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

FORM S-1

**REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933
MUSTANG BIO, INC.**

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

47-3828760
(I.R.S. Employer
Identification Number)

**377 Plantation Street
Worcester, Massachusetts 01605
(781) 652-4500**
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Manuel Litchman, M.D.
President and Chief Executive Officer
Mustang Bio, Inc.
377 Plantation Street
Worcester, Massachusetts 01605
(781) 652-4500**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

Non-accelerated filer

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 7(a)(2)(B) of the Securities Act.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is prohibited.

SUBJECT TO COMPLETION, DATED JANUARY 15, 2025

PRELIMINARY PROSPECTUS



Up to	Shares of Common Stock
Pre-funded Warrants to Purchase up to	Shares of Common Stock
Series C-1 Warrants to Purchase up to	Shares of Common Stock
Series C-2 Warrants to Purchase up to	Shares of Common Stock
Series C-3 Warrants to Purchase up to	Shares of Common Stock
Placement Agent Warrants to Purchase up to	Shares of Common Stock
Up to	Shares of Common Stock Issuable Upon Exercise of
the Series C-1 Warrants, Series C-2 Warrants, Series C-3 Warrants, Pre-funded Warrants and Placement Agent Warrants	

We are offering up to _____ shares of common stock, together with accompanying Series C-1 warrants (the “Series C-1 Warrants”) to purchase up to _____ shares of common stock, Series C-2 warrants (the “Series C-2 Warrants”) to purchase up to _____ shares of common stock, and Series C-3 warrants to purchase up to _____ shares of common stock (the “Series C-3 Warrants” and collectively with the Series C-1 Warrants and Series C-2 Warrants, the “Warrants”), pursuant to this prospectus. The combined public offering price for each share of common stock, together with one Series C-1 Warrant, one Series C-2 Warrant and one Series C-3 Warrant, each to purchase one share of common stock, is \$ _____, which is equal to the last reported sale price of our common stock on the Nasdaq Capital Market on _____, 2025. The shares of common stock and Warrants will be separately issued. Each Warrant will have an exercise price of \$ _____ per share, will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Warrants (“Warrant Stockholder Approval”), provided, however, if the Pricing Conditions (as defined below) are met, the Warrants will be exercisable upon issuance (the “Initial Exercise Date”). The Series C-1 Warrant will expire on the five-year anniversary of the Initial Exercise Date. The Series C-2 Warrant will expire on the twenty-four-month anniversary of the Initial Exercise Date. The Series C-3 Warrant will expire on the nine-month anniversary of the Initial Exercise Date. As used herein “Pricing Conditions” mean that the combined offering price per share and accompanying Warrants is such that the Warrant Stockholder Approval is not required under the rules of The Nasdaq Stock Market LLC (“Nasdaq”) because either (i) the offering is an at-the-market offering under Nasdaq rules and such price equals or exceeds the sum of (a) the applicable “Minimum Price” per share under Nasdaq Rule 5635(d) plus (b) \$0.125 per whole share of common stock underlying the Warrants or (ii) the offering is a discounted offering where the pricing and discount (including attributing a value of \$0.125 per whole share underlying the Warrants) meet the pricing requirements under Nasdaq’s rules.

We are also offering up to _____ pre-funded warrants (the “pre-funded warrants”), together with accompanying Series C-1 warrants to purchase up to _____ shares of common stock, Series C-2 warrants to purchase up to _____ shares of common stock, and Series C-3 warrants to purchase up to _____ shares of common stock to those purchasers whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering or if such purchaser otherwise elects to purchase pre-funded warrants, in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each pre-funded warrant will be exercisable for one share of common stock at an exercise price of \$0.0001 per share. Each pre-funded warrant is being issued together with the same Warrants described above being issued with each share of common stock. The combined public offering price for each such pre-funded warrant, together with accompanying Warrants, is \$ _____, which is the combined public offering price per share and Warrants (equal to the last reported sale price of our common stock on the Nasdaq Capital Market on _____, 2025), minus \$0.0001. Each pre-funded warrant will be exercisable upon issuance and may be exercised at any time until all of the pre-funded warrants are exercised in full. The pre-funded warrants and accompanying Warrants are immediately separable and will be issued separately in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the Warrants, pre-funded warrants and Placement Agent Warrants (as defined herein).

There is no established public trading market for the Warrants or the pre-funded warrants, and we do not expect a market to develop. We do not intend to apply for listing of the Warrants or the pre-funded warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Warrants and the pre-funded warrants will be limited.

The securities will be offered at a fixed combined public offering price and are expected to be issued in a single closing. We expect this offering to be completed on or about _____, 2025, and we will deliver all securities to be issued in connection with this offering delivery versus payment/receipt versus payment upon receipt by us of investor funds. Accordingly, neither we nor the placement agent have made any arrangements to place investor funds in an escrow account or trust account since the placement agent will not receive investor funds in connection with the sale of the securities offered hereunder.

We have engaged _____ (the “Placement Agent”), to act as our exclusive placement agent in connection with this offering. The Placement Agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The Placement Agent is not purchasing or selling any of the securities we are offering and the Placement Agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the Placement Agent the Placement Agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no minimum number of securities or amount of proceeds required as a condition to closing in this offering. Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue our business goals described in this prospectus. In addition, because there is no escrow trust or similar arrangement and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill all of our contemplated objectives due to a lack of interest in this offering. Further, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. We will bear all costs associated with the offering. See “Plan of Distribution” on page 136 of this prospectus for more information regarding these arrangements.

Our common stock is listed on the Nasdaq Capital Market under the symbol “MBIO”. On January 14, 2025, the last reported sale price of our common stock on the Nasdaq Capital Market was \$0.1438 per share.

The combined offering price per share of common stock and accompanying Warrants and the combined offering price per pre-funded warrant and accompanying Warrants we are offering and the exercise price and other terms of the Warrants were negotiated between us and the purchasers, in consultation with the Placement Agent based on the trading of our common stock prior to this offering, among other factors. Other factors considered in determining the offering price of the securities we are offering and the exercise price and other terms of the Warrants include the history and prospects of our company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

We are a “smaller reporting company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to comply with reduced public company reporting requirements in future filings. See “Prospectus Summary—Implications of Being a Smaller Reporting Company.”

Investing in our securities involves risks. Before deciding whether to invest in our securities, you should consider carefully the risks that we have described on page 16 of this prospectus under the caption “Risk Factors.”

	<u>Per Share and Accompanying Warrants</u>	<u>Per Pre- Funded Warrant and Accompanying Warrants</u>	<u>Total</u>
Public offering price	\$	\$	\$
Placement Agent’s fees ⁽¹⁾	\$	\$	\$
Proceeds to us, before expenses ⁽²⁾	\$	\$	\$

- (1) We have agreed to pay the Placement Agent a total cash fee equal to 7.0% of the gross proceeds raised in this offering. We have also agreed to pay the Placement Agent a management fee equal to 1.0% of the gross proceeds raised in this offering and to reimburse the Placement Agent for its non-accountable expenses in the amount of \$25,000 and for its legal fees and expenses and other out-of-pocket expenses in an amount up to \$100,000, up to \$3,500 for road show expenses, and for its clearing expenses in the amount of \$15,950. In addition, we have agreed to issue to the Placement Agent, or its designees, warrants to purchase a number of shares of our common stock equal to 6.0% of the aggregate number of shares of common stock and pre-funded warrants being offered at an exercise price equal to 125% of the combined public offering price per share of common stock and accompanying Warrants. We refer you to “Plan of Distribution” on page 136 of this prospectus for additional information regarding Placement Agent compensation.
- (2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing in this offering, the actual offering amount, Placement Agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. We refer you to “Plan of Distribution” on page 136 of this prospectus for additional information regarding Placement Agent compensation.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

We expect to deliver the securities to the purchasers in the offering on or about _____, 2025, subject to satisfaction of certain conditions.
_____, 2025

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ABOUT THIS PROSPECTUS

The registration statement we filed with the Securities and Exchange Commission (the “SEC”) includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus and the related exhibits filed with the SEC before making your investment decision. You should rely only on the information provided in this prospectus. You should not assume that the information contained in this prospectus or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document, even though this prospectus or any related free writing prospectus is delivered, or securities are sold, on a later date. This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been or will be filed as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under the heading “Where You Can Find More Information.”

You should rely only on the information that we have included in this prospectus and any related free writing prospectus that we may authorize to be provided to you. Neither we, nor the placement agent, have authorized any dealer, salesman or other person to give any information or to make any representation other than those contained in this prospectus or any related free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained in this prospectus or any related free writing prospectus. This prospectus and any related free writing prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor does this prospectus or any related free writing prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

When we refer to “Mustang,” “we,” “our,” “us” and the “Company” in this prospectus, we mean Mustang Bio, Inc., unless otherwise specified. When we refer to “you,” we mean the potential holders of the applicable securities.

Solely for convenience, tradenames referred to in this prospectus appear without the[®] and[™] symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these tradenames.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. Before investing in our common stock, you should carefully read the entire prospectus, including the risks of investing in our securities discussed under the heading “Risk Factors” and “Special Note Regarding Forward-Looking Statements.” You should also carefully read our financial statements and the exhibits to the registration statement of which this prospectus forms a part. Unless the context otherwise requires, the terms “Mustang” “Mustang Bio” “the Company,” “we,” “us,” “our” and similar references in this prospectus refer to Mustang Bio, Inc., the registrant on the cover page of the registration statement of which this prospectus forms a part.

Our Business

Overview and Product Candidate Development

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 in two core areas: CAR T therapies for hematologic malignancies and CAR T 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”), Fred Hutchinson Cancer Center (“Fred Hutch”), and Nationwide Children’s Hospital (“Nationwide”).

CAR T Therapies

Our pipeline of CAR T therapies is being developed under exclusive licenses from several world class research institutions. Our strategy is to license these technologies, support preclinical and clinical research activities by our partners and transfer the underlying technology to our or our contract manufacturer’s cell processing facility in order to conduct our own clinical trials.

We are developing CAR T therapy for hematologic malignancies in partnership with Fred Hutch targeting CD20 (MB-106). In May 2021, we announced that the U.S. Food and Drug Administration (“FDA”) accepted our Investigational New Drug (“IND”) Application for MB-106. As of January 2025, 53 patients have been treated in an ongoing Phase 1 clinical trial sponsored by Fred Hutch (ClinicalTrials.gov Identifier: NCT03277729) and 20 patients have been treated in the Phase 1 clinical trial sponsored by us (ClinicalTrials.gov Identifier: NCT05360238). In 2023, we received Safety Review Committee approval to continue dose escalation in all three active arms of the ongoing Mustang-sponsored Phase 1 trial. We presented the latest results, demonstrating a favorable safety profile, complete response rate, and durability, from the ongoing Mustang-sponsored Phase 1 trial at the 2023 American Society of Hematology (“ASH”) Annual Meeting.

We are also developing CAR T therapy for solid tumors in partnership with COH targeting IL13R α 2 (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) began during the third quarter of 2019. 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 IL13R α 2+ relapsed or refractory glioblastoma (“GBM”) and high-grade astrocytoma.

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

In the first quarter of 2024, we completed a successful End-of-Phase 1 meeting with the FDA regarding a potential pivotal Phase 2 single-arm clinical trial for the treatment of WM. Per the discussions, the FDA agreed with the proposed overall design of the pivotal trial for Waldenström macroglobulinemia (“WM”) at the recommended dose of 1×10^7 CAR-T cells/kg and requested only minimal modifications to the study protocol. No additional nonclinical studies are expected prior to Phase 2 or a Biologics License Application (“BLA”) filing. Due to limited resources, and as a result of the reduction in work force described below, we do not expect to initiate our pivotal Phase 2 single-arm clinical trial of MB-106 for the treatment of WM trial in 2025. Subject to available funds, we intend to rely on third party service providers to conduct study and manufacturing services to advance our priority potential product candidates.

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Also in the first quarter of 2024, we completed enrollment of the indolent lymphoma arm in our multicenter Phase 1 trial. The tenth and final patient enrolled on that arm was a patient with follicular lymphoma (FL) who achieved a complete response following treatment with 1×10^7 CAR-T cells/kg. As a result, the overall complete response rate for FL in the Phase 1 portion of this trial was sustained at 100% (N=6), with no occurrence of cytokine release syndrome (“CRS”) above grade 1 and no immune effector cell-associated neurotoxicity syndrome (“ICANS”) of any grade, despite not using prophylactic tocilizumab or dexamethasone.

In March 2024, we announced plans to collaborate with Fred Hutch for a proof-of-concept Phase 1 investigator-sponsored clinical trial evaluating MB-106 in autoimmune diseases.

In March 2024, we were granted the Regenerative Medicine Advanced Therapy (“RMAT”) designation by the FDA for the treatment of relapsed or refractory CD20 positive WM and FL, based on potential improvement in response as seen in clinical data to date. Drugs eligible for RMAT designation are those intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and that present preliminary clinical evidence indicating the drug has the potential to address unmet medical needs for such disease or condition. RMAT designation provides regenerative medicine advanced therapy products with the same benefits to expedite the development and review of a marketing application that are available to drugs that receive Breakthrough Therapy Designation. These advantages include timely advice and interactive communications with FDA, as well as proactive and collaborative involvement by senior FDA managers and experienced review and regulatory health project management staff. A product designated as an RMAT also may be eligible for other FDA-expedited programs, such as Priority Review. The FDA also may conduct a rolling review of products in its expedited programs, reviewing portions of a marketing application before the complete application is submitted.

In June 2024, we announced that updated data for MB-106 in the Phase 1/2 Fred Hutch investigator-sponsored trial showed a favorable safety and efficacy profile in 10 patients with WM. There was an overall response rate (“ORR”) of 90% with durable responses observed, including three complete responses (“CR”), two very good partial responses (“VGPR”), and four partial responses (“PR”). One of the patients who achieved a CR remained in remission for 31 months, with an immunoglobulin M (IgM) level that decreased rapidly to the normal range after treatment with MB-106 and remained normal since. Patients had a median of nine prior lines of therapy, and only one patient started additional anti-WM treatment after being treated with MB-106. From a safety perspective, CRS occurred in nine patients: five patients with grade 1 and four patients with grade 2. One patient experienced grade 1 ICANS. No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS was observed, despite dose escalation.

In May 2024, we informed the clinical sites participating in the Mustang-sponsored Phase 1/2 study in non-Hodgkin lymphoma and chronic lymphocytic leukemia, MB106-CD20-001, that we had decided to close the trial. In June 2024, we similarly informed the clinical sites participating in the Mustang-sponsored Long-term Follow-up Study in Patients Previously Treated with Mustang Bio, Inc. CAR-T Cell Investigational Products, MB100-OBS-001, that we had decided to close that trial. As a result, further clinical development of MB-106 is currently focused solely on autoimmune diseases unless funding and resources become available to restart the program for hematologic malignancies. Planning for the aforementioned Phase 1 investigator-sponsored clinical trial in autoimmune diseases is in progress, with initiation of the trial planned for 2025.

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

In October 2023, we received a safe-to-proceed “approval” from the FDA for our MB-109 IND application allowing us to initiate a Phase 1, open-label, non-randomized, multicenter study of MB-109 in patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma. In this Phase 1 clinical study, we intend to evaluate the combination of CAR-T cells (MB-101) and the herpes simplex virus type 1 oncolytic virus (MB-108) in patients with IL13R α 2+ high-grade gliomas. The design of this study involves first a lead-in cohort, wherein patients are treated with MB-101 alone without prior MB-108 administration. After successful confirmation of the safety profile of MB-101 alone, the study will then investigate increasing doses of intratumorally administered MB-108 followed by dual intratumoral (ICT) and intraventricular (ICV) administration of MB-101.

On November 7, 2024, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-108, a herpes simplex virus type 1 (“HSV-1”) oncolytic virus, for the treatment of malignant glioma. 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 to conduct an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma with MB-109 and could potentially be initiated in the second half of 2025.

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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. As of September 30, 2024, we have an accumulated deficit of \$395.8 million.

Recent Developments

October 2024 Private Placement

On October 24, 2024, we entered into an inducement offer letter agreement (the “Inducement Letter”) with an institutional accredited investor (the “Investor”) which held certain outstanding (i) Series A-1 Warrants to purchase up to an aggregate of 16,877,638 shares of common stock, (ii) Series A-2 Warrants to purchase up to an aggregate of 16,877,638 shares of common stock, and (iii) Series A-3 Warrants to purchase up to an aggregate of 16,877,638 shares of common stock, originally issued to the Investor on May 2, 2024 (the “May 2024 Warrants”). The May 2024 Warrants had an exercise price of \$0.237 per share.

Pursuant to the Inducement Letter, the Investor agreed to exercise in full, for cash, the Series A-3 Warrants (the “Existing Warrants”) at the exercise price of \$0.237 per share in consideration for our agreement to issue in a private placement (x) new Series B-1 Warrants to purchase Series B-1 Warrant Shares and (y) new Series B-2 Warrants to purchase Series B-2 Warrant Shares. In addition, we issued to H.C. Wainwright & Co., LLC (“H.C. Wainwright,” together with the Investor, the “Holders”) or its designees Placement Agent Warrants to purchase Placement Agent Warrant Shares. The Placement Agent Warrants have the same terms as the Series B-1 Warrants, except that the Placement Agent Warrants have an exercise price equal to \$0.2963 per share. The transactions contemplated by the Inducement Letter closed on October 25, 2024. We received aggregate gross proceeds of approximately \$4 million from the exercise of the Existing Warrants by the Investor, before deducting placement agent fees and other expenses payable by us.

Non-Compliance with Nasdaq Continued Listing Requirements

On March 13, 2024, we received a deficiency letter (the “Letter”) from the Listing Qualifications Department (the “Staff”) of Nasdaq notifying us that we were not in compliance with the minimum stockholders’ equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1) (the “Equity Rule”). The Equity Rule requires companies listed on the Nasdaq Capital Market to maintain stockholders’ equity of at least \$2.5 million (or, in the alternative, a market value of listed securities of \$35 million or net income from continued operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years). As of December 31, 2023, we reported stockholders’ equity of \$123,000, and as of September 30, 2024, we reported stockholders’ deficit of approximately \$8.7 million.

