards

As of September 30, 2026, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2025 Form 10-K that affect the Company's present or future results of operations, overall financial condition, liquidity, or disclosures upon adoption.

Note 3 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

With respect to the Company's Management Services Agreement (the "Management Services Agreement") with Fortress for the three and nine months ended September 30, 2026 and 2025, expenses related to the Management Services Agreement 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, 2026 and 2025, the Company recorded expense of $0.1 million and $0.1 million, respectively, related to the Management Services Agreement. For the nine months ended September 30, 2026 and 2025, the Company recorded expense of $0.4 million and $0.4 million, respectively, related to the Management Services 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 the Company's common stock equal to two and one-half percent (2.5%) of the gross amount of any equity or debt financing.

For the three and nine months ended September 30, 2026, the Company did not have any equity or debt financing activities and therefore, did not issue any shares to Fortress under these agreements.

For the three months ended September 30, 2025, the Company did not have any equity or debt financing activities and therefore, did not issue any shares to Fortress. For the nine months ended September 30, 2025, the Company issued 67,806 shares to Fortress in connection with equity financings and recorded expense of approximately $0.2 million in general and administrative expenses related to these shares.

Annual Stock Dividend

Pursuant to the Company's Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), the Company issued 278,385 shares of common stock to Fortress as the Annual Stock Dividend on January 1, 2026 (as such term is defined in the Certificate of Incorporation), representing 2.5% of the fully-diluted outstanding equity of the Company on December 31, 2025. The value of these shares was recorded as Common stock issuable – Annual Stock Dividend to Fortress in the Statement of Stockholders' Equity (Deficit) at December 31, 2025. The Company recorded an expense of approximately $0.3 million in research and development expenses related to these issuable shares during the year ended December 31, 2025.

Payables and Accrued Expenses Related Party

In the normal course of business Fortress pays certain expenses on behalf of the Company. Such expenses are recorded as payables and accrued expenses - related party and are recorded at the invoiced amount and reimbursed to Fortress in the normal course of business. The Company believes that the difference, if any, between the amounts invoiced and the amounts that would have been incurred if the Company operated as an unaffiliated entity is not material.

Note 4 - Accounts Payable and Accrued Expenses

At September 30, 2026, and December 31, 2025, accounts payable and accrued expenses consisted of the following:

($ in thousands)	September 30, 2026	December 31, 2025
Accounts payable	$ 3,122	$ 3,510
Accrued research and development	309	250
Accrued compensation	429	24
Other[(1)]	1,556	1,627
Total accounts payable and accrued expenses	$ 5,416	$ 5,411

(1) Includes approximately $1.4 million of accrued consideration, including approximately $81,000 of accrued interest, related to the repurchase of assets from uBriGene (Boston) Biosciences, Inc. (“uBriGene”) in 2024. The asset repurchase consisted of purchase consideration of an upfront payment of $0.1 million, and a deferred amount of approximately $1.3 million due twelve months after closing; however, the Company can elect to delay its payment obligation for the deferred amount for additional 6-month periods, upon written notice to uBriGene, if the Company’s net assets are below $20 million. Additionally, beginning in June 2025, the deferred amount began accruing interest at a rate of 5% per annum. In June 2026, the Company’s net assets were below $20 million, and it elected to delay the payment.

Note 5 - Stockholders’ Equity

Registration Statement on Form S-3

On May 31, 2024, the Company filed a shelf registration statement on Form S-3 (File No. 333-279891) (the “2024 S-3”), which was declared effective on June 12, 2024. Under the 2024 S-3, the Company may sell up to a total of $40.0 million of its securities. As of September 30, 2026, approximately $34.2 million of the 2024 S-3 remains available for sales of securities.

As of the filing of this Quarterly Report on Form 10-Q (this “Form 10-Q”), the Company is subject to the General Instruction I.B.6 to Form S-3, known as the “baby shelf rules,” which limits the amount of securities it can sell under its registration statement on Form S-3 in any 12-month period.

February 2025 Equity Offering

On February 5, 2025, the Company commenced a best efforts public offering (the "February 2025 Equity Offering") of an aggregate of (i) 495,000 shares (the "Shares") of its common stock, par value $0.0001 per share, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 2,162,807 shares of common stock, (iii) Series C-1 warrants (the "Series C-1 Warrants") to purchase up to an aggregate of 2,657,807 shares of common stock (the "Series C-1 Warrant Shares"), and (iv) Series C-2 warrants (the "Series C-2 Warrants," and together with the Series C-1 Warrants, the "Warrants") to purchase up to an aggregate of 2,657,807 shares of common stock (the "Series C-2 Warrant Shares," and together with the Series C-1 Warrant Shares, the "Warrant Shares"). Each Share or Pre-Funded Warrant was sold together with one Series C-1 Warrant to purchase one share of common stock and one Series C-2 Warrant to purchase one share of common stock. The combined public offering price for each Share and accompanying Warrants was $3.01, and the combined public offering price for each Pre-Funded Warrant and accompanying Warrant was $3.0099. The Pre-Funded Warrants had an exercise price of $0.0001 per share, were exercisable immediately upon issuance and expired when exercised in full. Each Warrant has an exercise price of $3.01 per share and became exercisable beginning on the effective date of stockholder approval of the issuance of the Warrant Shares (the "Warrant Stockholder Approval"), which was obtained on March 23, 2025. The Series C-1 Warrants expire five years from the Warrant Stockholder Approval and the Series C-2 Warrants expire twenty-four months from the Warrant Stockholder Approval.

The net proceeds of the February 2025 Equity Offering, after deducting the fees and expenses of the Placement Agent (as defined below), described in more detail below, and other offering expenses payable by the Company, but excluding the net proceeds, if any, from the exercise of the Warrants, were approximately $6.8 million. The February 2025 Equity Offering closed on February 10, 2025.

Pursuant to an Engagement Letter (the "Engagement Letter") with H.C. Wainwright & Co., LLC ("Wainwright" or the "Placement Agent"), the Company agreed to pay the Placement Agent in connection with the February 2025 Equity Offering (i) a cash fee equal to 7.0% of the aggregate gross proceeds raised in the February 2025 Equity Offering, (ii) a management fee equal to 1.0% of the aggregate gross proceeds raised in the February 2025 Equity Offering, (iii) up to $100,000 for fees and expenses of the Placement Agent's counsel and other out of pocket expenses, (iv) a non-accountable expense allowance of $25,000, (v) up to $3,500 for road show expenses, and (vi) $15,950 for the clearing expenses.

Also pursuant to the Engagement Letter, the Company, in connection with the February 2025 Equity Offering, agreed to issue to the Placement Agent or its designees warrants (the "Placement Agent Warrants") to purchase up to an aggregate of 159,468 shares of common stock (which represented 6.0% of the Shares and Pre-Funded Warrants sold in the February 2025 Equity Offering). The Placement Agent Warrants became exercisable beginning on the effective date of the Warrant Stockholder Approval, have an exercise price of $3.7625 (125% of the combined public offering price per share of common stock and accompanying Warrants) and will terminate on the five-year anniversary of commencement of sales in the February 2025 Equity Offering.

At-the-Market Offering

On May 31, 2024, the Company entered into an At-the-Market Offering Agreement (the "ATM Agreement") with Wainwright (the "Manager") under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock through or to the Manager pursuant to the 2024 S-3. Under the ATM Agreement, the Company pays the Manager a commission of 3.0% of the gross proceeds from the sales of any shares of common stock. The Company will also reimburse the Manager for certain expenses incurred in connection with the ATM Agreement. The Company and the Manager may each terminate the ATM Agreement at any time upon specified prior written notice.

During the nine months ended September 30, 2026, the Company did not issue any shares in connection with the ATM Agreement. During the nine months ended September 30, 2025, the Company issued approximately 54,000 shares of common stock at an average price of $11.55 per common share for gross proceeds of $0.6 million under the ATM Agreement. In connection with these sales, the Company paid aggregate fees of approximately $27,000.

Warrants

A summary of warrant activities for the nine months ended September 30, 2026, is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2025	4,678,646	$ 6.93	3.37
Expired	(675,104)	12.68	—
Outstanding as of September 30, 2026	4,003,542	$ 5.96	3.16

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

Equity Incentive Plan

The Company has in effect the Mustang Bio, Inc. 2016 Incentive Plan (the "Incentive Plan"). The Incentive Plan was adopted in 2016 by the Company's stockholders and the compensation committee of the Company's board of directors (the "Board") and is authorized to grant stock-based awards to directors, officers, employees and consultants. The Incentive Plan initially authorized grants to issue up to 2,666 shares of authorized but unissued common stock and had an initial term of 10 years. The Incentive Plan stipulates, however, that, in the event of any stockholder-approved amendment that increases the number of shares subject to the Incentive Plan, the expiration date of the Incentive Plan extends until the tenth anniversary of such approval. In June 2018, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 4,000 shares, for a total of 6,666 shares. In June 2021, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 4,000 shares, for a total of 10,666 shares. In June 2022, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 4,000 shares, for a total of 14,666 shares. In December 2025, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares of common stock issuable by 2,500,000 shares, for a total of 2,514,666 shares of common stock.

As of September 30, 2026, 2,506,958 shares were available for future issuance under the Incentive Plan.

Stock Options

The following table summarizes stock option activities for the nine months ended September 30, 2026:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding at December 31, 2025	1,521	$ 4,297.50	1.31
Outstanding at September 30, 2026	1,521	$ 4,297.50	0.56
Options vested and exercisable at September 30, 2026	951	$ 4,297.50	0.56

As of September 30, 2026, the Company had no unrecognized stock-based compensation expense related to options. The Company accounts for forfeited awards as they occur.

Restricted Stock

The following table summarizes restricted stock award activities for the nine months ended September 30, 2026:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2025	720	$ 345.00
Vested	(720)	345.00
Nonvested at September 30, 2026	—	$ —

As of September 30, 2026, the Company had no unrecognized stock-based compensation expense related to restricted stock.

Restricted Stock Units

Certain employees and consultants have been awarded restricted stock units with time-based vesting. The following table summarizes restricted stock units activity for the nine months ended September 30, 2026:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2025	96	$ 310.81
Vested	(63)	355.60
Nonvested at September 30, 2026	33	$ 225.29

As of September 30, 2026, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately $1,000, which is expected to be recognized over the remaining weighted average vesting period of approximately one year.

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2026	2025	2026	2025
General and administrative	$ 2	$ 22	$ 45	$ 116
Research and development [1]	—	1	—	(10)
Total stock-based compensation expense	$ 2	$ 23	$ 45	$ 106

[1] Credit reflects the forfeitures of restricted stock units and the reversal of previously incurred stock-based compensation expense.

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.

As of September 30, 2026, 9,333 shares have been purchased, and 250,000 shares are available for future sale under the Company's Employee Stock Purchase Plan.

Note 6 – Net Loss per Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding, including prefunded warrants, during the period, without consideration of potential dilutive securities. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. The Company has generated a net loss for all periods presented; therefore, diluted net loss per share is the same as basic net loss per share, since the inclusion of potentially dilutive securities 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,	
	2026	2025
Warrants	4,003,542	4,678,646
Options	1,521	1,521
Class A preferred shares [1]	333	333
Unvested restricted stock awards	—	720
Unvested restricted stock units	33	96
Total	4,005,429	4,681,316

[1] Class A preferred shares are reflected on an as-if converted basis.

The Company considers Class A common stock and Class A preferred stock to be additional classes of common stock for the purpose of calculating net loss per share, as they do not have preferential rights when compared to the Company's common stock, and therefore losses are allocated to these additional classes using the two-class method. The two-class method is an earnings allocation formula that treats participating securities as having rights that would otherwise have been available to common stockholders. Earnings allocated to the Class A preferred stock and Class A common stock are not material for the three and nine months ended September 30, 2026 and 2025. At September 30, 2026, the Class A common stock and Class A preferred stock have rights to convert to a total of 1,460 common shares.

Note 7 – 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.