The Letter had no immediate effect on our continued listing on Nasdaq, subject to our compliance with the other continued listing requirements. In accordance with the Nasdaq Listing Rules, we were provided 45 calendar days, or until April 29, 2024, to submit a plan to regain compliance with the Equity Rule (the “Compliance Plan”). We submitted our Compliance Plan on April 29, 2024, and the Staff granted our request for an extension of 180 calendar days through September 9, 2024, to regain compliance with the Equity Rule. We were unable to demonstrate compliance with the Equity Rule by September 9, 2024.

On September 10, 2024, the Staff formally notified us that it had determined to delist our securities from Nasdaq based upon our continued non-compliance with the Equity Rule unless we timely request a hearing before the Nasdaq Hearings Panel (the “Panel”). On September 17, 2024, we requested a hearing before the Panel, which stayed any further action by Nasdaq at least pending completion of the hearing and the expiration of any extension that may be granted by the Panel to us following the hearing.

On May 16, 2024, we received a notice (the “Second Letter”) from the Staff of Nasdaq indicating that the bid price of our common stock had closed below \$1.00 per share for 31 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 Rule”). The Second Letter from Nasdaq had no immediate effect on the listing of our common stock on Nasdaq. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were afforded a 180-calendar day grace period, or until November 12, 2024, to regain compliance with the Bid Price Rule. Compliance can be achieved by evidencing a closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days (but generally not more than 20 consecutive business days) during the 180-calendar day grace period.

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The hearing before the Panel occurred on October 29, 2024. By decision dated November 8, 2024, the Panel granted our request for an extension to evidence compliance with all applicable criteria for continued listing on the Nasdaq Capital Market, including the Bid Price Rule, through January 31, 2025, and the Equity Rule through February 18, 2025. We are considering all available options that may enable us to timely evidence compliance with the continued listing criteria and maintain our listing on Nasdaq. There can be no assurance that we will be successful in our efforts to maintain the listing of our common stock on the Nasdaq Capital Market.

Reverse Stock Split

On January 14, 2025, we announced that we will effect a 1-for-50 reverse stock split of our issued and outstanding common stock. The reverse stock split was approved on June 27, 2024 by our board of directors and stockholders representing approximately 56% of the voting power of our outstanding capital stock, with the authorization to determine the final ratio having been granted to our board of directors. The reverse stock split is intended to bring the Company into compliance with Nasdaq's Bid Price Rule.

The reverse stock split will be effected on our common stock by the filing of a certificate of amendment (the "Amendment") to our amended and restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware on January 15, 2025, without any change to par value. The Amendment will become effective upon such filing. No fractional shares will be issued in connection with the reverse stock split as all fractional shares will be rounded down to the next whole share.

Corporate Information

We are a majority-controlled subsidiary of Fortress Biotech, Inc. ("Fortress"). We were incorporated under the laws of the State of Delaware on March 13, 2015. Our principal executive offices are located at 377 Plantation Street, Worcester, Massachusetts 01605, and our telephone number is 781-652-4500. We maintain a website on the Internet at www.mustangbio.com and our e-mail address is info@mustangbio.com. Information on our website, or any other website, is not incorporated by reference in this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being a Smaller Reporting Company

We are a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of our voting and non-voting common stock held by non-affiliates is less than \$250 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than \$700 million measured on the last business day of our second fiscal quarter. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and have reduced disclosure obligations regarding executive compensation, and if we are a smaller reporting company with less than \$100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Risks Associated with the Company

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled "Risk Factors" immediately following this prospectus summary. These risks include, among others, the following:

Risks Related to our Finances and Capital Requirements

- We have incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future.
- There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional financing in upcoming periods, which may not be available on acceptable terms to us, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our potential product candidates.

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- 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 (“CAR”) engineered T cell (“CAR T”) technology and oncolytic virus product candidates.
- Our strategic pivot for our lead product candidate, MB-106, and our disposal of non-core assets, including our facility, may not result in the cost savings we anticipate and could result in total costs and expenses that are greater than expected.

Risks Inherent in Drug Development and Commercialization

- Preclinical development is highly speculative and carries a high failure risk.
- We may not receive the required regulatory approvals for any of our product candidates on our projected timelines, if at all, which may result in increased costs and delay our ability to generate revenue.
- We may not obtain the desired labeling claims or intended uses for product promotion, or favorable scheduling classifications, to successfully promote our product candidates, if approved.
- If a product candidate demonstrates adverse side effects, we may need to abandon or limit the development of such product candidate.
- Even if a product candidate is approved, it may be subject to various post-marketing requirements, including studies or clinical trials, and increased regulatory scrutiny.
- Our competitors may develop treatments for our products’ target indications, which could limit our product candidates’ commercial opportunity and profitability.
- If our 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 products.

Risks Related to Reliance on Third Parties

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

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

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

- We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations, particularly with the new presidential administration in the United States.
- 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.

Risks Relating to this Offering

- You will experience immediate dilution in the book value per share of the common stock purchased in the offering.
- If you purchase our securities in this offering, you may experience future dilution as a result of future equity offerings or other equity issuances.
- A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock.
- We have broad discretion to determine how to use the funds raised in this offering and may use them in ways that may not enhance our operating results or the price of our common stock.
- There is no public market for the Warrants and pre-funded warrants being offered in this offering.
- The holders of Warrants and pre-funded warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Warrants and pre-funded warrants and acquire shares of our common stock, except as set forth in the Warrants and pre-funded warrants.

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- The Warrants are speculative in nature.
- The Warrants are not exercisable until stockholder approval, provided however, if the Pricing Conditions are met, the Warrants will be exercisable upon issuance.
- The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future.
- This is a “best efforts” offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

THE OFFERING

Securities we are offering	Up to _____ shares of common stock and accompanying Series C-1 Warrants to purchase up to _____ shares of common stock, Series C-2 Warrants to purchase up to _____ shares of common stock, and Series C-3 Warrants to purchase up to _____ shares of common stock, or pre-funded warrants to purchase _____ shares of common stock and accompanying Series C-1 Warrants to purchase up to _____ shares of common stock, Series C-2 Warrants to purchase up to _____ shares of common stock, and Series C-3 Warrants to purchase up to _____ shares of common stock. The shares of common stock, or pre-funded warrants, and in each case the accompanying Series C-1 Warrants, Series C-2 Warrants, and Series C-3 Warrants will be separately transferable immediately upon issuance, but the shares of common stock, or pre-funded warrants, and in each case the accompanying Warrants will be issued to purchasers in the ratio of one to one.
Description of Series C-1, Series C-2, and Series C-3 Warrants	Each Series C-1 Warrant, Series C-2 Warrant, and Series C-3 Warrant is exercisable for one share of common stock, will have an exercise price of \$ _____ per share, and will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided, however, that if the Pricing Conditions are met, the Warrants will be exercisable upon issuance (the "Initial Exercise Date"). The Series C-1 Warrants will expire on the five-year anniversary of the Initial Exercise Date. The Series C-2 Warrants will expire on the twenty-four-month anniversary of the Initial Exercise Date. The Series C-3 Warrants will expire on the nine-month anniversary of the Initial Exercise Date.
Description of pre-funded warrants	If the issuance of shares of our common stock to a purchaser in this offering would result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering or if such purchaser otherwise elects to purchase pre-funded warrants, then such purchaser may purchase, if they so choose, in lieu of the shares of our common stock that would result in such excess ownership, a pre-funded warrant to purchase shares of our common stock for a purchase price per share of common stock subject to such pre-funded warrant equal to the per share public offering price for the common stock to be sold in this offering less \$0.0001. Each pre-funded warrant will have an exercise price of \$0.0001 per share, will be exercisable upon issuance and may be exercised at any time until all of the pre-funded warrants are exercised in full. Purchasers of pre-funded warrants will also receive accompanying warrants as if such purchasers were buying shares of our common stock in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of these pre-funded warrants.
Common stock outstanding before offering:	64,768,830 shares
Common stock outstanding after this offering	_____ shares of common stock, assuming full exercise of the pre-funded warrants issued in this offering and no exercise of the Warrants being issued in this offering.
Use of proceeds:	We currently intend to use the net proceeds from this offering for working capital and general corporate purposes. See "Use of Proceeds" on page 59 of this prospectus.
Risk factors	An investment in our securities involves a high degree of risk and could result in a loss of your entire investment. Prior to making an investment decision, you should carefully consider all of the information in this prospectus and, in particular, you should evaluate the risk factors set forth under the caption "Risk Factors" beginning on page 16.
Nasdaq Capital Market symbol	Our common stock is listed on the Nasdaq Capital Market under the symbol "MBIO". There is no established public trading market for the Warrants and pre-funded warrants, and we do not expect a market to develop. We do not intend to apply for listing of the Warrants or pre-funded warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Warrants and pre-funded warrants will be limited.

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The number of shares of our common stock to be outstanding after this offering is based on 64,768,830 shares of our stock outstanding as of January 10, 2025, and excludes:

- 76,112 shares of our common stock issuable upon the exercise of outstanding stock options as of January 10, 2025, with a weighted-average exercise price of \$85.95 per share;
- 11,176 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units as of January 10, 2025;
- 78,847,300 shares of our common stock issuable upon the exercise of outstanding warrants as of January 10, 2025, with a weighted-average exercise price of \$0.29 per share;
- 56,359 shares of our common stock issuable upon conversion of the Class A Common Stock, at the holders' election;
- 16,666 shares of our common stock issuable upon conversion of the Class A Preferred Stock, at the holders' election;
- 398,614 shares of our common stock reserved for future issuance under the Mustang Bio, Inc. 2016 Equity Incentive Plan, as amended (the "2016 Plan"), plus any future increases in the number of shares of common stock reserved for issuance thereunder; and
- 338,315 shares of our common stock reserved for future issuance under the Mustang Bio, Inc. 2019 Employee Stock Purchase Plan, as amended (the "ESPP"), plus any future increases, including annual automatic evergreen increases, in the number of shares of common stock reserved for issuance thereunder.

Unless otherwise indicated, all information contained in this prospectus assumes:

- no exercise of the outstanding options, warrants, or pre-funded warrants, and no settlement of the restricted stock units described in the bullets above; and
- no exercise of the Warrants or the Placement Agent Warrants issued in this offering.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. We have listed below (not necessarily in order of importance or probability of occurrence) what we believe to be the most significant risk factors applicable to us. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Some of the statements in the following risk factors constitute forward-looking statements. Please see the section titled “Special 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 and 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 \$14.8 million and \$43.0 million for the nine months ended September 30, 2024 and 2023, respectively, and we had an accumulated deficit of \$395.8 million as of September 30, 2024. 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.

There is substantial doubt regarding our ability to continue as a going concern. We will need to raise additional funding (which may not be available on acceptable terms to us, or at all) and/or delay, limit or terminate our product development efforts or other operations. If we are unable to raise capital, we could be required to 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 hematologic cancers and 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.

As of September 30, 2024, our cash and cash equivalents were \$3.5 million. Based on our current business plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended September 30, 2024, are issued. Our fundraising efforts to raise additional funding may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our potential products following marketing approval if and when obtained. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. Potential indebtedness, if incurred, would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

In addition, in order to address our current funding constraints, we may be required to further revise our business plan and strategy, which may result in us (i) further curtailing, delaying or discontinuing 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) may result in our 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, we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.

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

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

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

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

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

Our operations have consumed substantial amounts of cash since inception. We will need to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we may receive regulatory approval, including building our own commercial organizations to address certain markets. We will require 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. As of September 30, 2024, we had \$3.9 million in cash and restricted cash and have not generated positive cash flows from operations. We cannot provide any assurance that we will be able to raise funds to complete the development of our product candidates. Additionally, if we are unable to secure additional funding, it is likely that we will need to delay or terminate the development of certain product candidates; any such delay or termination, or the announcement of any such delay or termination, may impact our potential growth and have a material adverse effect on the value of our Securities.

In order to carry out our business plan and implement our strategy, we will need to obtain substantial additional financing and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. Additional funding may be more difficult to obtain, or may be more expensive, as a result of recent increases in inflation and interest rates in the U.S. economy generally. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or, if approved, commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

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

- the 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 a New Drug Application (“NDA”) or Biologics License Application (“BLA”) for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of our product candidates from our contract manufacturers for clinical trials and in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates;

- 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.

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

As of the date of the 2023 Form 10-K, our public float was less than \$75 million. As a result, for sales following the date of the 2023 Form 10-K, and until we again have a public float with a value in excess of \$75 million, if ever, we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the amount of securities we may sell under our Form S-3 shelf registration statements will also decrease.

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

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and license and development agreements in connection with any collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, including through lending arrangements, and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, (the “Sarbanes-Oxley Act”), as well as rules subsequently implemented by the SEC, and the rules of the Nasdaq Stock Exchange. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board, 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 more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than \$100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

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

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

We may, from time to time, carry net operating loss carryforwards (“NOLs”) as deferred tax assets on our balance sheet. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which changes are outside our control. As a result, our ability to use our pre-change NOLs and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

Risks Related to Our Business Strategy, Structure, and Organization

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

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

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

- developing our technology platform;
- identifying, developing, formulating, manufacturing and, 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 we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

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

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

Our 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 new approach to cancer treatment that presents significant challenges.

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

- obtaining regulatory approval from the FDA and other regulatory authorities that may have very limited experience with the commercial development of genetically modified T cell therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a patient's T cells ex vivo and infusing the engineered T cells back into the patient;
- conditioning patients with chemotherapy in conjunction with delivering each of our products, which may increase the risk of adverse side effects of our product candidates;
- educating medical personnel regarding the potential side effect profile of each of our product candidates;
- developing processes for the safe administration of these product candidates, including long-term follow-up for all patients who receive our product candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for types of cancers beyond those addressed by our current product candidates.

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 clinical research organizations (“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.

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.

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its establishment inspection program. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party suppliers and contract manufacturers, but we have little control over their compliance with these regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, restrictions on imports and exports, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product and customer confidence in our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recalls, re-stocking costs, damage to our reputation and potential for product liability claims.

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

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

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

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

- regulatory authorities may require the addition of unfavorable labeling statements, including specific warnings, black box warnings, adverse reactions, precautions, and/or contraindications;
- regulatory authorities may suspend or withdraw their approval of the product, and/or require it to be removed from the market;
- we may be required to 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 any of our product candidates or any future product candidate or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues, or any revenues, from 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 regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other applicable regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use and if we market any approved product for uses other than their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food Drug and Cosmetics Act ("FDCA") relating to the promotion of prescription drugs may lead to investigations, civil claims, and/or criminal charges alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

- restrictions on such products, operations, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters, untitled letters, 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 do not know what impact any changes made by the new presidential administration will have on our business. Such actions may impact the development and commercialization of drug products and could materially harm our business and financial condition.

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.

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

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

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

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

- the severity of the disease under investigation;

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

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates or future product candidates, which would cause the value of 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 candidates seen in a broader patient group, (i.e., based on actual use);
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- changes in regulatory requirements by government authorities for our product candidates;
- the relative convenience and ease of administration of the product candidate for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contradictions, warnings, drug interactions, or other precautions;
- changes in the standard of care for the targeted indications for our product candidate or future product candidates, which could reduce the marketing impact of any labeling or marketing claims that we could make following FDA approval;
- the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

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

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

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. We intend to seek approval to market our product candidates in the U.S., the European Union (“EU”) and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates, 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 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 a future product candidate, if approved, 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 candidate 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 many of our product candidates may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Public perception may be influenced by claims that one or more of the therapies underpinning our product candidates 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. Concern about environmental spread of our products, whether real or anticipated, may also hinder the commercialization of our products.

Risks Related to Reliance on Third Parties

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

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

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practices (“GLPs”) as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices (“GCPs”) for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register 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, Fred Hutch, and UAB for a substantial portion of our research and development efforts and the early clinical testing of our product candidates.

A substantial portion of our research and development has been and will continue to be conducted by COH, Fred Hutch, and UAB, pursuant to a sponsored research agreement and/or clinical trial agreements with each of those parties. As a result, our future success is heavily dependent on the results of research and development efforts of 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 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 our product candidates. If our manufacturers or we are unable to purchase these raw materials or equipment after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

The facilities used by contract manufacturers to potentially manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an 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 these items.

Our reliance on these third parties for manufacturing LV vector reduces our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For products that we develop and, 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 vectors are manufactured in accordance with GMP as applied in the relevant jurisdictions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, or manufacture our LV vectors in accordance with GMP, we will not be able to complete, or may be delayed in completing, the preclinical and clinical studies and manufacturing process validation activities required to support future IND, market authorization application and BLA submissions and approval of our product candidates, or to support commercialization of our products, if approved. Many of our agreements with these third parties contain termination provisions that allow these third parties to terminate their relationships with us at any time. If we need to enter into alternative arrangements, our product development and commercialization activities could be delayed.

We may be forced to enter into an agreement with a different manufacturer, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills required to manufacture LV vector for our drug product candidates may be unique or proprietary to the original manufacturer, and we may have difficulty or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Any of these events could lead to clinical study delays or failure to obtain marketing approval or impact our ability to successfully commercialize our product candidates or any future 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 candidate. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates or future product candidate, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised.

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

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

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

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

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

Any products for which we receive marketing authorization may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to successfully commercialize any product candidate for which we receive marketing authorization, will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the healthcare industry in the United States and elsewhere is cost containment. It is currently unknown what impact, if any, proposed changes by the federal and state governments in the U.S. and similar changes in foreign countries may have on pricing and reimbursement, particularly with respect to government programs such as Medicare and Medicaid.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. In the United States, the Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act.