Note 8 – Commitments and Contingencies

Indemnification

In accordance with its Certificate of Incorporation, amended and restated 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

In February 2025, the Company entered into the First Amendment to the Lease Agreement with WCS – 377 Plantation Street, Inc., pursuant to which the Company's lease of its Plantation Street Facility was terminated. Following the termination of the lease, the Company is no longer party to any leases for office space or equipment. Upon termination of the lease, the Company wrote off the remaining right of use assets, operating lease liabilities, and associated leasehold improvements and recorded a net gain of approximately $0.4 million in research and development expenses in the Unaudited Statements of Operations.

Upon termination of the lease, the Company moved its headquarters to 95 Sawyer Road, Suite 110, Waltham, MA, which is office space leased by Fortress. Fortress allocates a small portion of its rent and office related costs to the Company on a monthly basis which is recorded in general and administrative expenses in the Unaudited Statements of Operations. During the three months ended September 30, 2026, and 2025, the Company recorded approximately $12,000 and $15,000, respectively, of rent expense allocated from Fortress. During the nine months ended September 30, 2026, and 2025, the Company recorded approximately $37,000 and $45,000, respectively, of rent expense allocated from Fortress.

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

Special Cautionary Note Regarding 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 generally accepted accounting principles in the United States of America ("GAAP"). The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 timing of and our ability to make regulatory filings such as Investigational New Drug ("IND") applications 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 Part II, Item 1A "Risk Factors" herein.

Overview

We are a clinical-stage biopharmaceutical company focused on translating today's medical breakthroughs into potential cures for difficult-to-treat cancers. 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 on novel therapies for solid tumors. For these therapies we have partnered with world class research institutions, including the City of Hope National Medical Center ("COH" or "City of Hope"), and Nationwide Children's Hospital ("Nationwide").

We expect to incur substantial expenses for the foreseeable future relating to research, development and commercialization of our potential products and may never achieve profitability. We do not have any products that are approved for commercial sale and, therefore, we do not expect to generate any revenues from product sales in the foreseeable future, if ever. Additionally, there can be no assurance that we will be successful in securing additional resources when needed, on terms acceptable to us, if at all.

Development Pipeline

Our pipeline of anti-cancer therapies is being developed under exclusive licenses from two world class research institutions. Our strategy is to license these technologies, support preclinical and clinical research activities by our partners and develop these product candidates through to potential approval.

In partnership with COH, we are developing CAR T therapy for solid tumors targeting IL13Rα2 (MB-101). In addition, we have partnered with Nationwide for a herpes simplex virus type 1 ("HSV-1") oncolytic virus (MB-108) in order to enhance the activity of MB-101 for the treatment of patients with high-grade malignant brain tumors. The Phase 1 clinical trial sponsored by COH for MB-101 (ClinicalTrials.gov Identifier: NCT02208362) has completed the treatment phase and patients continue to be assessed for long-term safety. A Phase 1 clinical trial sponsored by the University of Alabama at Birmingham ("UAB") for MB-108 (ClinicalTrials.gov Identifier: NCT03657576) has also completed the treatment phase and patients continue to be assessed for long-term safety. In October 2023, we announced that the FDA accepted our IND application for the combination of MB-101 and MB-108 – which is referred to as MB-109 – for the treatment of patients with IL13Rα2+ relapsed or refractory glioblastoma ("GBM") and high-grade astrocytoma. We are exploring with COH and Nationwide the possibility of initiating the MB-109 clinical trial for GBM and high-grade astrocytoma as an investigator-sponsored single-institution study at COH in the first quarter of 2027.

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

On November 7, 2024, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-108, an HSV-1 oncolytic virus, for the treatment of malignant glioma. On July 7, 2025, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-101, IL13Ra2-targeted CAR T-cells, for the treatment of recurrent diffuse and anaplastic astrocytoma (astrocytomas) and glioblastoma. The Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials upon approval and prescription drug user fee waivers. If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in which it has Orphan Drug Designation, which is independent from intellectual property protection.

We are currently exploring with COH and Nationwide the possibility of conducting an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13Rα2+ recurrent GBM and high-grade astrocytoma with MB-109 that could potentially be initiated in the first quarter of 2027. Because cell processing for MB-101 reverted back to COH after the termination of the lease for the cell processing center – where the product continues to be manufactured today for other investigator-sponsored clinical trials being conducted by COH in malignant brain tumors (ClinicalTrials.gov Identifiers: NCT04003649, NCT04661384, NCT04510051) – we believe that it is reasonable to assume that the FDA will not require a lead-in cohort, wherein a cohort of patients would have to be treated with MB-101 alone prior to treatment of subsequent cohorts with the combination of MB-108 followed by MB-101. Should this, indeed, be the case, the first patient enrolled will receive combination therapy, which will represent a considerable savings of time and money – as well as afford the potential benefit of both therapies to every patient treated on study.

In collaboration with COH, Nationwide, and UAB, we are currently in discussion with potential vendors for stability testing of clinical material related to MB-108 for the Phase 1 trial at COH. Based on current timelines, we expect to complete the testing in advance of a potential IND allowance for COH's IND submission in the first quarter of 2027, followed by trial initiation.

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

The amount of securities we are able to sell pursuant to a registration statement on Form S-3 is limited due to General Instruction I.B.6 of Form S-3. See "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

Recent Developments

Non-Compliance with Nasdaq Continued Listing Requirements

On April 15, 2026, we received a notice (the "Letter") from the Listing Qualifications Department (the "Staff") of Nasdaq indicating that the bid price of our common stock had closed below $1.00 for 30 consecutive business days and, as a result, we were not in compliance with Nasdaq Listing Rule 5550(a)(2), which sets forth the minimum bid price requirement for continued listing on the Nasdaq Capital Market (the "Bid Price Requirement"). The Letter had no immediate effect on the listing of the Company's common stock on Nasdaq.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were afforded an initial 180-calendar day grace period, or until October 12, 2026, to regain compliance with the Bid Price Requirement. We were unable to demonstrate compliance with the Bid Price Requirement by that date. However, we submitted a request for an additional 180-calendar day grace period based upon (i) our belief that, as of October 12, 2026, we satisfied the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market, except for the Bid Price Requirement, and (ii) our written notice to Nasdaq of our intention to cure the deficiency during the second grace period by effecting a reverse stock split, if necessary.

On October 13, 2026, we received a letter from the Staff granting our request for an additional 180-calendar day period, or until April 12, 2027, to regain compliance with the Bid Price Requirement. Compliance can be achieved by evidencing a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days (but generally not more than 20 consecutive business days) during the second 180-calendar day grace period. In the event we do not regain compliance by the end of the second grace period, the Staff will provide written notification that our common stock will be delisted. At that time, we may appeal the Staff's determination to the Nasdaq Hearings Panel, although an appeal would not pause any suspension of trading.

We intend to closely monitor the closing bid price of our common stock and to take all reasonable measures available to regain compliance under the Nasdaq Listing Rules and remain listed on Nasdaq, including effecting a reverse stock split, if necessary. However, there can be no assurance that we will ultimately regain compliance with all applicable requirements for continued listing.

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 GAAP. 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 Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2025 (the "2025 Form 10-K"). There were no material changes in our critical accounting estimates or accounting policies from December 31, 2025.

Accounting Pronouncements

During the nine months ended September 30, 2026, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2025 Form 10-K that are expected to materially affect our present or future financial statements.

Smaller Reporting Company Status

We are a "smaller reporting company," within the meaning of federal securities laws, because 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 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, 2026 and 2025

($ in thousands)	For the three months ended September 30, 2026	2025	Change $	Change %
Operating expenses:				
Research and development	$ 208	$ (333)	$ 541	(162)%
General and administrative	850	957	(107)	(11)%
Total operating expenses	1,058	624	434	70 %
Loss from operations	(1,058)	(624)	(434)	70 %
Other income				
Interest income, net	94	156	(62)	(40)%
Total other income	94	156	(62)	(40)%
Net Loss	**$ (964)**	**$ (468)**	**$ (496)**	**106 %**

Research and Development Expenses

For the three months ended September 30, 2026 and 2025, research and development expenses were approximately $0.2 million and $(0.3) million, respectively. The increase of approximately $0.5 million is primarily attributed to $0.5 million of non-repeat savings recognized from the settlement of aged payables in the third quarter of 2025.

We expect our research and development costs to increase with the initiation of the MB-109 investigator-sponsored study at COH.

General and Administrative Expenses

For the three months ended September 30, 2026, and 2025, general and administrative expenses were $0.9 million and $1.0 million, respectively. The decrease of approximately $0.1 million is primarily attributed to a $0.2 million decrease in the equity fee to Fortress related to financing activity in the prior year, partially offset by a $0.1 million increase in personnel-related expenses.

Total Other Income

For the three months ended September 30, 2026, and 2025, other income was $0.1 million and $0.2 million, respectively, all of which is related to interest income.

Comparison of the Nine Months Ended September 30, 2026 and 2025

($ in thousands)	For the nine months ended September 30, 2026	2025	Change $	Change %
Operating expenses:				
Research and development	$ 610	$ (1,199)	$ 1,809	(151)%
General and administrative	2,676	2,961	(285)	(10)%
Total operating expenses	3,286	1,762	1,524	86 %
Loss from operations	(3,286)	(1,762)	(1,524)	86 %
Other income				
Interest income, net	295	379	(84)	(22)%
Total other income	295	379	(84)	(22)%
Net Loss	**$ (2,991)**	**$ (1,383)**	**$ (1,608)**	**116 %**

Research and Development Expenses

For the nine months ended September 30, 2026 and 2025, research and development expenses were approximately $0.6 million and $(1.2) million, respectively. The increase of approximately $1.8 million is primarily attributed to $1.4 million of non-repeat savings recognized from the settlement of aged payables during 2025, and $0.4 million non-repeat gain from the termination of the Plantation Street Facility lease that occurred during the first quarter of 2025.

We expect our research and development costs to increase with the initiation of the MB-109 investigator-sponsored study at COH.

General and Administrative Expenses

For the nine months ended September 30, 2026 and 2025, general and administrative expenses were $2.7 million and $3.0 million, respectively. The decrease of approximately $0.3 million is primarily attributed to a $0.4 million decrease in non-cash stock-based compensation expense, primarily related to the equity fee to Fortress, and a $0.2 million decrease in professional and outside services, partially offset by a $0.3 million increase in personnel-related expenses.

Total Other Income

For the nine months ended September 30, 2026 and 2025, other income was $0.3 million and $0.4 million, respectively, all of which is related to interest income.

Liquidity and Capital Resources

We have incurred substantial operating losses and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. To date, we have funded our operations primarily with the proceeds from various public and private offerings of our equity securities. As of September 30, 2026, we had an accumulated deficit of $401.6 million and cash and cash equivalents of $14.3 million.

We expect to continue generating operating losses and negative operating cash flows as we develop our product candidates through to potential approval; however, we believe we have sufficient cash and cash equivalents to fund our operations for at least twelve months from the date of this Form 10-Q.

In addition, the amount of proceeds we may be able to raise pursuant to our existing shelf registration statement on Form S-3 may be limited. As of the filing of this Form 10-Q, we are subject to General Instruction I.B.6 to 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 a registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by our non-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, clinical research organizations (“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 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 three and nine months ended September 30, 2026, there were no material changes in our contractual obligations and commitments, as described in our 2025 Form 10-K.

Cash Flows for the Nine Months Ended September 30, 2026 and 2025

($ in thousands)	For the nine months ended September 30, 2026	2025
Statement of cash flows data:		
Total cash (used in) provided by:		
Operating activities	$ (2,851)	$ (3,546)
Investing activities	—	1,165
Financing activities	(139)	14,526
Net change in cash and cash equivalents	$ (2,990)	$ 12,145

Operating Activities

Net cash used in operating activities was $2.9 million for the nine months ended September 30, 2026, compared to $3.5 million for the nine months ended September 30, 2025.

Net cash used in operating activities for the nine months ended September 30, 2026, was primarily due to approximately $3.0 million in net loss during the period, partially offset by $0.1 million of non-cash savings from the settlement of payables.