Changes to and under the Affordable Care Act remain possible but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. We also expect that the Affordable Care Act, as well as other healthcare reform measures that have and 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 our products and product candidates, if approved. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers.

The Inflation Reduction Act of 2022 (the “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. Orphan drugs that treat only one rare disease are exempt from the IRA’s drug negotiation program. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The effects of the IRA on the pharmaceutical industry in general are not yet known.

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, once 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 product or future product candidate. 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 products. 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 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. We also do not know what impact any changes made by the new presidential administration will have on our business. Such actions may impact the development and commercialization of drug products and could materially harm our business and financial condition.

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. There is additional uncertainty with the new presidential administration.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business or the business of our partners. The U.S. government has shut down several times 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 health care benefit program through false representations or knowingly and willingly 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 (“HITECH”), 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 governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, including climate-related initiatives. 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.

The use of artificial intelligence in the healthcare industry and challenges with properly managing its use could adversely affect our business.

We may incorporate artificial intelligence ("AI") solutions into our business, and applications of AI may become important in our operations over time. Our competitors or other third parties may incorporate AI into their businesses more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations. There are also significant risks involved in developing and deploying AI, and there can be no assurance that the usage of AI will enhance the development of our product candidates or be beneficial to our business, including our efficiency or profitability. For example, any AI-related efforts, particularly those related to generative AI, could subject us to risks related to harmful content, inaccuracies, bias, discrimination, toxicity, intellectual property infringement or misappropriation, defamation, data privacy, cybersecurity, and sanctions and export controls, among others. It is also uncertain how various laws will apply to content generated by AI. We are subject to the risks of new or enhanced governmental or regulatory scrutiny, litigation, or other legal liability, ethical concerns, negative consumer perceptions as to automation and AI, or other complications that could adversely affect our business, reputation, or financial results.

AI's rapid development is the subject of evolving review by various U.S. governmental and regulatory agencies, and other foreign jurisdictions are applying, or are considering applying, their intellectual property, cybersecurity, data protection and other laws to AI, and/or are considering general legal frameworks on AI. We may not be able to timely comply with these frameworks and, if such regulatory actions are contrary to our use of AI, would require us to expend our limited resources to adjust our use accordingly.

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, Fred Hutch, Nationwide and Mayo Clinic. 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 Second Amended and Restated Founders Agreement (the “Founders Agreement”), which became effective July 22, 2016, Fortress will receive a grant of shares of our common stock equal to two and one-half percent (2.5%) of the gross amount of any equity or debt financing. 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

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

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

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 preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

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

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

Our business could be adversely affected by the effects of health pandemics or epidemics, which could cause significant disruptions in our operations.

Health pandemics or epidemics, such as the COVID-19 pandemic, have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. In addition, impact on the operations of the FDA or other regulatory authorities could negatively affect our planned approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated. The effects of epidemics and pandemic are highly uncertain and subject to change. If we are not able to respond to and manage the impact of such events effectively, our business, operating results, financial condition and cash flows could be adversely affected.

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 consolidated cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Geopolitical changes, including war or other conflicts (including the conflicts between Russia and Ukraine and Israel and Hamas), 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. Tensions between the United States and China have led to a series of tariffs being imposed by the United States on imports from China mainland, 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. With the new presidential administration in the U.S. in 2025, additional and higher tariffs and sanctions may be imposed on goods imported from China and other countries which could increase the cost of goods needed to commercialize our products 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 our products 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.

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

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

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

If any of the foregoing events were to occur, our business operations could be disrupted in ways that would require the incurrence of substantial expenditures to remedy. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for one or more of our product conducts could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data and applications, or inappropriate/unauthorized disclosure of confidential or proprietary information (including trade secrets), we could incur liability and our business and financial condition could be harmed.

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

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

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 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 maintain 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. On March 13, 2024, we received a deficiency letter (the "Letter") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying us that we were not in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1) (the "Equity Rule"). The Equity Rule requires companies listed on the Nasdaq Capital Market to maintain stockholders' equity of at least \$2.5 million (or, in the alternative, a market value of listed securities of \$35 million or net income from continued operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years). As of December 31, 2023, we reported stockholders' equity of \$123,000, and as of September 30, 2024, we reported stockholders' deficit of approximately \$8.7 million.

The Letter had no immediate effect on our continued listing on Nasdaq, subject to our compliance with the other continued listing requirements. In accordance with the Nasdaq Listing Rules, we were provided 45 calendar days, or until April 29, 2024, to submit a plan to regain compliance with the Equity Rule (the "Compliance Plan"). We submitted our Compliance Plan on April 29, 2024, and the Staff granted our request for an extension of 180 calendar days through September 9, 2024, to regain compliance with the Equity Rule. We were unable to demonstrate compliance with the Equity Rule by September 9, 2024.

On September 10, 2024, the Staff formally notified us that it had determined to delist our securities from Nasdaq based upon our continued non-compliance with the Equity Rule unless we timely request a hearing before the Nasdaq Hearings Panel (the "Panel"). On September 17, 2024, we requested a hearing before the Panel, which stayed any further action by Nasdaq at least pending completion of the hearing and the expiration of any extension that may be granted by the Panel to us following the hearing.

On May 16, 2024, we received a notice (the "Second Letter") from the Staff of Nasdaq indicating that the bid price of our common stock had closed below \$1.00 per share for 31 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 Rule"). The Second Letter from Nasdaq had no immediate effect on the listing of our common stock on Nasdaq. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were afforded a 180-calendar day grace period, or until November 12, 2024, to regain compliance with the Bid Price Rule. Compliance can be achieved by evidencing a closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days (but generally not more than 20 consecutive business days) during the 180-calendar day grace period.

The hearing before the Panel occurred on October 29, 2024. By decision dated November 8, 2024, the Panel granted our request for an extension to evidence compliance with all applicable criteria for continued listing on the Nasdaq Capital Market, including the Bid Price Rule, through January 31, 2025, and the Equity Rule through February 18, 2025. We are considering all available options that may enable us to timely evidence compliance with the continued listing criteria and maintain our listing on Nasdaq. There can be no assurance that we will be successful in our efforts to maintain the listing of our common stock on the Nasdaq Capital Market.

If 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.

Risks Related to this Offering

We believe that the proceeds of this offering, combined with our limited funds currently on hand, will only be sufficient for us to operate for a relatively limited amount of time. Since we will be unable to generate sufficient funds, if any, to fund our operations for at least several years, we will need to seek additional equity or debt financing to provide the capital required to implement our business plan. If we are unable to raise capital, we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.

We believe that the proceeds of this offering, combined with our limited funds currently on hand, will only be sufficient for us to operate for a relatively limited amount of time. Since we will be unable to generate sufficient, if any, revenue or cash flow to fund our operations for at least several years, we will need to seek additional equity or debt financing to provide the capital required to implement our business plan.

Additionally, this offering is being made on a “best efforts” basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering, which will provide us only limited working capital. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will meet our capital needs for the next six to nine months under our current business plan. Without giving effect to the receipt of any proceeds from this offering, we currently estimate that our existing cash and cash equivalents are sufficient to fund business operations into the fourth quarter of 2025.

We do not currently have any arrangements or credit facilities in place as a source of funds. There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to further delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. Furthermore, if we are unable to raise capital, we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.

You will experience immediate dilution in the book value per share of the common stock purchased in the offering.

Since the public offering price of our common stock in this offering is substantially higher than the net tangible book value per share of our outstanding common stock outstanding prior to this offering, you will suffer dilution in the book value of the common stock you purchase in this offering. The shares of common stock sold in this offering, if any, will be sold from time to time at various prices. After giving effect to the sale of our common stock in the aggregate offering amount of \$ million at an offering price of \$ per share, and after deducting estimated offering commissions and expenses payable by us, you would suffer immediate dilution of \$ per share in the net tangible book value of the common stock. See the section titled “Dilution” for a more detailed discussion of the dilution you will incur if you purchase shares in this offering.

If you purchase our securities in this offering you may experience future dilution as a result of future equity offerings or other equity issuances.

We will likely offer and issue additional shares of our common stock or other equity or convertible debt securities in order to raise additional capital. Future equity offerings or other equity issuances may be at a price per share that is equal to or greater than the price per share paid by investors in this offering. Future investors in such offerings may have rights superior to existing stockholders, and the price per share at which we sell additional shares of common stock or other equity or convertible debt securities in future transactions may be at a higher or lower price per share than the price per share in this offering.

A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock.

The securities offered hereby will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the “Securities Act”). Sales of a substantial number of shares of our common stock in the public market following this offering, or the perception that such sales could occur, could cause the market price of our common stock to decline.

We have broad discretion to determine how to use the funds raised in this offering and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of net proceeds from this offering, and we could spend the net proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds from this offering for working capital and general corporate purposes, including costs and expenses associated with being a public company. However, our use of these net proceeds may differ substantially from our current plans. If we do not invest or apply the net proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

FINRA sales practice requirements may limit a stockholder’s ability to buy and sell our securities.

Effective June 30, 2020, the SEC implemented Regulation Best Interest requiring that “[a] broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer.” This is a significantly higher standard for broker-dealers to recommend securities to retail customers than before under FINRA “suitability rules. FINRA suitability rules do still apply to institutional investors and require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending securities to their customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status, investment objectives and other information, and for retail customers determine the investment is in the customer’s “best interest” and meet other SEC requirements. Both SEC Regulation Best Interest and FINRA’s suitability requirements may make it more difficult for broker-dealers to recommend that their customers buy speculative, low-priced securities. They may affect investing in our common stock, which may have the effect of reducing the level of trading activity in our securities. As a result, fewer broker-dealers may be willing to make a market in our common stock, reducing a stockholder’s ability to resell our common stock.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including, but not limited to: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings for one year from closing, subject to certain exceptions; (iii) agreement to not enter into any financings for 45 days from closing, subject to certain exceptions; and (iv) indemnification for breach of contract.

There is no public market for the Warrants and pre-funded warrants being offered in this offering.

There is no established public trading market for the Warrants and pre-funded warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Warrants or pre-funded warrants on any securities exchange or nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the Warrants or pre-funded warrants will be limited.

The holders of Warrants and pre-funded warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Warrants or pre-funded warrants and acquire shares of our common stock, except as set forth in the Warrants and pre-funded warrants.

Until a holder of Warrants and pre-funded warrants acquires the shares of common stock upon exercise of the Warrants and pre-funded warrants, as the case may be, such holder will have no rights with respect to the shares of common stock underlying such Warrants and pre-funded warrants, except as set forth in the Warrants and pre-funded warrants. Upon exercise of the Warrants and pre-funded warrants, holders will be entitled to exercise the rights of common stockholders only as to matters for which the record date occurs after the exercise date.

The Warrants are speculative in nature.

The Warrants do not confer any rights of common stock ownership on their holders, such as voting rights, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the Warrants, and consequently, it may not ever be profitable for holders of the Warrants to exercise the Warrants.

The Warrants are not exercisable until stockholder approval, provided however, if the Pricing Conditions are met, the Warrants will be exercisable upon issuance.

The Warrants will have an exercise price of \$ _____ per share and will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided, however, if the Pricing Conditions are met, the Warrants will be exercisable upon issuance (the “Initial Exercise Date”). The Series C-1 Warrants will expire on the five-year anniversary of the Initial Exercise Date. The Series C-2 Warrants will expire on the twenty-four-month anniversary of the Initial Exercise Date. The Series C-3 Warrants will expire on the nine-month anniversary of the Initial Exercise Date.

While we intend to promptly seek Warrant Stockholder Approval, there is no guarantee that the Warrant Stockholder Approval will ever be obtained. If we are unable to obtain the Warrant Stockholder Approval, the Warrants may have no value.

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 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.

This is a "best efforts" offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The Placement Agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The Placement Agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth herein. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds to complete such short-term operations. Such additional fundraises may not be available on terms acceptable to us, or at all.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical or current facts included in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that “we believe” or similar statements reflect our beliefs and opinions on the relevant subject. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those expressed in, or implied by these, forward-looking statements and therefore, you should not unduly rely on such statements, including, but not limited to:

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products we may acquire or in-license;
- use of clinical research centers and other contractors;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our product candidates, if approved;
- expectations for the acceptance of our product candidates, if approved, by doctors, patients or payors;
- ability to compete against other companies and research institutions;
- our ability to attract, hire and retain qualified personnel, including the impact of our recently announced reduction in force;
- ability to secure adequate protection for our intellectual property;
- ability to attract and retain key personnel;
- ability to obtain reimbursement for our products, if approved;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;
- stock price and the volatility of the equity markets;
- expected losses; and
- expectations for future capital requirements.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts, and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section entitled “Risk Factors” in this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ _____ million, after deducting the Placement Agent's fees and estimated offering expenses payable by us, and assuming no exercise of the Warrants being issued in this offering. However, because this is a "best efforts" offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, the Placement Agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus.

These estimates exclude the proceeds, if any, from the exercise of Warrants issued in this offering. If all of the Warrants issued in this offering were to be exercised in cash at an exercise price of \$ _____ per share of common stock, we would receive additional proceeds of approximately \$ _____ million. We cannot predict when or if these Warrants will be exercised. It is possible that these Warrants may expire and may never be exercised. Additionally, the Warrants contain a cashless exercise provision that permit exercise of Warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act covering the issuance of the underlying shares.

We intend to use the net proceeds of this offering for working capital, general corporate purposes and the payment of outstanding payables incurred in the ordinary course. General corporate purposes may include, and are not limited to, research and development costs, manufacturing costs, the acquisition or licensing of other businesses, products or product candidates, working capital and capital expenditures. These expected uses represent our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, as well as any new collaborations that we may enter into with third parties for our product candidates, the commercialization of our products or our product candidates, if approved, and any unforeseen cash needs. As a result, our management will have broad discretion in the application of the net proceeds from this offering, and the investors will be relying on the judgment of our management regarding the application of the net proceeds from this offering.

Pending application of the net proceeds as described above, we intend to invest the net proceeds of this offering in short-term, investment-grade, interest-bearing securities.

MARKET INFORMATION FOR COMMON STOCK AND DIVIDEND POLICY

Market Information

Our common stock is currently listed on the Nasdaq Capital Market under the symbol “MBIO”.

As of January 10, 2025, we had approximately 64,768,830 shares of common stock issued and outstanding held of record by approximately 72 registered holders.

Dividends

We have never declared or paid cash dividends on our common stock. We intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2024 as follows:

- on an actual basis; and
- on an as adjusted basis to reflect the issuance and sale by us of up to _____ shares of common stock, pre-funded warrants to purchase up to _____ shares of common stock, Series C-1 Warrants to purchase up to _____ shares of common stock, Series C-2 Warrants to purchase up to _____ shares of common stock, and Series C-3 Warrants to purchase up to _____ shares of common stock in this offering at a public offering price of \$ _____ per share and accompanying Warrants and after deducting Placement Agent fees and estimated offering expenses payable by us, and assuming exercise in full of any pre-funded warrants offered in this offering, no exercise of the Warrants being offered in this offering, that no value is attributed to such Warrants and that such Warrants are classified as and accounted for as equity.

You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as our financial statements and related notes and the other financial information appearing elsewhere in this prospectus. The information presented in the capitalization table has been adjusted to reflect the effect of this current offering.

(in thousands, except share and per share amounts)	As of September 30, 2024	
	Actual	As adjusted
Cash and cash equivalents	\$ 3,525	\$ _____
Stockholders’ equity		
Common stock, par value \$0.0001 per share; 200,000,000 shares authorized at September 30, 2024; 36,827,671 shares issued and outstanding, actual; shares issued and outstanding, as adjusted	3	
Additional paid-in capital	387,112	
Accumulated deficit	(395,771)	
Total stockholders’ equity/(deficit)	\$ (8,656)	\$ _____
Total capitalization	\$ (8,656)	\$ _____

The foregoing discussion and tables above are based on 36,827,671 shares of common stock outstanding as of September 30, 2024, and excludes:

- 76,112 shares of our common stock issuable upon the exercise of outstanding stock options as of September 30, 2024, with a weighted-average exercise price of \$85.95 per share;
- 11,379 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units as of September 30, 2024;
- 60,957,004 shares of our common stock issuable upon the exercise of outstanding warrants as of September 30, 2024, with a weighted-average exercise price of \$0.29 per share;
- 56,359 shares of our common stock issuable upon conversion of the Class A Common Stock, at the holders’ election;
- 16,666 shares of our common stock issuable upon conversion of the Class A Preferred Stock, at the holders’ election;
- 398,317 shares of our common stock reserved for future issuance under the 2016 Plan, plus any future increases in the number of shares of common stock reserved for issuance thereunder; and
- 338,315 shares of our common stock reserved for future issuance under the ESPP, plus any future increases, including annual automatic evergreen increases, in the number of shares of common stock reserved for issuance thereunder.

DILUTION

If you invest in our common stock, your interest will be immediately diluted to the extent of the difference between the public offering price per share and the as adjusted net tangible book value per share of our common stock after this offering. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding.

As of September 30, 2024, our net tangible book deficit was \$(8.7) million, or \$(0.24) per share of common stock, based on 36,827,671 shares of common stock outstanding as of September 30, 2024.

After giving effect to the sale of up to _____ shares of common stock, pre-funded warrants to purchase up to _____ shares of common stock, Series C-1 Warrants to purchase up to _____ shares of common stock, Series C-2 Warrants to purchase up to _____ shares of common stock, and Series C-3 Warrants to purchase up to _____ shares of common stock at a public offering price per share of common stock and accompanying Warrants of \$ _____ assuming exercise in full of any pre-funded warrants offered in this offering, and after deducting the estimated placement agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the Warrants issued in this offering, our as adjusted net tangible book value as of September 30, 2024 would have been approximately \$ _____ million, or approximately \$ _____ per share. This represents an immediate increase in net tangible book value to existing shareholders of \$ _____ per share and an immediate dilution in net tangible book value of \$ _____ per share of our common stock to the investors purchasing securities in this offering.