Net cash used in operating activities for the nine months ended September 30, 2025, was primarily due to approximately $1.4 million in net loss, $0.9 million change in operating assets and liabilities, $1.3 million non-cash savings from the settlement of payables, and $0.4 million gain on the termination of the Plantation Street Facility lease, partially offset by $0.5 million of non-cash items, primarily related to the $0.4 million equity fee to Fortress for financing activity and $0.1 million of non-cash stock based compensation expenses.

Investing Activities

During the nine months ended September 30, 2026, no cash was used in or provided by investing activities.

For the nine months ended September 30, 2025, net cash provided by investing activities was $1.2 million which primarily reflects the proceeds from the sale of equipment to AbbVie.

Financing Activities

Net cash used in financing activities was approximately $0.1 million during the nine months ended September 30, 2026, primarily reflecting offering costs related to the ATM Agreement.

Net cash provided by financing activities was $14.5 million during the nine months ended September 30, 2025, primarily reflecting proceeds from the February 2025 Equity Offering, the ATM Agreement and the July 2025 warrant exercises.

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 and financial officer, we conducted an evaluation of the effectiveness, as of September 30, 2026, 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 and financial officer 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 management, including our principal executive and 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 reasonably 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, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" 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. Some of the statements in the following risk factors constitute forward-looking statements. Please see the section titled "Special Cautionary Note Regarding Forward-Looking Statements."

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 organizing, acquiring, developing and securing our proprietary technology and identifying and obtaining preclinical data for various product candidates, with the goal of supporting regulatory approval for these product candidates. We have incurred losses since our inception in March 2015. Our net losses were $3.0 million and $1.4 million for the nine months ended September 30, 2026 and 2025, respectively, and we had an accumulated deficit of $401.6 million as of September 30, 2026. 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 our Company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our Company could also cause you to lose all or part of your investment in our Securities.

We may in the future need to raise substantial additional funding, which may not be available on acceptable terms to us, or at all. If we are unable to raise capital, we could be required to delay, limit or terminate our product development efforts or other operations, or seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.

We are currently advancing our programs in solid tumors through clinical development. Developing and commercializing CAR T 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. 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 substantial 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.

Since our inception, we have incurred substantial operating losses and expect to continue to incur significant operating losses for the foreseeable future, and we may never become profitable. To date, we have not generated positive cash flows from operations and have funded our operations primarily with the proceeds from sales of equity securities. As of September 30, 2026, we had an accumulated deficit of $401.6 million, and cash and cash equivalents of $14.3 million.

We expect to continue generating operating losses and negative operating cash flows as we develop our product candidates, and we may need to raise substantial additional financing in the future to fund our operations and to support the continued development and potential commercialization of our product candidates. We 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. Our future fundraising efforts 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. 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.

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.

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

- the scope, 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 an NDA or 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;
- the success of the commercialization of one or more of our product candidates, if approved;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and

- macroeconomic factors such as inflationary pressures, rising interest rates, liquidity constraints, failures and instability in U.S. and international financial banking systems, supply disruptions due to political unrest, conflict and war or other factors, and pandemics.

In addition, in order to address our current or future funding constraints, we may be required to further revise our business plan and strategy, which may result in us (i) curtailing, delaying or discontinuing one or more of our research or development programs or the commercialization of any product candidates, (ii) selling certain of our assets and/or (iii) being unable to expand our operations or otherwise capitalize on our business opportunities. Such actions 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. Furthermore, if we are unable to raise capital, the value of our stock could decline, or we could be required to wind down our operations or seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.

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

We have 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.

SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration statement on Form S-3.

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 a shelf registration statement on Form S-3 is limited to an aggregate of one-third of our public float, which is commonly 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 the 2025 Form 10-K, our public float was less than $75 million. As a result, for sales following the date of the 2025 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 an amount of securities up to one-third of our public float under a shelf registration statement on Form S-3 in any twelve-month period. If our public float decreases, the number of securities we may sell under our Form S-3 shelf registration statement will also decrease.

Furthermore, if we are required or choose to file a new registration statement on a form other than Form S-3, we may incur additional costs and be subject to delays due to review by the SEC staff.

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 (the "Sarbanes-Oxley Act"), as well as rules subsequently implemented by the SEC, and the rules of Nasdaq. 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, 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.

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 $250 million or more measured on the last business day of our second fiscal quarter, and our annual revenues are $100 million or more during the most recently completed fiscal year or 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.

Our ability to use our pre-change net operating loss carryforwards 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 the 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. 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, if approved, 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;
- maintaining patent protection and regulatory exclusivity for our product candidates; and

- raising additional required capital on acceptable terms.

Our operations have historically 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 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 product 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 relatively 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 candidate in particular. Because CAR T is a relatively new approach to cancer immunotherapy and cancer treatment generally, developing and commercializing our CAR T product candidate, if approved, 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;
- complying with evolving regulatory requirements specifically applicable to gene and cell therapies, including potential class-wide safety concerns and long-term patient follow-up obligations, any of which could delay, limit or prevent the development and approval of our CAR T product candidate;
- 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 our CAR T product candidate, which may increase the risk of adverse events associated with our product candidate;
- educating medical personnel regarding the potential side effect profile of our CAR T product candidate;
- developing processes for the safe administration of this product candidate, including long-term follow-up for all patients who receive our product candidate;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our CAR T product candidate;
- 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 indications beyond those addressed by our current product candidate.

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.

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.

Clinical trials are expensive and can take many years to complete, and the outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or will be completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage and our future clinical trials may not be successful. The commencement or conduct of clinical trials can be delayed for a variety of reasons, including, but not necessarily limited to, delays in:

- commencing a clinical trial as a result of regulatory authority action;
- 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 candidate or generate product revenues, if approved.

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. 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 cGMPs; 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. It is also unclear what actions will be taken by the U.S. government that could impact the FDA and our ability to obtain regulatory approvals.

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

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, if approved, 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, if approved.

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, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our approved product and we would lose potential revenues.

If serious adverse events 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 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 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 be associated with 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 associated with 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, if approved. Adverse events 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 adverse events associated with 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 recall a product, 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 our product candidates or any future product candidate, if approved, 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 their 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 market any approved product in a way which is not consistent with the approved labeling, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetics Act 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, Form 483s, 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 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, if approved.

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 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 expanded 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 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 this product candidate, if approved, 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 our 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, if approved, 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 approved product 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 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 such product;
- the relative convenience and ease of administration of such product for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contraindications, warnings, drug interactions, or other precautions;
- changes in the standard of care for the targeted indications for such product or future products, 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 events; 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 candidate, if approved, 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, if approved. 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, if approved, 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, if approved, 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, if approved, 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 product candidates, if approved, 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 for a future product candidate, if approved, that 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 candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, and, if approved, during 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 candidates or future product candidates, if approved.

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 product candidates, if approved, 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.

Negative public opinion and increased regulatory scrutiny of the therapies that underpin 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 is unsafe, and such therapy may not gain the acceptance of the public or the medical community. 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.

Changes in U.S. government policy, regulation, enforcement priorities, and funding decisions could adversely affect our business, financial condition and results of operations.

There may be significant shifts in policies that directly impact the life sciences industry, including policies relating to FDA regulation and enforcement, drug approval and review processes, reimbursement and pricing (including Medicare, Medicaid and other government programs), healthcare reform, intellectual property protection, trade and tariffs, and federal research and public health funding. The administration's approach, together with actions by Congress and federal agencies such as the FDA, USPTO, Centers for Medicare & Medicaid Services, HHS, NIH and the Centers for Disease Control and Prevention, is inherently uncertain and may materially differ from historical norms or from our current expectations.

Potential changes may include, among others: (i) modifications to standards, procedures or timelines for the review, clearance, approval or post-market oversight of drugs; (ii) changes to policies on real-world evidence, accelerated approval, emergency use authorizations, and clinical trial requirements; (iii) reforms or restrictions affecting drug pricing, reimbursement levels, coverage decisions and formulary placement for products paid for by federal healthcare programs; (iv) increased or decreased enforcement of laws and regulations relating to manufacturing, promotion, fraud abuse, data integrity, privacy and cybersecurity; (v) changes in federal funding priorities for biomedical research and public health programs that may impact key customers, collaborators and research partners; and (vi) trade, tariff and supply-chain measures that could affect our access to critical materials, components, contract manufacturers, or international markets.

Any such actions, or uncertainty regarding potential actions, could increase development, regulatory, compliance, and commercialization costs; delay, limit or prevent the development, approval, launch or commercial success of future product candidates or marketed products; affect pricing, reimbursement and market access; disrupt our supply chain; alter the behavior and financial condition of our customers, clinical sites, collaborators and payors; and contribute to volatility in capital markets that could affect our ability to raise additional financing on acceptable terms or at all. Because we cannot predict the timing, scope, direction, or ultimate impact of policy or regulatory changes, we may not be able to anticipate or fully mitigate their effects. Any of the foregoing could materially and adversely affect our business, financial condition, and results of operations.

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 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 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 third parties on which we rely 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 certain 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 approved.

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, Nationwide and UAB for all 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, Nationwide, and UAB pursuant to a sponsored research agreement and/or clinical trial agreements between us and COH, as well as a Memorandum of Understanding between Nationwide and UAB under which UAB is conducting its MB-108 Phase 1 clinical trials. As a result, our future success is heavily dependent on the results of research and development efforts of these institutions and their personnel. 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.

Due to limited resources, and in light of our reduction in work force in April 2024, we may increase our reliance 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 could disrupt the global supply chain, including imposition of tariffs, 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 product candidates, 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 such product candidate. 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 a New Drug Application ("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 current Good Manufacturing Practices ("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.

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 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 this item.

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, if approved, 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 vector is 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 CAR T product candidate, or to support commercialization of our CAR T product, 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. The technical skills required to manufacture LV vector for our CAR T drug product candidate 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 CAR T product candidate or any future CAR T product candidates, if approved. 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 candidates. 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 candidates, 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 of our product candidates and commercialization, if approved. 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 may consider such a collaboration to be more attractive than the one with us for any future product candidate.

The contractual provisions we may be forced to agree upon in services, manufacturing, supply and other agreements may be inordinately one-sided, vis-à-vis current or historical standard market terms (especially as it pertains to contractual liability and indemnification paradigms), and as a result we may be subject to liabilities that are not attributable to our own actions or the actions of our personnel.

There is a finite number of service providers who can perform the services or produce the materials or product candidates that we need, and we therefore often have a limited number of options in choosing such service providers. The standard market terms in many of the agreements into which we customarily enter with such service providers are subject to evolution over time, often-times in favor of our counterparties. Also, some such agreements are "adhesion contracts" under which our contractual counterparties refuse to entertain any modifications to their template documentation. One area where service providers often have and exert leverage over us is the negotiation of liability language – specifically in broadly-scoped indemnification by us of service providers and/or the application of liability damages "caps" to certain of such service providers' indemnification obligations. In any circumstance where we've been compelled to agree to such language, it is conceivable that we will be liable to third parties for liabilities in excess of such caps that are attributable to the actions, forbearances and/or culpability of such service providers and their indemnitees (and not to those of us and our personnel).

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.

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "PPACA" or collectively, the "ACA"), substantially regulates the way healthcare is financed by both governmental and private insurers in the United States. Among other things, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded the eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at the CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Drug pricing continues to be a subject of debate at the executive and legislative levels of U.S. government. The American Rescue Plan Act of 2021 signed into law by President Biden in March 2021, includes a provision that eliminated the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the rebate cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug. Additionally, the Inflation Reduction Act of 2022 ("IRA") contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. Although the IRA exempts orphan drugs that treat only one rare disease from the drug pricing negotiation provisions, we do not know if additional drug pricing reforms could eliminate this exemption. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our product candidates, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations, and growth prospects. The effect of the IRA on our business and the pharmaceutical industry in general is not yet known.