The following table illustrates this per share dilution to the new investors purchasing shares of common stock in this offering:

Combined public offering price per share of common stock and accompanying Warrants		\$
Historical net tangible book value (deficit) per share as of September 30, 2024	\$	(0.24)
Increase in net tangible book value per share attributable to investors purchasing in this offering	\$	
As adjusted net tangible book value per share as of September 30, 2024 after this offering		\$
Dilution per share to investors purchasing in this offering		\$

The foregoing discussion and tables above are based on 36,827,671 shares of common stock outstanding as of September 30, 2024, and excludes:

- 76,112 shares of our common stock issuable upon the exercise of outstanding stock options as of September 30, 2024, with a weighted-average exercise price of \$85.95 per share;
- 11,379 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units as of September 30, 2024;
- 60,957,004 shares of our common stock issuable upon the exercise of outstanding warrants as of September 30, 2024, with a weighted-average exercise price of \$0.29 per share;
- 56,359 shares of our common stock issuable upon conversion of the Class A Common Stock, at the holders' election;
- 16,666 shares of our common stock issuable upon conversion of the Class A Preferred Stock, at the holders' election;
- 398,317 shares of our common stock reserved for future issuance under the 2016 Plan, plus any future increases in the number of shares of common stock reserved for issuance thereunder; and
- 338,315 shares of our common stock reserved for future issuance under the ESPP, plus any future increases, including annual automatic evergreen increases, in the number of shares of common stock reserved for issuance thereunder.

To the extent that any outstanding options or warrants are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares in the future, there will be further dilution to new investors participating in this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the sections entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

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 in two core areas: CAR T therapies for hematologic malignancies and CAR T 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"), Fred Hutchinson Cancer Center ("Fred Hutch"), 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. However, there can be no assurance that we will be successful in securing additional resources when needed, on terms acceptable to us, if at all. Therefore, there exists substantial doubt about our ability to continue as a going concern. The financial statements included in this prospectus do not include any adjustments related to the recoverability of assets that might be necessary despite this uncertainty.

CAR T Therapies

Our pipeline of CAR T therapies is being developed under exclusive licenses from several world class research institutions. Our strategy is to license these technologies, support preclinical and clinical research activities by our partners and transfer the underlying technology to our or our contract manufacturer's cell processing facility in order to conduct our own clinical trials.

We are developing CAR T therapy for hematologic malignancies in partnership with Fred Hutch targeting CD20 (MB-106). In May 2021, we announced that the U.S. Food and Drug Administration ("FDA") accepted our Investigational New Drug ("IND") Application for MB-106. As of January 2025, 53 patients have been treated in an ongoing Phase 1 clinical trial sponsored by Fred Hutch (ClinicalTrials.gov Identifier: NCT03277729) and 20 patients have been treated in the Phase 1 clinical trial sponsored by us (ClinicalTrials.gov Identifier: NCT05360238). In 2023, we received Safety Review Committee approval to continue dose escalation in all three active arms of the ongoing Mustang-sponsored Phase 1 trial. We presented the latest results, demonstrating a favorable safety profile, complete response rate, and durability, from the ongoing Mustang-sponsored Phase 1 trial at the 2023 American Society of Hematology ("ASH") Annual Meeting.

We are also developing CAR T therapy for solid tumors in partnership with COH targeting IL13R α 2 (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) began during the third quarter of 2019. 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 IL13R α 2+ relapsed or refractory glioblastoma ("GBM") and high-grade astrocytoma.

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

In the first quarter of 2024, we completed a successful End-of-Phase 1 meeting with the FDA regarding a potential pivotal Phase 2 single-arm clinical trial for the treatment of WM. Per the discussions, the FDA agreed with the proposed overall design of the pivotal trial for Waldenstrom macroglobulinemia (“WM”) at the recommended dose of 1×10^7 CAR-T cells/kg and requested only minimal modifications to the study protocol. No additional nonclinical studies are expected prior to Phase 2 or a Biologics License Application (“BLA”) filing. Due to limited resources, and as a result of the reduction in work force described below, we do not expect to initiate our pivotal Phase 2 single-arm clinical trial of MB-106 for the treatment of WM trial in 2025. Subject to available funds, we intend to rely on third party service providers to conduct study and manufacturing services to advance our priority potential product candidates.

Also in the first quarter of 2024, we completed enrollment of the indolent lymphoma arm in our multicenter Phase 1 trial. The tenth and final patient enrolled on that arm was a patient with follicular lymphoma (FL) who achieved a complete response following treatment with 1×10^7 CAR-T cells/kg. As a result, the overall complete response rate for FL in the Phase 1 portion of this trial was sustained at 100% (N=6), with no occurrence of cytokine release syndrome (“CRS”) above grade 1 and no immune effector cell-associated neurotoxicity syndrome (“ICANS”) of any grade, despite not using prophylactic tocilizumab or dexamethasone.

In March 2024, we announced plans to collaborate with Fred Hutch for a proof-of-concept Phase 1 investigator-sponsored clinical trial evaluating MB-106 in autoimmune diseases.

In March 2024, we were granted the Regenerative Medicine Advanced Therapy (“RMAT”) designation by the FDA for the treatment of relapsed or refractory CD20 positive WM and FL, based on potential improvement in response as seen in clinical data to date. Drugs eligible for RMAT designation are those intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and that present preliminary clinical evidence indicating the drug has the potential to address unmet medical needs for such disease or condition. RMAT designation provides regenerative medicine advanced therapy products with the same benefits to expedite the development and review of a marketing application that are available to drugs that receive Breakthrough Therapy Designation. These advantages include timely advice and interactive communications with FDA, as well as proactive and collaborative involvement by senior FDA managers and experienced review and regulatory health project management staff. A product designated as an RMAT also may be eligible for other FDA-expedited programs, such as Priority Review. The FDA also may conduct a rolling review of products in its expedited programs, reviewing portions of a marketing application before the complete application is submitted.

In June 2024, we announced that updated data for MB-106 in the Phase 1/2 Fred Hutch investigator-sponsored trial showed a favorable safety and efficacy profile in 10 patients with WM. There was an overall response rate (“ORR”) of 90% with durable responses observed, including three complete responses (“CR”), two very good partial responses (“VGPR”), and four partial responses (“PR”). One of the patients who achieved a CR remained in remission for 31 months, with an immunoglobulin M (IgM) level that decreased rapidly to the normal range after treatment with MB-106 and remained normal since. Patients had a median of nine prior lines of therapy, and only one patient started additional anti-WM treatment after being treated with MB-106. From a safety perspective, CRS occurred in nine patients: five patients with grade 1 and four patients with grade 2. One patient experienced grade 1 ICANS. No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS was observed, despite dose escalation.

In May 2024, we informed the clinical sites participating in the Mustang-sponsored Phase 1/2 study in non-Hodgkin lymphoma and chronic lymphocytic leukemia, MB106-CD20-001, that we had decided to close the trial. In June 2024, we similarly informed the clinical sites participating in the Mustang-sponsored Long-term Follow-up Study in Patients Previously Treated with Mustang Bio, Inc. CAR-T Cell Investigational Products, MB100-OBS-001, that we had decided to close that trial. As a result, further clinical development of MB-106 is currently focused solely on autoimmune diseases unless funding and resources become available to restart the program for hematologic malignancies. Planning for the aforementioned Phase 1 investigator-sponsored clinical trial in autoimmune diseases is in progress, with initiation of the trial planned for 2025.

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

In October 2023, we received a safe-to-proceed “approval” from the FDA for our MB-109 IND application allowing us to initiate a Phase 1, open-label, non-randomized, multicenter study of MB-109 in patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma. In this Phase 1 clinical study, we intend to evaluate the combination of CAR-T cells (MB-101) and the herpes simplex virus type 1 oncolytic virus (MB-108) in patients with IL13R α 2+ high-grade gliomas. The design of this study involves first a lead-in cohort, wherein patients are treated with MB-101 alone without prior MB-108 administration. After successful confirmation of the safety profile of MB-101 alone, the study will then investigate increasing doses of intratumorally administered MB-108 followed by dual intratumoral (ICT) and intraventricular (ICV) administration of MB-101.

On November 7, 2024, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-108, a herpes simplex virus type 1 (“HSV-1”) oncolytic virus, for the treatment of malignant glioma. 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 to conduct an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma with MB-109 and could potentially be initiated in the second half of 2025.

Terminated Product Candidates (Gene Therapies and in vivo CAR-T)

We previously developed several gene therapy product candidates, which included MB-117 and MB-217 (based on technologies licensed from St. Jude Children’s Research Hospital (“St. Jude”)) and MB-110 (based on technologies licensed from Leiden University Medical Centre (“LUMC”)). In April 2024, we entered into a termination and release agreement with St. Jude, pursuant to which we agreed to terminate the license agreement underpinning the MB-117 and MB-217 product candidates in exchange for a mutual release of liability and forgiveness by St. Jude of all amounts previously owing to them. Also in April 2024, we delivered a termination notice to LUMC pursuant to which we terminated the license agreement underpinning the MB-110 product candidate; we are currently in discussions with LUMC regarding the terms that will govern such termination. In June 2024, we also agreed with Mayo Foundation for Medical Education and Research (“Mayo Clinic”) to terminate the license agreement underpinning our (now former) preclinical *in vivo* CAR-T program, together with a related sponsored research agreement, in exchange for a mutual release of liability and forgiveness by Mayo Clinic of all amounts previously owed to them.

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.

Recent Developments

April 2024 Reduction in Work Force

On April 10, 2024, our board of directors approved a reduction of our workforce by approximately 81% of our employee base in order to reduce costs and preserve capital due to the fundraising environment and continued uncertainty regarding the CFIUS review of the sale of the Facility and the Transaction with uBriGene (Boston) Biosciences, Inc., a Delaware corporation (“uBriGene”). The workforce reduction took place primarily in April 2024 and was completed in the second quarter of 2024. As a result of these actions, we incurred personnel-related restructuring charges of approximately \$0.2 million in connection with one-time employee termination cash expenditures, which were incurred in the second quarter of 2024.

Sale of Manufacturing Facility – Overview of Transaction

On May 18, 2023, we entered into an Asset Purchase Agreement (the “Original Asset Purchase Agreement”) with uBriGene, pursuant to which we agreed to sell our leasehold interest in our cell processing facility located in Worcester, Massachusetts (the “Facility”), and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene (the “Transaction”). We and uBriGene subsequently entered into Amendment No. 1, dated as of June 29, 2023, and Amendment No. 2, dated as of July 28, 2023, to the Original Asset Purchase Agreement (the Original Asset Purchase Agreement, as so amended, the “Prior Asset Purchase Agreement”).

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

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

uBriGene is an indirect, wholly owned subsidiary of UBriGene (Jiangsu) Biosciences Co., Ltd., a Chinese contract development and manufacturing organization. Under the Prior Asset Purchase Agreement, we and uBriGene agreed to use our reasonable best efforts to obtain clearance for the Transaction from the U.S. Committee on Foreign Investment in the United States (“CFIUS”), although obtaining such clearance was not a condition to closing the Transaction. In accordance with the Prior Asset Purchase Agreement, we and uBriGene previously submitted a voluntary joint notice to CFIUS on August 10, 2023.

Following an initial 45-day review period and subsequent 45-day investigation period, on November 13, 2023, CFIUS requested that we and uBriGene withdraw and re-file our joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon CFIUS’s request, we and uBriGene submitted a request to withdraw and re-file our joint voluntary notice to CFIUS, and on November 13, 2023, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period on November 14, 2023. CFIUS’s 45-day review ended on December 28, 2023. Since CFIUS had not concluded its review by December 28, 2023, the proceeding transitioned to a subsequent 45-day investigation period, which ended on February 12, 2024.

Following the 45-day review period and subsequent 45-day investigation period described above, on February 12, 2024, we and uBriGene requested permission to withdraw and re-file our joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon our joint request to withdraw and re-file their joint voluntary notice to CFIUS, on February 12, 2024, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period on February 13, 2024. CFIUS’s new 45-day review ended on March 28, 2024. Because CFIUS had not yet concluded its action, the proceeding transitioned to a second 45-day phase as CFIUS further investigated the Transaction. On March 28, 2024, CFIUS advised us that its investigation would be completed no later than May 13, 2024.

On May 13, 2024, together with uBriGene and CFIUS, we executed a National Security Agreement (the “NSA”), pursuant to which we and uBriGene agreed to abandon the Transaction and all other transactions contemplated by the Asset Purchase Agreement and the agreements entered into in connection therewith. The execution of the NSA was the result of CFIUS’ determination that such transactions posed a risk to the national security of the United States. We disagree with this position but did not feel a meaningful likelihood existed that the Transaction would be consummated in light of CFIUS’ objections. The NSA imposes certain conditions on us and uBriGene and its affiliates. Most significantly, we agreed (i) not to effect the Transaction with uBriGene or any of its affiliates; and (ii) to appoint a point of contact representative with whom CFIUS and uBriGene’s designated contact person may interact as needed. The NSA also obligates uBriGene to sell, or otherwise dispose of, the equipment assets purchased within 180 days after the execution of the NSA, with uBriGene able to eliminate some of its obligations under the NSA if it is able to sell the equipment assets purchased back to us within 45 days after the execution of the NSA (an “Expedited Divestment”).

June 2024 Repurchase of Assets

On June 27, 2024 (the “Effective Date”), we entered into an Asset Purchase Agreement (the “Asset Purchase Agreement”) with uBriGene, pursuant to which we agreed, subject to the terms and conditions set forth therein, to repurchase (the “Repurchase Transaction”) the assets, properties and rights previously transferred by the Company to uBriGene under the Prior Asset Purchase Agreement, excluding any inventory transferred under the Purchase Agreement that has been consumed or transferred to a third party by uBriGene since the closing of the Prior Asset Purchase Agreement (collectively, the “Repurchased Assets”). For the avoidance of doubt, “Repurchased Assets” also includes all Mustang Assets (as such term is defined in the NSA) that were previously sold, transferred, conveyed, assigned, delivered, or contributed by us or our affiliates to uBriGene or its affiliates, to the extent such assets have not been consumed or transferred to a third party by uBriGene since the closing of the Prior Asset Purchase Agreement. The Repurchased Assets do not include inventory acquired by uBriGene after the closing of the Prior Asset Purchase Agreement. We further agreed to assume all obligations, liabilities and commitments previously transferred by us to uBriGene under the Prior Asset Purchase Agreement. The Repurchase Transaction was intended to constitute an Expedited Divestment by uBriGene pursuant to the NSA with CFIUS.

As consideration for the Repurchase Transaction, we agreed to pay to uBriGene a total purchase price (the “Purchase Price”) of \$1,395,138, consisting of (i) an upfront payment of \$100,000 due within five (5) business days of the Effective Date and a (ii) subsequent amount of \$1,295,138 due on the date that is twelve (12) months after the Closing (the “Deferred Amount”). In the event that as of the original (or any extended) date on which the Deferred Amount is payable we have, as of the date of the public reporting of our then-most recent quarterly audited or unaudited financial statements, net assets below \$20 million, then we may, upon written notice to uBriGene, elect to delay our payment obligation of the Deferred Amount by an additional six (6) months, with no limit on the number of such extensions available to us. Notwithstanding the foregoing, if we have not paid the Deferred Amount in full as of the date that is 12 (twelve) months after closing of the Repurchase Transaction, any amounts that remain outstanding will accrue interest at a rate of 5% per annum beginning on the date that is 12 (twelve) months after closing and until the Deferred Amount is paid in full.

The Asset Purchase Agreement contains customary representations and warranties from both us and uBriGene with respect to each party. Additionally, we agreed to provide a purchase price allocation schedule to uBriGene within sixty (60) days of the Effective Date.

Pursuant to the terms of the Asset Purchase Agreement, we and uBriGene terminated the following agreements between us that were entered into in connection with the Asset Purchase Agreement: (i) the Manufacturing Services Agreement, dated July 28, 2023, and work orders entered into under such agreement, (ii) the Quality Services Agreement, dated July 28, 2023, (iii) the Subcontracting CDMO Agreement, dated July 28, 2023, and work orders entered into under such agreement, (iv) the Subcontracting Quality Services Agreement, dated July 28, 2023, and (v) the Transition Services Agreement.

Notification of Non-Compliance with Nasdaq Continued Listing Requirements

On March 13, 2024, we received a deficiency letter (the “Letter”) from the Listing Qualifications Department (the “Staff”) of The Nasdaq Stock Market LLC (“Nasdaq”) notifying us that we were not in compliance with the minimum stockholders’ equity requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1) (the “Equity Rule”). The Equity Rule requires companies listed on the Nasdaq Capital Market to maintain stockholders’ equity of at least \$2.5 million (or, in the alternative, a market value of listed securities of \$35 million or net income from continued operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years). As of December 31, 2023, we reported stockholders’ equity of \$123,000, and as of September 30, 2024, we reported stockholders’ deficit of approximately \$8.7 million.

The Letter had no immediate effect on our continued listing on Nasdaq, subject to our compliance with the other continued listing requirements. In accordance with the Nasdaq Listing Rules, we were provided 45 calendar days, or until April 29, 2024, to submit a plan to regain compliance with the Equity Rule (the “Compliance Plan”). We submitted our Compliance Plan on April 29, 2024, and the Staff granted our request for an extension of 180 calendar days through September 9, 2024, to regain compliance with the Equity Rule. We were unable to demonstrate compliance with the Equity Rule by September 9, 2024.

On September 10, 2024, the Staff formally notified us that it had determined to delist our securities from Nasdaq based upon our continued non-compliance with the Equity Rule unless we timely request a hearing before the Nasdaq Hearings Panel (the “Panel”). On September 17, 2024, we requested a hearing before the Panel, which stayed any further action by Nasdaq at least pending completion of the hearing and the expiration of any extension that may be granted by the Panel to us following the hearing.