In May 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, the HHS, in coordination with other federal agencies, is directed to take actions to ensure that the price of prescription drugs paid by federal health insurers, including Medicare and Medicaid, is in line with the prices paid in comparably developed nations.

As an alternative to the ACA, President Trump recently announced the Great Healthcare Plan. As presented, the Great Healthcare Plan is intended to lower drug prices by increasing competition and benchmarking U.S. drug prices to other countries, reduce insurance premiums by redirecting subsidies from insurers to individuals, increase accountability and transparency from insurers, and promote consumer choice by giving individuals more direct control over how healthcare dollars are spent. Legislative and regulatory action will be required to fully implement the Great Healthcare Plan. It is unclear how these proposed changes will impact our business and the pharmaceutical industry in general.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, if approved, or additional pricing pressures.

These and 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 current or future product candidates. 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 product candidates, if approved. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of any current or future product candidates, if any, may be. In addition, increased Congressional scrutiny 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, including reductions in force, 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 in the past, 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.

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, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either (1) the referral of an individual to a person for, furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal healthcare program;

- The False Claims Act and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from the federal government or making or using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the healthcare benefit program through false representations or knowingly and willfully falsifying, concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of, or payment for, health care benefits or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- The provision under the Affordable Care Act ("ACA") commonly referred to as the Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and

other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations; applicable manufacturers are also required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;

- The Foreign Corrupt Practices Act ("FCPA") generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA; and

- State law equivalents of each of the above federal laws, such as the Anti-Kickback Statute and False Claims Act, and state laws concerning security and privacy of health care information, which may differ in substance and application from state-to-state thereby 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 government 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 COH and Nationwide. 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 our Company 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, 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 our Company 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 us, and they are not required to notify us prior to pursuing such opportunities. Any conflict of interest or pursuit by Fortress of such a corporate opportunity could expose us to claims by our investors and/or creditors and could harm our results of operations.

General Risks and Risks Associated with Ownership of our Common Stock

We rely on information technology, and our business, reputation and operations would suffer in the event of any internet or internal computer system failures, inadequacies, interruptions, compromises, deficiencies, cyber-attacks, or other cybersecurity incidents affecting our systems or those of our third-party providers, or by any compromise of confidential information.

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.

Despite the implementation of our internal security and business continuity measures and 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 effective preventive measures 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.

Our growth is subject to economic and geopolitical conditions.

Our business is affected by global and local economic and geopolitical 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 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. Geopolitical changes, including wars, armed conflicts, acts of terrorism, civil or political unrest, trade disputes, the imposition of sanctions or other economic measures or other regional or global conflicts, some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location.

Additionally, trade policies and geopolitical disputes and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures occur in regions where drug products are manufactured or raw materials are sourced. For example, tensions between the United States and China have led to a series of tariffs being imposed by the United States on imports from mainland China, as well as other business restrictions. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain. As these tensions continue to rise, more targeted approaches by the U.S. or Chinese governments on certain products, industries or companies could significantly impact our development and commercialization efforts. The U.S. government may impose additional or higher tariffs, sanctions or other trade restrictions on goods imported from China and other countries which could increase the cost of goods needed to commercialize any products for which we obtain marketing authorization and continue development of our product candidates. Further, such actions by the U.S. could result in retaliatory action by those countries which could impact our ability to profitably commercialize any products for which we obtain marketing authorization in those jurisdictions. As a result, our business, operations, and financial condition could be materially harmed.

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.

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 the physical impacts of climate change and other natural or man-made 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. Our operations, and those of our third-party manufacturers, suppliers, clinical sites and other partners, depend on infrastructure and facilities that may be located in areas increasingly subject to extreme weather events and other physical risks and natural or man-made disasters. These events could cause damage to or disrupt the operations of our contract manufacturers, suppliers, clinical trial sites, laboratories, data centers and other critical infrastructure, which could in turn:

- delay, interrupt or prevent the manufacture, release, storage and shipment of our product candidates and the materials used to produce them, including LV vector and other critical components;
- disrupt the conduct of our preclinical studies and clinical trials, including by impairing the ability of clinical trial sites to enroll or treat patients, collect or ship clinical specimens or perform required assessments;
- impede the ability of our employees, contractors and collaborators to work at our or their respective facilities or to otherwise carry out our business activities; and

- damage or destroy data, biological samples, equipment or facilities, or result in prolonged outages of critical information technology systems or other infrastructure.

Any of the foregoing events or developments could result in increased costs, delays in our research and development activities, disruptions to our supply chain and clinical development programs, reduced revenue opportunities, or otherwise have a material adverse effect on our business, financial condition and results of operations.

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 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.

The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future.

An active, liquid and orderly market for our common stock may not be sustained, which could depress the trading price of our common stock or cause it to continue to be highly volatile or subject to wide fluctuations. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include, among other things:

- the commencement, enrollment, or results of our current and future preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- manufacturing, supply or distribution delays or shortages;
- our ability to identify and successfully acquire or in-license new product candidates on acceptable terms;
- FDA, state or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- legislative or regulatory changes;
- judicial pronouncements interpreting laws and regulations;
- changes in government programs;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- changes in accounting principles;
- litigation or public concern about the safety of our product candidates or similar product candidates;

- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders; and
- our ability to obtain additional financing to advance our development operations.

These broad market and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. The stock market in general has from time to time experienced extreme price and volume fluctuations. In addition, in the past, following periods of volatility in the overall market and decreases in the market price of a company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

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.

If we are unable to regain compliance with all applicable continued listing requirements and standards of Nasdaq, our common stock may be delisted from Nasdaq.

Our common stock is listed on the Nasdaq Capital Market under the symbol "MBIO." The Nasdaq Capital Market requires that listed companies satisfy continued listing standards to maintain their listing. We are currently not in compliance with certain standards for continued listing on the Nasdaq Capital Market, namely, Nasdaq Listing Rule 5550(a)(2), which sets forth the minimum bid price requirement for continued listing on the Nasdaq Capital Market (the "Bid Price Requirement"), and as described below, we may not be in compliance with the newly adopted minimum Market Value of Listed Securities requirement, if and when such rule becomes effective.