On May 16, 2024, we received a notice (the “Second Letter”) from the Staff of Nasdaq indicating that the bid price of our common stock had closed below \$1.00 per share for 31 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 Rule”). The Second Letter from Nasdaq had no immediate effect on the listing of our common stock on Nasdaq. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were afforded a 180-calendar day grace period, or until November 12, 2024, to regain compliance with the Bid Price Rule. Compliance can be achieved by evidencing a closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days (but generally not more than 20 consecutive business days) during the 180-calendar day grace period.

The hearing before the Panel occurred on October 29, 2024. By decision dated November 8, 2024, the Panel granted our request for an extension to evidence compliance with all applicable criteria for continued listing on the Nasdaq Capital Market, including the Bid Price Rule, through January 31, 2025, and the Equity Rule through February 18, 2025. We are considering all available options that may enable us to timely evidence compliance with the continued listing criteria and maintain our listing on Nasdaq. There can be no assurance that we will be successful in our efforts to maintain the listing of our common stock on the Nasdaq Capital Market.

Reverse Stock Split

On January 14, 2025, we announced that we will effect a 1-for-50 reverse stock split of our issued and outstanding common stock. The reverse stock split was approved on June 27, 2024 by our board of directors and stockholders representing approximately 56% of the voting power of our outstanding capital stock, with the authorization to determine the final ratio having been granted to our board of directors. The reverse stock split is intended to bring the Company into compliance with Nasdaq’s Bid Price Rule.

The reverse stock split will be effected on our common stock by the filing of a certificate of amendment (the “Amendment”) to our amended and restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware on January 15, 2025, without any change to par value. The Amendment will become effective upon such filing. No fractional shares will be issued in connection with the reverse stock split as all fractional shares will be rounded down to the next whole share.

Financing Activities

May 2024 Equity Offering

On April 29, 2024, we commenced a best efforts equity offering with an institutional investor (the “Investor”) (the “May 2024 Offering”) of an aggregate of (i) 1,160,000 shares of common stock, (ii) pre-funded warrants (the “May 2024 Pre-Funded Warrants”) to purchase up to an aggregate of 15,717,638 shares of common stock (the “May 2024 Pre-Funded Warrant Shares”), (iii) Series A-1 warrants (the “Series A-1 Warrants”) to purchase up to an aggregate of 16,877,638 shares of common stock (the “Series A-1 Warrant Shares”), (iv) Series A-2 warrants (the “Series A-2 Warrants”) to purchase up to an aggregate of 16,877,638 shares of common stock (the “Series A-2 Warrant Shares”), and (v) Series A-3 warrants (the “Series A-3 Warrants,” and together with the Series A-1 Warrants and Series A-2 Warrants, the “Warrants”) to purchase up to an aggregate of 16,877,638 shares of common stock (the “Series A-3 Warrant Shares”). Each share of common stock or May 2024 Pre-Funded Warrant was sold together with one Series A-1 Warrant to purchase one share of common stock, one Series A-2 Warrant to purchase one share of common stock, and one Series A-3 Warrant to purchase one share of common stock. The equity offering price for each share of common stock and accompanying Warrants was \$0.237, and the equity offering price for each May 2024 Pre-Funded Warrant and accompanying Warrants was \$0.2369.

The May 2024 Pre-Funded Warrants have an exercise price of \$0.0001 per share, were exercisable immediately and will expire when exercised in full. Each Warrant has an exercise price of \$0.237 per share, will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Warrants (the “Warrant Stockholder Approval”), which was obtained on June 27, 2024. The Series A-1 Warrant will expire on the five-year anniversary of the Warrant Stockholder Approval. The Series A-2 Warrant will expire on the twenty-four-month anniversary of the Warrant Stockholder Approval. The Series A-3 Warrant will expire on the nine-month anniversary of the Warrant Stockholder Approval.

The net proceeds of the May 2024 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 us, but excluding the net proceeds, if any, from the exercise of the Warrants, were approximately \$3.2 million. The May 2024 Offering closed on May 2, 2024.

In connection with the May 2024 Offering, we also entered into a warrant amendment agreement (the “Warrant Amendment Agreement”) with the Investor. Under the Warrant Amendment Agreement, we agreed to amend certain existing warrants to purchase

up to 2,588,236 shares of common stock that were previously issued in October 2023 to the Investor, with an exercise price of \$1.58 per share (the “Existing Warrants”), in consideration for their purchase of the securities in the May 2024 Offering, as follows: (i) lower the exercise price of the Existing Warrants to \$0.237 per share, (ii) provide that the Existing Warrants, as amended, will not be exercisable until the receipt of Warrant Stockholder Approval for the exercisability of the Warrants in the May 2024 Offering, and (iii) extend the original expiration date of the Existing Warrants by five years following the receipt of such Warrant Stockholder Approval. The Warrant Amendment Agreement became effective on May 2, 2024.

June 2024 Registered Direct Offering and Concurrent Private Placement of Warrants (the “June 2024 Offering”)

On June 19, 2024, we entered into a Securities Purchase Agreement (the “June 2024 SPA”) with an institutional accredited investor, pursuant to which we agreed to issue and sell, in a registered direct offering priced at-the-market under the rules of Nasdaq (the “Registered Direct Offering”), (i) 3,025,000 shares of common stock, at a price per Share of \$0.41 and (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 3,105,000 shares of our common stock, at a price per Pre-Funded Warrant equal to \$0.4099, the price per share of common stock, less \$0.0001.

The Pre-Funded Warrants were sold, in lieu of shares of common stock, to the investor, whose purchase of shares of common stock in the Registered Direct Offering would otherwise result in the investor, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the investor’s option upon issuance, 9.99%) of our outstanding common stock immediately following the completion of the Registered Direct Offering. The Pre-Funded Warrants have an exercise price of \$0.0001 per share, became exercisable upon issuance and remain exercisable until exercised in full.

The Registered Direct Offering closed on June 21, 2024. We intend to use the net proceeds of approximately \$2.1 million from the Registered Direct Offering for general corporate purposes and working capital requirements.

In a concurrent private placement, pursuant to the terms of the June 2024 SPA, we also agreed to issue and sell to the investor unregistered warrants (the “Private Placement Warrants”) to purchase up to 6,130,000 shares of common stock, at an offering price of \$0.41 per Private Placement Warrant to purchase one share of common stock (the “Private Placement”) and, together with the Registered Direct Offering, the “Offerings”) (which offering price was included in the purchase price per share of common stock or Pre-Funded Warrant). The Private Placement Warrants have an exercise price of \$0.41 per share (subject to customary adjustments as set forth in the Private Placement Warrants), were exercisable upon issuance and will expire five years from the date of issuance. The Private Placement Warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions. The Private Placement Warrants were subsequently registered in July 2024 on Form S-1 (File No. 333-280927).

H.C. Wainwright & Co., LLC (“Wainwright”) acted as the exclusive placement agent in connection with the Offerings under an Engagement Letter, dated as of June 18, 2024, between us and Wainwright (the “Engagement Letter”). Pursuant to the Engagement Letter, we issued to Wainwright (or its designees) warrants to purchase up to 367,800 shares of common stock (the “Wainwright Warrants” and, together with the Private Placement Warrants, the “2024 Warrants”). The Wainwright Warrants have substantially the same terms as the Private Placement Warrants, except that the Wainwright Warrants will expire five years from the commencement of the sales of the Offerings and have an exercise price of \$0.5125 per share (subject to customary adjustment as set forth in the Wainwright Warrants), representing 125% of the purchase price per share of common stock in the Registered Direct Offering.

Warrant Inducement

On October 24, 2024, we entered into an inducement offer letter agreement (the “Inducement Letter”) with a certain investor (the “Holder”) that held outstanding Series A-3 warrants (the “Existing Warrants”) to purchase up to an aggregate of 16,877,638 shares of our common stock, originally issued to the Holder on May 2, 2024.

Pursuant to the Inducement Letter, the Holder agreed to exercise for cash the Series A-3 warrants at the exercise price of \$0.237 per share in partial consideration for our agreement to issue in a private placement new Series B Common Stock purchase warrants to purchase up to (i) 16,877,638 shares of common stock (the “New Series B-1 Warrant Shares”) and (ii) 16,877,638 shares of common stock (the “New Series B-2 Warrant Shares”). Each Warrant has an exercise price of \$0.27 per share and will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Warrants (the “Warrant Stockholder Approval”). The New Series B-1 Warrant will expire on the five-year anniversary of the Warrant Stockholder Approval. The New Series B-2 Warrant will expire on the twelve-month anniversary of the Warrant Stockholder Approval.

The closing of the transaction contemplated pursuant to the Inducement Letter occurred on October 25, 2024 (the “Closing Date”). We received aggregate gross proceeds of approximately \$4.0 million from the exercise of the Existing Warrants by the Holder, before deducting placement agent fees and other expenses payable by us. We intend to use the proceeds for general corporate purposes and working capital requirements.

We engaged Wainwright to act as our exclusive agent in connection with the transaction summarized above and paid Wainwright a cash fee equal to 7.0% of the aggregate gross proceeds from the exercise of the Existing Warrants. In addition, we (i) reimbursed Wainwright for \$50,000 of the fees and expenses of Wainwright’s legal counsel and other of its out-of-pocket expenses, (ii) reimbursed Wainwright for its non-accountable expenses in the amount of \$25,000, and (iii) paid a management fee equal to 1.0% of the gross proceeds raised. We also issued to Wainwright or its designees (“PA Warrant Holders”) placement agent warrants (the “Placement Agent Warrants”) to purchase up to 1,012,658 shares of Common Stock (the “Placement Agent Warrant Shares”). The Placement Agent Warrants have the same terms as the New Series B-1 Warrants, except that the Placement Agent Warrants have an exercise price equal to \$0.2963 per share.

Termination of 2018 At Market Issuance Sales Agreement

On May 31, 2024, we delivered notice to B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.), Cantor Fitzgerald & Co., and the Manager (collectively, the “Agents”) to terminate our At Market Issuance Sales Agreement, dated July 27, 2018, as amended on July 20, 2020, December 31, 2020, and April 14, 2023 (collectively, the “2018 Sales Agreement”), with the Agents. Termination of the 2018 Sales Agreement was effective June 5, 2024, pursuant to Section 13(b) of the 2018 Sales Agreement.

May 2024 At the Market Offering Agreement

On May 31, 2024, we entered into an At the Market Offering Agreement (the “ATM Agreement”) with Wainwright (the “Manager”) under which we may offer and sell, from time to time at our sole discretion, shares of our common stock (the “ATM Shares”), through or to the Manager. The offer and sale, if any, of ATM Shares by us under the Offering Agreement will be made pursuant to our registration statement on Form S-3 (File No. 333-279891) (the “Registration Statement”) under the Securities Act, and the related prospectus included therein, filed with the SEC on May 31, 2024, and declared effective on June 12, 2024.

Under the ATM Agreement, the Manager may sell ATM Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act. The Manager will use commercially reasonable efforts to sell the ATM Shares from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay the Manager a commission of 3.0% of the gross proceeds from the sales of ATM Shares sold through the Manager under the ATM Agreement and have provided the Manager with customary indemnification and contribution rights. We will also reimburse the Manager for certain expenses incurred in connection with the ATM Agreement. Together with the Manager, we may each terminate the ATM Agreement at any time upon specified prior written notice.

The offering of ATM Shares pursuant to the ATM Agreement will terminate upon the earlier of (i) the sale of all ATM Shares subject to the ATM Agreement or (ii) the termination of the ATM Agreement in accordance with its terms.

During the nine months ended September 30, 2024, we issued approximately 2.7 million shares of common stock at an average price of \$0.44 for gross proceeds of \$1.2 million under the ATM Agreement. In connection with these sales, we paid aggregate fees of approximately \$45,000.

Since September 30, 2024, we issued approximately 7.1 million shares of common stock at an average price of \$0.30 for gross proceeds of approximately \$2.1 million under the ATM Agreement. In connection with these sales, we paid aggregate fees of approximately \$0.1 million.

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

Critical Accounting Policies and Use of Estimates

Our financial statements include certain amounts that are based on management’s best estimates and judgments. Our significant estimates include, but are not limited to, useful lives assigned to long-lived assets and amortizable intangible assets, fair value of stock

options and warrants, stock-based compensation, accrued expenses, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in the notes to our financial statements included elsewhere in this prospectus, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Research and Development

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

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

In accordance with ASC 730 10 25 1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. In each case, we evaluate if the license agreement results in the acquisition of an asset or a business. Such licenses purchased by us require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired during the period was reflected as research and development - licenses acquired on the Statements of Operations for the years ended December 31, 2023, and 2022.

Accrued Research and Development Expense

We record accruals for estimated costs of research, preclinical, clinical and manufacturing development within accrued expenses which are significant components of research and development expenses. A substantial portion of our ongoing research and development activities is conducted by third-party service providers. We accrue the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses until the services are rendered.

If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust accrued expenses or prepaid expenses accordingly, which impact research and development expenses. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Accounting Pronouncements

See Note 2 to the financial statements included in this prospectus for the years ended December 31, 2023 and 2022 for a discussion of accounting pronouncements that are expected to materially affect the Company's present or future financial statements.

Smaller Reporting Company Status

We are a “smaller reporting company,” within the meaning of federal securities laws, meaning that the market value of our shares held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K, have reduced disclosure obligations regarding executive compensation and certain other matters, and smaller reporting companies are permitted to delay adoption of certain recent accounting pronouncements discussed in Note 2 to our unaudited financial statements for the nine months ended September 30, 2024 included in this prospectus.

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, 2024 and 2023

(\$ in thousands)	For the three months ended September 30,		Change	
	2024	2023	\$	%
Operating expenses:				
Research and development	\$ 57	\$ 9,527	\$ (9,470)	(99)%
Gain on the sale of property and equipment	—	(1,351)	1,351	100%
General and administrative	1,400	2,131	(731)	(34)%
Total operating expenses	1,457	10,307	(8,850)	(86)%
Loss from operations	(1,457)	(10,307)	8,850	(86)%
Other income (expense)				
Other income	—	138	(138)	(100)%
Interest income	48	115	(67)	(58)%
Interest expense	(1)	(4)	3	(75)%
Total other income (expense)	47	249	(202)	(81)%
Net Loss	\$ (1,410)	\$ (10,058)	\$ 8,648	(86)%

Research and Development Expenses

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

For the three months ended September 30, 2024 and 2023, research and development expenses were \$57,000 and \$9.5 million, respectively. The decrease of approximately \$9.5 million is primarily attributed to decreased expenses of \$1.6 million for personnel related costs, primarily driven by the reduction in workforce, \$3.3 million for R&D other expense, primarily related to higher expenses in the third quarter of 2023 of approximately \$1.5 million of expense incurred for uBriGene services and \$1.5 million of expense for vector supply, \$2.5 million for lab supplies, \$1.0 million for program related expenses, which includes approximately \$0.3 million savings on payables owed to clinical sites, \$0.1 million for facility and depreciation expenses, and \$0.9 million for consulting expenses.

The following table provides a breakout of the components of research and development expenses for the three months ended September 30, 2024 and 2023:

(\$ in thousands)	For the three months ended September 30,	
	2024	2023
R&D program related expenses ⁽¹⁾		
MB-102	\$ —	\$ 394
MB-106 ⁽²⁾	(468)	92
MB-107/207 ⁽³⁾	—	(389)
MB-109	72	356
MB-110	—	125
Mayo in situ CAR T	—	6
All others ⁽⁴⁾	14	30
Total R&D development expense	(382)	614
R&D personnel related expenses	191	1,826
R&D facility and depreciation expense	260	398
R&D consulting expenses	(88)	819
R&D lab supplies	(8)	2,520
R&D other expense ⁽⁵⁾	84	3,350
Total research and development expense	\$ 57	\$ 9,527

(1) Includes sponsored research, license and clinical trial related costs.

(2) Credit for the three months ended September 30, 2024, primarily reflects the savings on the settlement of payables owed to clinical sites.

(3) Credit for the three months ended September 30, 2023, reflects the refunds and credit memos received upon the termination services for the MB-107/207 program.

(4) Includes costs for long-term follow-up and programs that were terminated.

(5) Includes approximately \$1.5 million of expense incurred for uBriGene services and \$1.5 million of expense for vector supply in the third quarter of 2023.

Gain on the Sale of Property and Equipment

During the three months ended September 30, 2023, we recorded a gain on the sale of equipment of approximately \$1.4 million in connection with the sale of assets to uBriGene. There were no sales of property and equipment during the three months ended September 30, 2024.

General and Administrative Expenses

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

For the three months ended September 30, 2024, and 2023, general and administrative expenses were \$1.4 million and \$2.1 million, respectively. The decrease of approximately \$0.7 million is primarily attributed to a \$0.4 million decrease in personnel costs, \$0.2 million decrease in legal and patent protection expenses, and \$0.1 million decrease in consulting.

Other Income or Expense

For the three months ended September 30, 2024, and 2023, other income was \$47,000 and \$0.2 million, respectively. The decrease of approximately \$0.2 million in income is primarily attributed to a \$0.1 million decrease in interest income, and \$0.1 million decrease in other income.

Comparison of the Nine Months Ended September 30, 2024 and 2023

<i>(\$ in thousands)</i>	For the nine months ended September 30,		Change	
	2024	2023	\$	%
Operating expenses:				
Research and development	\$ 8,221	\$ 34,363	\$ (26,142)	(76)%
Asset impairment	2,649	—	2,649	100 %
Gain on the sale of property and equipment	—	(1,351)	1,351	100 %
General and administrative	4,358	7,507	(3,149)	(42)%
Total operating expenses	15,228	40,519	(25,291)	(62)%
Loss from operations	(15,228)	(40,519)	25,291	(62)%
Other income (expense)				
Other income	314	918	(604)	(66)%
Interest income	118	727	(609)	(84)%
Interest expense	(4)	(4,112)	4,108	(100)%
Total other income (expense)	428	(2,467)	2,895	(117)%
Net Loss	\$ (14,800)	\$ (42,986)	\$ 28,186	(66)%

Research and Development Expenses

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

For the nine months ended September 30, 2024 and 2023, research and development expenses were \$8.2 million and \$34.4 million, respectively. The decrease of approximately \$26.2 million is primarily attributed to decreased expenses of \$12.5 million for personnel related costs, reflecting decreased headcount and includes the reversal of \$1.3 million of 2023 accrued bonus that will not be paid due to the reduction in the workforce that occurred in April 2024, \$7.4 million for lab supplies, \$4.2 million for program related expenses, which includes approximately \$0.6 million forgiveness of payables to St. Jude as a result of the mutual termination of the license agreement and \$0.3 million forgiveness of payables to the Mayo Clinic as a result of the termination of the license agreement, \$1.5 million for facility and depreciation expenses, and \$2.1 million for consulting expenses, offset by approximately \$1.5 million increase in other expenses, primarily related to approximately \$3.2 million of expenses incurred related to the June 2024 Repurchase of Assets from uBriGene.

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The following table provides a breakout of the components of research and development expenses for the nine months ended September 30, 2024 and 2023:

(\$ in thousands)	For the nine months ended September 30,	
	2024	2023
R&D program related expenses ⁽¹⁾		
MB-102	\$ (2)	\$ 505
MB-106	1,099	3,026
MB-107/207 ⁽²⁾	(562)	(862)
MB-109	476	945
MB-110	241	309
Mayo in situ CAR T	(294)	588
All others ⁽³⁾	21	648
Total R&D development expense	979	5,159
R&D personnel related expenses ⁽⁴⁾	(948)	11,541
R&D facility and depreciation expense	918	2,463
R&D consulting expenses	670	2,750
R&D lab supplies	175	7,573
R&D other expense ⁽⁵⁾	6,427	4,877
Total research and development expense	\$ 8,221	\$ 34,363

(1) Includes sponsored research, license and clinical trial related costs.

(2) Credit for the nine months ended September 30, 2024, reflects the forgiveness of outstanding payables and accrued expenses due to the mutual termination of the license agreement and related data transfer agreement with St. Jude. Credit for the nine months ended September 30, 2023, reflects credit memos and reimbursements received from termination of services with vendors.

(3) Includes costs for long-term follow-up and programs that were terminated.

(4) Credit for the nine months ended September 30, 2024, primarily reflects the reversal of 2023 accrued bonus that will not be paid due to the reduction in the workforce in April 2024.

(5) Includes approximately \$3.2 million of expenses incurred related to the June 2024 Repurchase of Assets from uBriGene.

Asset Impairment

For the nine months ended September 30, 2024, we incurred impairment charges of \$2.6 million attributable to our assessment of the recoverability of the asset group consisting of leasehold improvements and associated right-of-use asset. No impairment was recorded in the nine months ended September 30, 2023.

Gain on the Sale of Property and Equipment

During the nine months ended September 30, 2023, we recorded a gain on the sale of equipment of approximately \$1.4 million in connection with the sale of assets to uBriGene. No gain on the sale of property and equipment was recorded in the nine months ended September 30, 2024.

General and Administrative Expenses

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

For the nine months ended September 30, 2024, and 2023, general and administrative expenses were \$4.4 million and \$7.5 million, respectively. The decrease of approximately \$3.1 million is primarily attributed to a \$1.3 million decrease in personnel costs, \$1.2 million decrease in legal and patent protection expenses, \$0.3 million decrease in consulting expenses, \$0.1 million decrease in professional services, and a \$0.4 million decrease across various other general and administrative expenses, offset by \$0.2 million increase in the equity fee to Fortress, in connection with the financings and ATM activity.

Other Income or Expense

For the nine months ended September 30, 2024, and 2023, other income (expense) was \$0.4 million and \$(2.5) million, respectively. The increase of approximately \$2.9 million in income is primarily attributed to a \$4.1 million decrease in interest expense, related to the repayment of the Term Loan, partially offset by a \$0.6 million decrease in other income and a \$0.6 million decrease in interest income.

Comparison of the Years Ended December 31, 2023, and 2022

(\$ in thousands)	For the year ended December 31,		Change	
	2023	2022	\$	%
Operating expenses:				
Research and development	\$ 40,513	\$ 62,475	\$ (21,962)	(35)%
Research and development – licenses acquired	527	1,474	(947)	(64)%
Gain on sale of property and equipment	(1,466)	—	(1,466)	100 %
General and administrative	9,686	12,210	(2,524)	(21)%
Total operating expenses	49,260	76,159	(26,899)	(35)%
Loss from operations	(49,260)	(76,159)	26,899	(35)%
Other income (expense)				
Other income	917	1,304	(387)	(30)%
Interest income	850	689	161	23 %
Interest expense	(4,109)	(3,359)	(750)	22 %
Total other income (expense)	(2,342)	(1,366)	(976)	71 %
Net Loss	\$ (51,602)	\$ (77,525)	\$ 25,923	(33)%

Research and Development Expenses

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

Research and development expenses decreased by approximately \$22.0 million from \$62.5 million for the year ended December 31, 2022, to \$40.5 million for the year ended December 31, 2023. The decrease in research and development expense for the year ended December 31, 2023, was primarily attributable to the following:

- \$7.7 million decreased research and development employee compensation costs, including stock compensation, which includes approximately \$3.4 million of costs reimbursed through the subcontracting agreement with uBriGene;
- \$8.2 million decreased laboratory supply costs, including vector manufacturing costs, which includes approximately \$0.9 million of costs reimbursed through the subcontracting agreement with uBriGene;
- \$6.7 million decreased for program related costs, which primarily reflects the reduction of spend on the discontinued programs;
- \$2.9 million decreased other costs including facility related costs, depreciation, consulting; and
- offset by approximately \$3.5 million for increase costs for services provided by uBriGene.

Research and development expenses - licenses acquired decreased by \$0.9 million from \$1.5 million for the year ended December 31, 2022, to \$0.5 million for the year ended December 31, 2023. The decrease in research and development expenses - licenses acquired for the year ended December 31, 2023, reflects approximately \$0.6 million decrease for the annual stock dividend to Fortress, and \$0.3 million decrease in milestone payments related to our licenses with COH in the prior year.

The following table provides a breakout of the components of research and development expenses for the year ended December 31, 2023, and 2022:

(\$ in thousands)	For the year ended December 31,	
	2023	2022
R&D program related expenses ⁽¹⁾		
MB-102	\$ (290)	\$ 1,269
MB-106	4,727	3,953
MB-107/207	(778)	1,588
MB-109	1,140	1,511
MB-110	350	505
Mayo in situ CAR T	594	994
All others ⁽²⁾	672	3,339
Total R&D development expense	6,415	13,159
R&D personnel related expenses	12,835	20,494
R&D facility and depreciation expense	2,765	3,777
R&D consulting expenses	3,286	4,312
R&D lab supplies	8,267	16,438
R&D other expense ⁽³⁾	6,945	4,295
Total research and development expense	\$ 40,513	\$ 62,475

(1) Includes sponsored research, license and clinical trial related costs

(2) Includes the costs for long-term follow-up and programs that were terminated.

(3) Includes services provided by uBriGene under the manufacturing services agreement.

(4) Credits reflect the termination of the programs and refunds from vendors.

Our research and development expenses may vary significantly from period to period depending on where we are in the development plans for our various programs, and the resources we have at the time to commit to those programs. The more significant costs impacting the level of expense include:

- employee-related expenses, which include salaries and benefits;
- license fees and milestone payments related to in-licensed products and technology;
- expenses incurred under agreements with CROs, investigative sites and consultants that conduct our clinical trials and our preclinical activities;
- costs associated with non-clinical activities, and regulatory approvals.

Gain on the Sale of Property and Equipment

Gain on the sale of property and equipment for the year ended December 31, 2023, is attributable to the difference between the base proceeds of \$6.0 million received upon the closing of the uBriGene transaction and the relative fair value of the fixed assets sold.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses, including stock-based compensation, for executives and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor

relations, legal activities including patent fees, and facilities-related expenses. General and administrative expense decreased by approximately \$2.5 million from \$12.2 million for the year ended December 31, 2022, to \$9.7 million for the year ended December 31, 2023. The decrease in general and administrative expense for the year ended December 31, 2023, was primarily attributable to the following:

- \$0.3 million decreased general and administrative employee compensation costs, including stock based;
- \$0.7 million decreased third-party consulting;
- \$0.6 million decreased outside services, including recruiting fees;
- \$0.8 million decreased expense related to equity fees to Fortress;
- \$0.5 million decreased other costs, including business insurance and the Management Services Agreement with Fortress; and
- offset by \$0.4 million increased professional services.

Our general and administrative expenses may vary significantly from period to period depending on the level of effort required to support our research and development group and our ongoing requirements of being a publicly traded company. The more significant costs contributing to our general and administrative expenses include the following:

- support of our research and development activities, including potential product candidates entering the clinic;
- stock compensation granted to key employees and non-employees;
- support of business development activities; and
- professional fees and other costs associated with the regulatory requirements and increased compliance associated with being a publicly traded company.

Other Income (Expense)

Other income (expense) consists primarily of funds received from the NIH grant, interest income earned on cash balances and interest expense on our Term Loan. For the year ended December 31, 2023, and 2022, total other expense was approximately \$2.3 million and \$1.3 million, respectively. The \$1.0 million increase in other expense for the year ended December 31, 2023 was primarily attributable to increased interest expense of \$0.8 million, which reflects \$2.8 million loss on the extinguishment of debt offset by \$2.0 million decrease in interest expense related to the repayment of the Term Loan, \$0.4 million decrease in other income reflecting the end of the NIH grant in August 2023, partially offset by \$0.2 million increase in 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. As of September 30, 2024 and December 31, 2023, we had an accumulated deficit of \$395.8 million and \$381.0 million, respectively.

We have funded our operations to date primarily through the sale of equity. For example, on May 2, 2024, we completed the May 2024 Offering and on June 21, 2024, we completed the June 2024 Offering (together the "Offerings") described in "Financing Activities" above. The net proceeds of the Offerings, after deducting the fees and expenses of the placement agent and other offering expenses payable by us, but excluding the net proceeds from the exercise of the Warrants, were approximately \$5.3 million.

As of September 30, 2024 and December 31, 2023, the Company had cash and cash equivalents of \$3.5 million and 6.2 million, respectively.

On April 10, 2024, our Board approved a reduction in our workforce of approximately 81%, in order to reduce costs and preserve capital due to the fundraising environment and continued uncertainty regarding the CFIUS review of the sale of the Facility and the Transaction with uBriGene. The reduction occurred primarily in April 2024 and was completed in the second quarter. Additionally in April 2024,

we terminated our license agreements with St. Jude and Leiden University Medical Centre. The mutual termination of the St. Jude license and associated Data Transfer Agreement included the forgiveness of outstanding amounts owed by us. In June 2024, we terminated our license agreement with the Mayo Clinic, which included the forgiveness of the outstanding amounts owed by us of approximately \$0.3 million. In June 2024, we also terminated the sublease of the Mercantile Center Facility.

Based on our current operating plan, reflecting these changes described above, we currently expect that such cash and cash equivalents, together with the approximately \$1.4 million net proceeds received from the ATM and \$3.6 million net proceeds from the exercise of warrants in October, as described above, together with the proceeds from this offering, will be sufficient to fund our operations through the fourth quarter of 2025. We will continue to seek additional funding through corporate partnerships and capital markets fundraising. See “Risk Factors—Risks Related to Our Finances and Capital Requirements.”

The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of September 30, 2024, there was substantial doubt about our ability to continue as a going concern for the next 12 months from the date of issuance of the unaudited financial statements included in this prospectus. The financial statements included in this prospectus do not include any adjustments that might be necessary should operations discontinue.

In addition, the amount of proceeds we may be able to raise pursuant to our existing shelf registration statements on Form S-3 may be limited. As of the filing of this prospectus, 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 our registration statements on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by our 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, 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 cancellation/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 cancellation and/or delay fees and penalties.

Cash Flows for the Nine Months Ended September 30, 2024 and 2023

<i>(\$ in thousands)</i>	For the nine months ended September 30,	
	2024	2023
Statement of cash flows data:		
Total cash (used in) provided by:		
Operating activities	\$ (9,413)	\$ (42,223)
Investing activities	—	5,916
Financing activities	6,329	(30,037)
Net change in cash, cash equivalents and restricted cash	<u>\$ (3,084)</u>	<u>\$ (66,344)</u>

Operating Activities

Net cash used in operating activities was \$9.4 million for the nine months ended September 30, 2024, compared to \$42.2 million for the nine months ended September 30, 2023.

Net cash used in operating activities for the nine months ended September 30, 2024, was primarily due to approximately \$14.8 million in net loss, partially offset by \$2.8 million of non-cash items, primarily related to the \$2.6 million asset impairment charge, and a \$2.6 million positive change in operating assets and liabilities.

Net cash used in operating activities for the nine months ended September 30, 2023, was primarily due to approximately \$43.0 million in net loss and a \$2.9 million negative change in operating assets and liabilities, offset in part by \$3.6 million of non-cash items, which

is primarily attributable to a \$2.8 million loss on extinguishment of debt, \$1.6 million of depreciation expense and \$0.4 million of non-cash stock compensation expenses, offset in part by the \$1.4 million gain on the sale of property and equipment to uBriGene.

Investing Activities

During the nine months ended September 30, 2024, no cash was used in or provided by investing activities. Net cash provided by investing activities was \$5.9 million for the nine months ended September 30, 2023, primarily reflecting proceeds from the sale of property and equipment to uBriGene of \$6.0 million.

Financing Activities

Net cash provided by financing activities was \$6.3 million during the nine months ended September 30, 2024, primarily reflecting the proceeds from the May and June 2024 Offerings and the ATM.

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

Cash Flows for the Years Ended December 31, 2023 and 2022

<i>(\$ in thousands)</i>	For the year ended December 31,	
	2023	2022
Statement of cash flows data:		
Total cash (used in) provided by:		
Operating activities	\$ (49,477)	\$ (65,066)
Investing activities	5,886	(2,952)
Financing activities	(26,081)	34,056
Net change in cash, cash equivalents and restricted cash	<u>\$ (69,672)</u>	<u>\$ (33,962)</u>

Operating Activities

Net cash used in operating activities was \$49.5 million for the year ended December 31, 2023, compared to \$65.1 million for the year ended December 31, 2022. Net cash used in operating activities for the year ended December 31, 2023, was primarily due to approximately \$51.6 million in net loss, \$3.0 million change in operating assets and liabilities, and \$1.5 million gain on the sale of property and equipment, partially offset by \$1.9 million of depreciation expense, \$0.6 million of non-cash stock compensation expenses, \$0.5 million of common shares issuable in connection with our Founders Agreement, \$0.1 million equity fee to Fortress related to Mustang ATM and the Registered Direct Offering, \$0.1 million of amortization of debt discount, \$2.8 million loss on extinguishment of debt due to the repayment of the Term Loan, \$0.4 million of amortization of operating lease right-of-use assets, and \$0.2 million gain on lease modification.

Net cash used in operating activities for the year ended December 31, 2022, was primarily due to approximately \$77.5 million in net loss, partially offset by \$4.0 million change in operating assets and liabilities, \$2.7 million of depreciation expense, \$2.3 million of non-cash stock compensation expenses, \$1.1 million of common shares issuable for the Founders Agreement, \$0.7 million equity fee to Fortress related to the Term Loan, \$0.5 million of amortization of debt discount, \$0.4 million of research and development-licenses acquired, \$0.2 million loss on disposal of property and equipment, \$0.3 million of amortization of operating lease right-of-use assets, and \$0.2 million of equity fee on issuance of common shares to Fortress.

Investing Activities

Net cash provided by investing activities was \$5.9 million for the year ended December 31, 2023, representing \$6.0 million of proceeds from the sale of property and equipment offset by \$0.1 million used in purchases of research and development licenses and fixed assets.

Net cash used in investing activities was \$3.0 million for the year ended December 31, 2022, representing \$2.7 million in purchases of fixed assets and \$0.4 million in purchases of research and development licenses, offset by \$0.1 million of proceeds from the sale of fixed assets.

Financing Activities

Net cash used in financing activities was \$26.1 million during the year ended December 31, 2023, driven by repayment of the Term Loan of \$30.4 million offset by \$4.4 million of gross proceeds from the Registered Direct Offering, net of offering costs of \$0.5 million, \$0.2 million of gross proceeds from the Mustang ATM and \$0.2 million raised from the issuance of our common stock in connection with our Employee Stock Purchase Plan (the "ESPP").

Net cash provided by financing activities was \$34.1 million during the year ended December 31, 2022, driven by (i) proceeds from the issuance of the Term Loan of \$30.0 million, net of financing costs of \$2.7 million; (ii) gross proceeds of \$6.6 million, net of offering costs of \$0.1 million, from the Mustang ATM; and (iii) \$0.2 million raised from the issuance of our common stock in connection with our ESPP.

BUSINESS

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 in two core areas: CAR T therapies for hematologic malignancies and CAR T 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"), Fred Hutchinson Cancer Center ("Fred Hutch"), and Nationwide Children's Hospital ("Nationwide").

CAR T Therapies

Our pipeline of CAR T therapies is being developed under exclusive licenses from several world class research institutions. Our strategy is to license these technologies, support preclinical and clinical research activities by our partners and transfer the underlying technology to our or our contract manufacturer's cell processing facility in order to conduct our own clinical trials.