On April 15, 2026, we received a notice (the "Letter") from the Listing Qualifications Department (the "Staff") of Nasdaq indicating that the bid price of our common stock had closed below $1.00 for 30 consecutive business days and, as a result, we were not in compliance with the Bid Price Requirement. The Letter had no immediate effect on the listing of the Company's common stock on Nasdaq.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were afforded an initial 180-calendar day grace period, or until October 12, 2026, to regain compliance with the Bid Price Requirement. We were unable to demonstrate compliance with the Bid Price Requirement by that date. However, we submitted a request for an additional 180-calendar day grace period based upon (i) our belief that, as of October 12, 2026, we satisfied the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market, except for the Bid Price Requirement, and (ii) our written notice to Nasdaq of our intention to cure the deficiency during the second grace period by effecting a reverse stock split, if necessary.

On October 13, 2026, we received a letter from the Staff granting our request for an additional 180-calendar day period, or until April 12, 2027, to regain compliance with the Bid Price Requirement. Compliance can be achieved by evidencing a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days (but generally not more than 20 consecutive business days) during the second 180-calendar day grace period. In the event we do not regain compliance by the end of the second grace period, the Staff will provide written notification that our common stock will be delisted. At that time, we may appeal the Staff's determination to the Nasdaq Hearings Panel (the "Panel"), although an appeal would not pause any suspension of trading.

We intend to closely monitor the closing bid price of our common stock and to take all reasonable measures available to regain compliance under the Nasdaq Listing Rules and remain listed on Nasdaq, including effecting a reverse stock split, if necessary. However, there can be no assurance that we will ultimately regain compliance with all applicable requirements for continued listing.

In addition to the Bid Price Requirement, on July 22, 2026, the Securities and Exchange Commission (the "SEC") approved a Nasdaq rule change that adopts a new continued listing requirement obligating companies listed on the Nasdaq Capital Market to maintain a minimum Market Value of Listed Securities ("MVLS") of at least $5 million (the "MVLS Requirement"). Although the SEC subsequently stayed the implementation of the MVLS Requirement on July 29, 2026, it is possible that the new rule may become effective in the near-term. The MVLS Requirement is set forth in new Nasdaq Listing Rule 5550(a)(6).

The consequences of failing to comply with the MVLS Requirement differ materially from, and are more severe than, those applicable to the Bid Price Requirement. Unlike the Bid Price Requirement, a company that fails to comply with the MVLS Requirement is not entitled to any cure or compliance period. Instead, if a company's MVLS remains below $5 million for a period of 30 consecutive business days, Nasdaq will issue a Staff Delisting Determination and the company's securities will be immediately subject to suspension and delisting. Furthermore, a timely request for a hearing before the Panel will not stay the suspension of the company's securities from trading pending the issuance of a written decision by the Panel, and the company's securities would generally trade in the over-the-counter market during the pendency of any such appeal. Although the Panel may reverse a delisting determination that it finds was made in error, or grant an exception for a period not to exceed 180 days from the Staff Delisting Determination for the company to demonstrate that it meets all requirements for initial listing (which are generally higher than the continued listing requirements), there can be no assurance that the Panel would grant any such exception or that we would be able to satisfy the initial listing standards; and in any event, our stock would not be traded on the Nasdaq Capital Market during such period.

As of the time of this filing, our MVLS is currently below $5 million. Because we are currently below the $5 million MVLS threshold, if and when the MVLS Requirement becomes effective, we may become subject to immediate suspension and delisting, without any opportunity to cure, if our MVLS remains below $5 million for 30 consecutive business days.

There can be no assurance that we will be able to regain compliance with Nasdaq's continued listing rules. If we are unable to regain compliance, we may be delisted from Nasdaq, and, in the case of the MVLS Requirement, if and when it becomes effective, any such suspension and delisting could occur immediately and without a compliance period. In the event we are delisted from Nasdaq, there can be no assurance that our common stock will be eligible for trading on another stock exchange or quotation on an over-the-counter market. If we are not able to obtain a listing on another stock exchange or quotation service for our common stock, it may be extremely difficult or impossible for stockholders to sell their shares. Additionally, if we are delisted from Nasdaq, but obtain a substitute listing or quotation service for our common stock, it will likely be on a market with less liquidity, and our common stock may therefore experience potentially more price volatility than it has historically experienced on Nasdaq. Stockholders may not be able to sell their shares of common stock on any such substitute market in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if our common stock is delisted from Nasdaq, the value and liquidity of our common stock would likely be adversely affected. A delisting of our common stock from Nasdaq could also adversely affect our ability to obtain financing for our operations and/or result in a loss of confidence by investors, employees and/or business partners.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

During the three months ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K under the Securities Act).

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
3.1	Amended and Restated Certificate of Incorporation of Mustang Bio, Inc. (formerly Mustang Therapeutics, Inc.), dated July 26, 2016 (incorporated by reference to the Exhibit 3.1 of the Registrant's Form 10-12G (File No. 000-55668) filed with the 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 the Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-38191) filed with the 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 the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the 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 the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the 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 the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the 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 the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on July 5, 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 the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on April 3, 2023).
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated January 15, 2025 (incorporated by reference to the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on January 17, 2025).
3.9	Amended and Restated Bylaws of Mustang Bio, Inc. (incorporated by reference to the Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on April 3, 2023).
31.1	Certification of President, Chief Executive Officer and Interim Chief Financial Officer (Principal Executive and Financial Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of President, Chief Executive Officer and Interim Chief Financial Officer (Principal Executive and Financial Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2026, formatted as Inline Extensible Business Reporting Language (iXBRL): (i) the Unaudited 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 5, 2026

By: /s/ Manuel Litchman, M.D.
Manuel Litchman, M.D., President, Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive and 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, Chief Executive Officer and Interim Chief Financial Officer (Principal Executive and 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) I am 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 my 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 my 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 the Registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

(5) I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

November 5, 2026

By: /s/ Manuel Litchman
Manuel Litchman, M.D., President, Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive and 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, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Manuel Litchman, M.D., President, Chief Executive Officer and Interim Chief Financial Officer (Principal Executive and 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 5, 2026

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