We are developing CAR T therapy for hematologic malignancies in partnership with Fred Hutch targeting CD20 (MB-106). In May 2021, we announced that the U.S. Food and Drug Administration ("FDA") accepted our Investigational New Drug ("IND") Application for MB-106. As of January 2025, 53 patients have been treated in an ongoing Phase 1 clinical trial sponsored by Fred Hutch (ClinicalTrials.gov Identifier: NCT03277729) and 20 patients have been treated in the Phase 1 clinical trial sponsored by us (ClinicalTrials.gov Identifier: NCT05360238). In 2023, we received Safety Review Committee approval to continue dose escalation in all three active arms of the ongoing Mustang-sponsored Phase 1 trial. We presented the latest results, demonstrating a favorable safety profile, complete response rate, and durability, from the ongoing Mustang-sponsored Phase 1 trial at the 2023 American Society of Hematology ("ASH") Annual Meeting.

We are also developing CAR T therapy for solid tumors in partnership with COH targeting IL13R α 2 (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) began during the third quarter of 2019. 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 IL13R α 2+ relapsed or refractory glioblastoma ("GBM") and high-grade astrocytoma.

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

In the first quarter of 2024, we completed a successful End-of-Phase 1 meeting with the FDA regarding a potential pivotal Phase 2 single-arm clinical trial for the treatment of WM. Per the discussions, the FDA agreed with the proposed overall design of the pivotal trial for Waldenstrom macroglobulinemia ("WM") at the recommended dose of 1×10^7 CAR-T cells/kg and requested only minimal modifications to the study protocol. No additional nonclinical studies are expected prior to Phase 2 or a Biologics License Application ("BLA") filing. Due to limited resources, and as a result of the reduction in work force described below, we do not expect to initiate our pivotal Phase 2 single-arm clinical trial of MB-106 for the treatment of WM trial in 2025. Subject to available funds, we intend to rely on third party service providers to conduct study and manufacturing services to advance our priority potential product candidates.

Also in the first quarter of 2024, we completed enrollment of the indolent lymphoma arm in our multicenter Phase 1 trial. The tenth and final patient enrolled on that arm was a patient with follicular lymphoma (FL) who achieved a complete response following treatment with 1×10^7 CAR-T cells/kg. As a result, the overall complete response rate for FL in the Phase 1 portion of this trial was sustained at 100% (N=6), with no occurrence of cytokine release syndrome ("CRS") above grade 1 and no immune effector cell-associated neurotoxicity syndrome ("ICANS") of any grade, despite not using prophylactic tocilizumab or dexamethasone.

In March 2024, we announced plans to collaborate with Fred Hutch for a proof-of-concept Phase 1 investigator-sponsored clinical trial evaluating MB-106 in autoimmune diseases.

In March 2024, we were granted the Regenerative Medicine Advanced Therapy (“RMAT”) designation by the FDA for the treatment of relapsed or refractory CD20 positive WM and FL, based on potential improvement in response as seen in clinical data to date. Drugs eligible for RMAT designation are those intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and that present preliminary clinical evidence indicating the drug has the potential to address unmet medical needs for such disease or condition. RMAT designation provides regenerative medicine advanced therapy products with the same benefits to expedite the development and review of a marketing application that are available to drugs that receive Breakthrough Therapy Designation. These advantages include timely advice and interactive communications with FDA, as well as proactive and collaborative involvement by senior FDA managers and experienced review and regulatory health project management staff. A product designated as an RMAT also may be eligible for other FDA-expedited programs, such as Priority Review. The FDA also may conduct a rolling review of products in its expedited programs, reviewing portions of a marketing application before the complete application is submitted.

In June 2024, we announced that updated data for MB-106 in the Phase 1/2 Fred Hutch investigator-sponsored trial showed a favorable safety and efficacy profile in 10 patients with WM. There was an overall response rate (“ORR”) of 90% with durable responses observed, including three complete responses (“CR”), two very good partial responses (“VGPR”), and four partial responses (“PR”). One of the patients who achieved a CR remained in remission for 31 months, with an immunoglobulin M (IgM) level that decreased rapidly to the normal range after treatment with MB-106 and remained normal since. Patients had a median of nine prior lines of therapy, and only one patient started additional anti-WM treatment after being treated with MB-106. From a safety perspective, CRS occurred in nine patients: five patients with grade 1 and four patients with grade 2. One patient experienced grade 1 ICANS. No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS was observed, despite dose escalation.

In May 2024, we informed the clinical sites participating in the Mustang-sponsored Phase 1/2 study in non-Hodgkin lymphoma and chronic lymphocytic leukemia, MB106-CD20-001, that we had decided to close the trial. In June 2024, we similarly informed the clinical sites participating in the Mustang-sponsored Long-term Follow-up Study in Patients Previously Treated with Mustang Bio, Inc. CAR-T Cell Investigational Products, MB100-OBS-001, that we had decided to close that trial. As a result, further clinical development of MB-106 is currently focused solely on autoimmune diseases unless funding and resources become available to restart the program for hematologic malignancies. Planning for the aforementioned Phase 1 investigator-sponsored clinical trial in autoimmune diseases is in progress, with initiation of the trial planned for 2025.

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

In October 2023, we received a safe-to-proceed “approval” from the FDA for our MB-109 IND application allowing us to initiate a Phase 1, open-label, non-randomized, multicenter study of MB-109 in patients with IL13Ra2+ recurrent GBM and high-grade astrocytoma. In this Phase 1 clinical study, we intend to evaluate the combination of CAR-T cells (MB-101) and the herpes simplex virus type 1 oncolytic virus (MB-108) in patients with IL13Ra2+ high-grade gliomas. The design of this study involves first a lead-in cohort, wherein patients are treated with MB-101 alone without prior MB-108 administration. After successful confirmation of the safety profile of MB-101 alone, the study will then investigate increasing doses of intratumorally administered MB-108 followed by dual intratumoral (ICT) and intraventricular (ICV) administration of MB-101.

On November 7, 2024, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-108, a herpes simplex virus type 1 (“HSV-1”) oncolytic virus, for the treatment of malignant glioma. 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 to conduct an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13Ra2+ recurrent GBM and high-grade astrocytoma with MB-109 and could potentially be initiated in the second half of 2025.

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. As of September 30, 2024, we have an accumulated deficit of \$395.8 million.

We are a majority-controlled subsidiary of Fortress Biotech, Inc. (“Fortress”).

THERAPEUTIC PIPELINE

Therapies for Oncology and Hematologic Malignancies

MB-106 (CD20 CAR T for B cell non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL))

We believe CD20 is a promising target for immunotherapy of B-cell malignancies. CD20 is a B-cell lineage-specific phosphoprotein that is expressed in high, homogeneous density on the surface of more than 95% of B-cell NHL and CLL. CD20 is stable on the cell surface with minimal shedding, internalization, or modulation upon antibody binding and is present at only nanomolar levels as a soluble antigen. It is well established as an effective immunotherapy target, with extensive studies demonstrating improved tumor responses and survival of B-NHL patients treated with rituximab and other anti-CD20 antibodies. Importantly, CD20 continues to be expressed on the lymphoma cells of most patients with relapsed B-NHL despite repetitive rituximab treatments, and loss of CD20 expression is not a major contributor to treatment resistance. Thus, there is strong rationale for testing CD20 CAR T cells as an immunotherapy for NHL.

More than 80,000 new cases of NHL are diagnosed each year in the United States, and over 20,000 patients die of this group of diseases annually. Most forms of NHL, including follicular lymphoma, mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytic lymphoma, and small lymphocytic lymphoma ("SLL"), which account collectively for approximately 45% of all cases of NHL, are incurable with available therapies, except for allogeneic stem cell transplant ("allo-SCT"). However, many NHL patients are not suitable candidates for allo-SCT, and this treatment is also limited by significant rates of morbidity and mortality due to graft-versus-host disease. Aggressive B-cell lymphomas such as diffuse large B-cell lymphoma, the most common subtype of lymphoma, account for an additional 30-35% of NHL. The majority of patients with aggressive B-NHL are successfully treated with combination chemotherapy, but a significant proportion relapse or have refractory disease, and the outcome of these patients is poor. Innovative new treatments are therefore urgently needed.

Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) is a mature B cell neoplasm characterized by a progressive accumulation of monoclonal B lymphocytes. CLL is considered to be identical (i.e., one disease with different manifestations) to the NHL SLL. The malignant cells seen in CLL and SLL have identical pathologic and immunophenotypic features. The term CLL is used when the disease manifests primarily in the blood, whereas the term SLL is used when involvement is primarily nodal.

CLL is the most common leukemia in adults in Western countries, accounting for approximately 25 to 35 percent of all leukemias in the United States. An estimated 20,700 new cases of CLL were expected to be diagnosed in the United States in 2024. CLL is considered to be mainly a disease afflicting older adults, with a median age at diagnosis of approximately 70 years; however, it is not unusual to make this diagnosis in younger individuals (e.g., from approximately 30 to 39 years of age). The incidence increases rapidly with increasing age. The natural history of CLL is extremely variable, with survival times from initial diagnosis that range from approximately 2 to 20 years, and a median survival of approximately 10 years.

Most patients will have a complete or partial response to initial therapy. However, conventional therapy for CLL is not curative and most patients experience relapse. In addition, many patients will require a change in therapy due to intolerance. Since patients with CLL are generally elderly with a median age older than 70 years, and due to the relatively benign course of the disease in the majority of patients, only selected patients are candidates for intensive treatments such as allo-SCT. Innovative new treatments with a favorable safety profile are therefore urgently needed for patients with relapsed and refractory disease.

Under their IND, Fred Hutch is currently conducting a Phase 1/2 clinical study to evaluate the anti-tumor activity and safety of administering CD20-directed third-generation CAR T cells incorporating both 4-1BB and CD28 co-stimulatory signaling domains (MB-106) to patients with relapsed or refractory B-cell NHL or CLL (ClinicalTrials.gov Identifier: NCT03277729). Secondary endpoints of this study include safety and toxicity, preliminary antitumor activity as measured by overall response rate and complete remission rate, progression-free survival, and overall survival. The study is also assessing CAR T cell persistence and the potential immunogenicity of the cells. Finally, this study was designed so that, together with Fred Hutch, we could determine a recommended Phase 2 dose. Fred Hutch intends to enroll approximately 50 subjects in this study, which is being led by the Principal Investigator Mazyar Shadman, M.D., M.P.H., Associate Professor of Fred Hutch's Clinical Research Division.

The Fred Hutch IND was amended in 2019 to incorporate an optimized manufacturing process that had been developed in collaboration with us.

In May 2021, we announced that the FDA issued a safe to proceed letter for our IND application allowing for initiation of a multi-center Phase 1/2 clinical study of MB-106 in patients with relapsed or refractory B cell NHL or CLL (Clinicaltrials.gov Identifier: NCT05360238). In August 2022, the first patient was treated in our study.

In November 2021, Mustang was awarded a grant of approximately \$2.0 million from NCI of the National Institutes of Health. This two-year award partially funded the Mustang-sponsored multicenter trial to assess the safety, tolerability and efficacy of MB-106. In August 2023, we fully utilized the grant.

In June 2022, MB-106 received Orphan Drug Designation for the treatment of Waldenstrom macroglobulinemia (“WM”).

In December 2023, Mustang presented preliminary clinical data for the indolent lymphoma patients treated in the ongoing Phase 1/2 clinical study at the American Society of Hematology (ASH) annual meeting. All 9 patients responded clinically to treatment; the observed overall response rate was 100%. All 5 follicular lymphoma patients achieved a complete response. Among the WN patients 1 patient attained a very good partial response, and 2 patients attained a partial response. The single patient with a hairy cell leukemia variant experienced stable disease. The safety profile demonstrated that MB-106 was well tolerated with no occurrences of CRS above grade 1, and no ICANS of any grade was reported. Cell expansion and persistence were also demonstrated.

In the first quarter of 2024, we completed a successful End-of-Phase 1 meeting with the FDA regarding a potential pivotal Phase 2 single-arm clinical trial for the treatment of WM. Per the discussions, the FDA agreed with the proposed overall design of the pivotal trial for WM at the recommended dose of 1×10^7 CAR-T cells/kg and requested only minimal modifications to the study protocol. No additional nonclinical studies are expected prior to Phase 2 or a Biologics License Application (“BLA”) filing. Due to limited resources, and as a result of the reduction in work force described below, we do not expect to initiate our pivotal Phase 2 single-arm clinical trial of MB-106 for the treatment of WM trial in 2025. Subject to available funds, we intend to rely on third party service providers to conduct study and manufacturing services to advance our priority potential product candidates.

Also in the first quarter of 2024, we completed enrollment of the indolent lymphoma arm in our multicenter Phase 1 trial. The tenth and final patient enrolled on that arm was a patient with follicular lymphoma (FL) who achieved a complete response following treatment with 1×10^7 CAR-T cells/kg. As a result, the overall complete response rate for FL in the Phase 1 portion of this trial was sustained at 100% (N=6), with no occurrence of CRS above grade 1 and no ICANS of any grade, despite not using prophylactic tocilizumab or dexamethasone.

In March 2024, we announced plans to collaborate with Fred Hutch for a proof-of-concept Phase 1 investigator-sponsored clinical trial evaluating MB-106 in autoimmune diseases.

In March 2024, we were granted the Regenerative Medicine Advanced Therapy (“RMAT”) designation by the FDA for the treatment of relapsed or refractory CD20 positive WM and FL, based on potential improvement in response as seen in clinical data to date. Drugs eligible for RMAT designation are those intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and that present preliminary clinical evidence indicating the drug has the potential to address unmet medical needs for such disease or condition. RMAT designation provides regenerative medicine advanced therapy products with the same benefits to expedite the development and review of a marketing application that are available to drugs that receive Breakthrough Therapy Designation. These advantages include timely advice and interactive communications with FDA, as well as proactive and collaborative involvement by senior FDA managers and experienced review and regulatory health project management staff. A product designated as an RMAT also may be eligible for other FDA-expedited programs, such as Priority Review. The FDA also may conduct a rolling review of products in its expedited programs, reviewing portions of a marketing application before the complete application is submitted.

In June 2024, we announced that updated data for MB-106 in the Phase 1/2 Fred Hutch investigator-sponsored trial showed a favorable safety and efficacy profile in 10 patients with WM. There was an overall response rate (“ORR”) of 90% with durable responses observed, including three complete responses (“CR”), two very good partial responses (“VGPR”), and four partial responses (“PR”). One of the patients who achieved a CR remained in remission for 31 months, with an immunoglobulin M (IgM) level that decreased rapidly to the normal range after treatment with MB-106 and remained normal since. Patients had a median of nine prior lines of therapy, and only one patient started additional anti-WM treatment after being treated with MB-106. From a safety perspective, CRS occurred in nine patients: five patients with grade 1 and four patients with grade 2. One patient experienced grade 1 ICANS. No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS was observed, despite dose escalation.

In May 2024, we informed the clinical sites participating in the Mustang-sponsored Phase 1/2 study in non-Hodgkin lymphoma and chronic lymphocytic leukemia, MB106-CD20-001, that we had decided to close the trial. In June 2024, we similarly informed the clinical sites participating in the Mustang-sponsored Long-term Follow-up Study in Patients Previously Treated with Mustang Bio, Inc. CAR-T Cell Investigational Products, MB100-OBS-001, that we had decided to close that trial. As a result, further clinical development of MB-106 is currently focused solely on autoimmune diseases unless funding and resources become available to restart the program for hematologic malignancies. Planning for the aforementioned Phase 1 investigator-sponsored clinical trial in autoimmune diseases is in progress, with initiation anticipated in 2025.

MB-109: Combination MB-101(IL13R α 2 CAR T Cell Program for Glioblastoma) and MB-108 (HSV-1 oncolytic virus CI34) as a Potential Treatment for IL13R α 2+ Relapsed or Refractory Glioblastoma (GBM) and High-Grade Astrocytoma.

An attractive novel approach to control glioblastoma is adoptive cellular immunotherapy utilizing CAR T cells. CAR T cells can be engineered to recognize very specific antigenically distinct tumor populations and to migrate through the brain parenchyma to kill malignant cells. In addition, oncolytic viruses (“OVs”) have been developed to effectively infect and kill cancer cells in the tumor, as well as modify the microenvironment to increase tumor immunogenicity and immune cell trafficking within the tumor. Due to these properties, OVs have been studied in combination with other treatments to enhance the effectiveness of immunotherapies.

Preliminary anti-tumor activity has been observed in clinical studies administering the OV (MB-108) and CAR T cell therapy (MB-101) as single agents; however, the combination has not yet been explored. To determine if the combination of both therapies will result in a synergistic effect, investigators from COH developed preclinical studies in orthotopic GBM models in nude mice. Dr. Christine Brown from City of Hope presented these preclinical studies at the American Association for Cancer Research 2022 Annual Meeting. It was observed that co-treatment with HSV-1 OV and IL13R α 2-directed CAR-T cells resulted in no additional adverse events beyond those seen with the individual therapies, and, more notably, that pre-treatment with HSV-1 OV re-shaped the tumor microenvironment by increasing immune cell infiltrates and enhanced the efficacy of sub-therapeutic doses of IL13R α 2-directed CAR-T cell therapy delivered either intraventricularly or intratumorally. These preclinical studies aimed to provide a deeper understanding of this combination approach to support the potential benefit of a combination study that will evaluate HSV-1 OV (MB-108) and IL13R α 2-directed CAR-T cells (MB-101).

In October 2023, we received a safe-to-proceed “approval” from the FDA for our MB-109 IND application allowing us to initiate a Phase 1, open-label, non-randomized, multicenter study of MB-109 in patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma. In this Phase 1 clinical study, we intend to evaluate the combination of CAR-T cells (MB-101) and the herpes simplex virus type 1 oncolytic virus (MB-108) in patients with IL13R α 2+ high-grade gliomas. The design of this study involves first a lead in cohort, wherein patients are treated with MB-101 alone without prior MB-108 administration. After successful confirmation of the safety profile of MB-101 alone, the study will then investigate increasing doses of intratumorally administered MB-108 followed by dual intratumoral (ICT) and intraventricular (ICV) administration of MB-101. We are currently exploring with COH to conduct an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma with MB-109 and could potentially be initiated in the second half of 2025.

On November 7, 2024, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-108, a herpes simplex virus type 1 (“HSV-1”) oncolytic virus, for the treatment of malignant glioma. 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.

MB-101 (IL13R α 2 CAR T Cell Program for Glioblastoma)

GBM is the most common brain and central nervous system (“CNS”) cancer, accounting for approximately 49.1% of malignant primary brain and CNS tumors, approximately 54% of all gliomas, and approximately 16% of all primary brain and CNS tumors. More than 14,490 new GBM cases were predicted to be diagnosed in the U.S. for 2023. Malignant brain tumors are the second leading cause of cancer-related deaths in adolescents and young adults aged 15-39 and the most common cancer occurring among 15-19-year-olds in the U.S. While GBM is a rare disease 2-3 cases per 100,000 persons per year in the U.S. and European Union (“EU”), it is quite lethal, with five-year survival rate historically under 10%, which has been virtually unchanged for decades. Standard of care therapy consists of maximal surgical resection, radiation, and chemotherapy with temozolomide, which, while rarely curative, is shown to extend median overall survival from 4.5 to 15 months. GBM remains difficult to treat due to the inherent resistance of the tumor to conventional therapies.

Immunotherapy approaches targeting brain tumors offer promise over conventional treatments. IL13R α 2 is an attractive target for CAR T therapy, as it has limited expression in normal tissue but is overexpressed on the surface of greater than 50% of GBM tumors. CAR-T cells are designed to express membrane-tethered IL-13 receptor ligand (“IL-13”) mutated at a single site (glutamic acid at position 13 to a tyrosine; E13Y) with high affinity for IL13R α 2 and reduced binding to IL13R α 1 in order to reduce healthy tissue targeting (Kahlon KS *et al. Cancer Research*. 2004;64:9160-9166).

We are developing an optimized CAR-T product incorporating enhancements in CAR-T design and T cell engineering to improve antitumor potency and T cell persistence. These include a second-generation hinge-optimized CAR containing mutations in the IgG4 linker to reduce off-target Fc interactions (Jonnalagadda M *et al. Molecular Therapy*. 2015;23(4):757-768.), a 4-1BB (CD137) co-stimulatory signaling domain for improved survival and maintenance of CAR T cells, and the extracellular domain of CD19 as a selection/tracking marker. In order to further improve persistence, either central memory T-cells (T_{CM}) or enriched CD62L+ naïve and memory T cells (T_{N/MEM}) are isolated and enriched. Our manufacturing process limits *ex vivo* expansion, which is designed to reduce T cell exhaustion and maintain a T_{CM} or T_{N/MEM} phenotype. Based on experiments with CAR-Ts in mouse xenograft models of GBM, these CAR-modified T_{CM} and T_{N/MEM} cells have been shown to be more potent and persistent than earlier generations of CAR-T cells.

Our academic partners at COH have recently completed the treatment phase of their Phase 1 study, which was designed to assess the feasibility and safety of using T_{CM} or T_{N/MEM} enriched IL13R α 2-specific CAR-engineered T cells for clinical study participants with IL13R α 2 recurrent/refractory malignant glioma (ClinicalTrials.gov Identifier: NCT02208362). In this study, COH enrolled and treated 65 patients, with 58 patients receiving 3 cycles of CAR T cells per the study protocol. In March 2024, results from this study were published in *Nature Medicine*. Preliminary data indicated that the CAR-T cells were well tolerated, and no dose-limiting toxicities were observed in any of the study arms nor where there any occurrences of CRS or treatment-related deaths. Of the 58 patients evaluable for disease response, 50% achieved stable disease (SD) or better; 22%, including 8 patients with grade 4 gliomas, achieved SD or better for at least 90 days. Two patients achieved partial response, and one patient achieved complete response on the study. In 2016 COH reported that a patient had achieved a complete response to treatment based on the imaging and clinical features set forth by the Response Assessment in Neuro-Oncology Criteria (“RANO”). This result was published as a case report in the *New England Journal of Medicine* (Brown CE *et al. NEJM*. 2016;375:2561-9). As described in the paper, this patient diagnosed with recurrent multifocal glioblastoma received multiple infusions of IL13R α 2-specific CAR-T cells over 220 days through two intracranial delivery routes – infusions into the resected tumor cavity followed by infusions into the ventricular system. Intracranial infusions of IL13R α 2-targeted CAR-T cells were not associated with any toxic effects of grade 3 or higher. After CAR-T cell treatment, regression of all intracranial and spinal tumors was observed, along with corresponding increases in levels of cytokines and immune cells in the cerebrospinal fluid. This clinical response was sustained for 7.5 months after the initiation of CAR T-cell therapy; however, the patient’s disease eventually recurred at four new locations that were distinct and non-adjacent to the original tumors, and biopsy of one of these lesions showed decreased expression of IL13R α 2.

Results from this COH study have laid the foundation for three new MB-101 studies:

1. MB-101 with or without nivolumab and ipilimumab in treating patients with recurrent or refractory glioblastoma (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04003649) sponsored by COH;
2. MB-101 in treating patients with recurrent or refractory glioblastoma with a substantial component of leptomeningeal disease (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04661384) sponsored by COH;
3. MB-101 in combination with the herpes simplex virus type 1 oncolytic virus (MB108) in treating patients with recurrent or refractory glioblastoma or high-grade astrocytoma, as described above. This combination therapy, to be administered in a phase 1 two-center trial under our IND, will be referred to as MB-109.

MB-108 (HSV-1 oncolytic virus C134)

MB-108 is a next-generation oncolytic herpes simplex virus (“oHSV”) that is conditionally replication competent; that is, it can replicate in tumor cells, but not in normal cells, thus killing the tumor cells directly through this process. Replication of C134 in the tumor itself not only kills the infected tumor cells but causes the tumor cell to act as a factory to produce new virus. These virus particles are released as the tumor cell dies and can then proceed to infect other tumor cells in the vicinity and continue the process of tumor kill. In addition to this direct oncolytic activity, the virus promotes an immune response against surviving tumor cells, which increases the antitumor effect of the therapy. The virus expresses a gene from another virus from the same overall virus family, human cytomegalovirus, which allows it to replicate better in the tumor cells than its first-generation predecessors. However, the virus has also been genetically engineered to minimize the production of any toxic effects for the patient receiving the therapy.

To improve this virus over its first-generation predecessors, modifications have focused on improving viral replication and spread within the tumor bed and on enhancing bystander damage to uninfected tumor cells. These effects cumulatively should result in converting an immunologically cold tumor to an immunologically hot tumor, which we anticipate will increase the efficacy of our IL13R α 2-directed CAR T for the treatment of GBM and high-grade astrocytoma.

The O’Neal Comprehensive Cancer Center at the UAB is the single clinical trial site for the Phase 1 trial of MB-108, and this site has initiated a Phase 1 trial that began enrolling patients in 2019 (ClinicalTrials.gov Identifier: NCT03657576). The primary objective of this study is to determine the safety and tolerability of a single dose of MB-108 administered via a stereotactic intracerebral injection and to determine the maximally tolerated dose (“MTD”) of the oncolytic virus. Secondary objectives are to obtain preliminary information about the potential benefit of MB-108 in the treatment of patients with recurrent malignant gliomas, including relevant data on markers of efficacy, including time to tumor progression and patient survival. As of January 2025, 19 patients had been enrolled in this study.

Terminated Product Candidates (CAR-T Therapies, Gene Therapies and in vivo CAR-T)

We previously developed four additional CAR-T product candidates licensed from City of Hope, which included MB-102 (CD123), MB-103 (HER2), MB-104 (CS1) and MB-105 (PSCA) programs. In May 2023, we announced a series of changes resulting from a review of our portfolio of product candidates to determine the future strategy of our programs and the proper allocation of our resources. Following this review, we determined to discontinue development of these four programs and terminated the associated license agreements.

In addition, we previously developed several gene therapy product candidates, which included MB-117 and MB-217 (based on technologies licensed from St. Jude Children’s Research Hospital (“St. Jude”)) and MB-110 (based on technologies licensed from Leiden University Medical Centre (“LUMC”)). In April 2024, we entered into a termination and release agreement with St. Jude, pursuant to which we agreed to terminate the license agreement underpinning the MB-117 and MB-217 product candidates in exchange for a mutual release of liability and forgiveness by St. Jude of all amounts previously owing to them. Also in April 2024, we delivered a termination notice to LUMC pursuant to which we terminated the license agreement underpinning the MB-110 product candidate; we are currently in discussions with LUMC regarding the terms that will govern such termination.

In June 2024, we also agreed with Mayo Foundation for Medical Education and Research (“Mayo Clinic”) to terminate the license agreement underpinning our (now former) preclinical *in vivo* CAR-T program, together with a related sponsored research agreement, in exchange for a mutual release of liability and forgiveness by Mayo Clinic of all amounts previously owed to them.

INTELLECTUAL PROPERTY AND PATENTS

General

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek to obtain, where appropriate, the broad intellectual property protection for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors (“know-how”). To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions that they generate or make, and which are important to our business.

Patents and other proprietary rights are crucial to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents, supported by regulatory exclusivity or are effectively maintained as trade secrets. We own or exclusively license a few patents and patent applications related to our compounds and other technologies, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the U.S. are maintained in secrecy for a period of 18 months or more. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference or derivation proceedings declared by the U.S. Patent and Trademark Office (“USPTO”) to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability to be extended through the patent restoration program, although any such extension could still be minimal. Additionally, statutory caps impose further limitation on any such extensions.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license, if available, under such patent or to develop or obtain alternative technology. In the event of litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third party proprietary rights. Litigation would not only involve substantial costs but would also involve substantial time commitments on the part of our key executives and research and development personnel.

In March 2015, we licensed intellectual property related to CAR T technology from COH. In May 2023, we announced a series of changes resulting from a review of our portfolio of product candidates to determine the future strategy of our programs and the proper allocation of our resources. Following this review, we determined to discontinue development of our MB-102 (CD123), MB-103 (HER2), MB-104 (CS1) and MB-105 (PSCA) programs and terminated the associated license agreements. The portfolio of rights licensed from COH now includes patents and applications directed to CARs targeting IL13R α 2, as well as rights related to modified CAR hinge regions, methods of preparing CAR T cells in particular subpopulations of cells and methods of administering CAR T cells. The intellectual property licensed thereunder relating to IL13R α 2-targeting CARs includes granted patents in the U.S., Australia, China, Europe, Russia, Japan, Hong Kong, Israel, and Mexico, and this patent family further includes pending applications in the U.S., Australia, Brazil, Canada, China, Europe, South Korea, Russia, Japan, Israel, Mexico, and New Zealand. Any patents issuing from the IL13R α 2-targeting CAR will expire no sooner than 2035. The licensed intellectual property relating to relating modified CAR hinge regions includes issued patents in China, Europe, and Japan, as well as pending applications in the U.S., Australia, China, and Europe. The patents issuing from the modified CAR hinge region family will expire no sooner than 2034. The licensed intellectual property relating to relating to method of preparing or administering CAR T cells includes issued patents in China, Europe, and Japan, as well as pending applications in the U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, Japan, Israel, Mexico, Russia, and New Zealand. The patents relating to these technologies will expire no sooner than 2035 or, in the case of the administration methods, 2036.

Also, in March 2015, we executed a sponsored research agreement with COH, pursuant to which research is performed in the laboratory of Drs. Stephen Forman and Christine Brown. The sponsored research agreement gives us the right to first negotiation under specified maximum terms regarding any future inventions arising from the laboratory.

In May 2017, we licensed intellectual property related to CAR T technology for targeting CD20 from Fred Hutch. The intellectual property includes an international application under the Patent Cooperation Treaty (i.e., a PCT application), which has now matured into several issued patents, including issued patents in the U.S. and Europe, as well as pending applications in the U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea, Mexico, New Zealand, and Russia. These applications contain claims relating to various CD20-targeting CAR constructs and CAR T cells, as well as methods of making and using the same. The national stage applications claiming priority to the PCT application were filed in May 2018 in order to begin substantive examination of the claims. Patents maturing from these national stage applications will expire no sooner than March 2037.

In February 2019, we licensed material and technical information related to the HSV-1 oncolytic virus C134 from Nationwide in Columbus, Ohio.

In addition to the technology we have in-licensed, we have also developed our own proprietary intellectual property, both alone and in conjunction with COH. In particular, we own pending applications in the U.S. and Europe directed to methods for manufacturing cell-based therapeutics, and pending PCT applications, and applications in the U.S. and Taiwan, relating to anti-idiotypic antibodies. We and COH also own, as co-applicants, pending PCT applications, and applications in the U.S. and Taiwan, directed to methods of treating hematological cancers with a combination therapy.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended (the “FDCA”), to provide market exclusivity for certain of our product candidates. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or diseases that affect more than 200,000 individuals in the U.S. but for which the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first approval of a designated orphan product from the FDA will be granted a seven-year period of marketing exclusivity for such FDA approved orphan product.

LICENSE, CLINICAL TRIAL AND SPONSORED RESEARCH AGREEMENTS

City of Hope National Medical Center

In February 2017, we and COH amended and restated our license agreement, dated March 17, 2015 (the “Original COH Agreement”), by entering into three separate amended and restated exclusive license agreements, one relating to the CD123-directed CAR T program, one relating to the IL13Ra2-directed CAR T program, and one relating to the Spacer technology (described below). As of January 2025, COH owns 845,385 shares of our Class A common stock, which are convertible into 56,359 shares of Common Stock, and has the right to appoint a member to our Board of Directors (the “Board”).

In addition, we entered into a sponsored research agreement with COH under which we have funded continued research in the amount of \$2.0 million per year, payable in four equal installments, which ended in the first quarter of 2020. The research covered under this arrangement was for the IL13Ra2-directed CAR T program, the CD123-directed CAR T program, and the Spacer technology.

In May 2023, we announced a series of changes resulting from a review of our portfolio of product candidates to determine the future strategy of our programs and the proper allocation of our resources. Following this review, we determined to discontinue development of the four CAR-T Therapies licensed from City of Hope listed above under “Terminated Product Candidates.”

IL13Ra2 License

In February 2017, we entered into an Amended and Restated Exclusive License Agreement with COH to acquire intellectual property rights pertaining to patent rights related to the IL13Ra2-directed CAR T program (the “IL13Ra2 License”). Pursuant to the IL13Ra2 License, we and COH acknowledged that an upfront fee had already been paid under the Original COH Agreement. In addition, COH is eligible to receive an annual maintenance fee, milestone payments totaling up to approximately \$14.5 million, and royalties on net sales of licensed products in the mid-single digits. We are obligated to pay COH a percentage of certain revenues received in connection with a sublicense ranging from the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product.

IL13Ra2 CRA (Glioblastoma)

In February 2017, we entered into a Clinical Research Support Agreement for the IL13Ra2-directed CAR T program (the “IL13Ra2 GBM CRA”). Pursuant to the terms of the IL13Ra2 CRA, we made an upfront payment of approximately \$9,000 and will contribute an additional \$140,000 per patient in connection with the on-going investigator-initiated study. Further, we agreed to fund approximately \$66,000 annually pertaining to the clinical development of the IL13Ra2-directed CAR T therapy (also known as MB-101).

IL13Ra2 CRA (Leptomeningeal Glioblastoma)

In October 2020, we entered into a Clinical Research Support Agreement for the IL13Ra2-directed CAR T program for adult patients with leptomeningeal glioblastoma, ependymoma or medulloblastoma (the “IL13Ra2 Leptomeningeal CRA”). Pursuant to the terms of the IL13Ra2 Leptomeningeal CRA, we made an upfront payment of approximately \$29,000 and will contribute an additional \$150,000 per patient in connection with the on-going investigator-initiated study. Further, we agreed to fund approximately \$200,000 annually pertaining to the clinical development of the IL13Ra2-directed CAR T therapy.

Sponsored Research Agreement - IL13Ra2 and C134 Combination

In October 2020, we entered into a Sponsored Research Agreement (“SRA”) with COH to conduct combination studies of a potential IL13Ra2 CAR and C134 oncolytic virus therapy (also known as MB-108). In November 2022, the SRA was amended to include additional funding. Pursuant to the amended SRA, we funded research in total of \$0.9 million for the program.

Spacer License

In February 2017, we entered into an Amended and Restated Exclusive License Agreement with COH to acquire intellectual property rights pertaining to patent rights related to Spacer (the “Spacer License”). Pursuant to the Spacer License, COH will receive an annual maintenance fee of \$10,000. No royalties are due if the Spacer technology is used in conjunction with an IL13Ra2 CAR, and royalty payments in the low single digits are due on net sales of licensed products if the Spacer technology is used in conjunction with other intellectual property. We are obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-thirties.

IV/ICV License

In February 2017, we entered into an exclusive license agreement (the “IV/ICV License”) with COH to acquire intellectual property rights in patent applications related to the intraventricular and intracerebroventricular methods of delivering T cells that express CARs. Pursuant to the IV/ICV License, in March 2017, we paid COH an upfront fee of \$0.1 million. COH is eligible to receive a milestone payment totaling approximately \$0.1 million, upon and subject to the achievement of a milestone, and an annual maintenance fee. Royalty payments in the low single digits are due on net sales of licensed products. We are obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-thirties.

Manufacturing License

On January 3, 2018, we entered into a non-exclusive license agreement with COH to acquire patent and licensed know-how rights related to developing, manufacturing, and commercializing licensed products. We paid \$75,000 in consideration for the licenses to the patent rights and the licensed know-how in addition to an annual maintenance fee. Royalty payments in the low-single digits are due on net sales of licensed products.

Fred Hutchinson Cancer Center

CD20 Technology License

Effective July 3, 2017, we entered into an exclusive, worldwide licensing agreement with Fred Hutch for the use of a CAR T therapy related to autologous T cells engineered to express a CD20-specific CAR (the “CD20 Technology License”). Pursuant to the CD20 Technology License, we paid Fred Hutch an upfront fee of \$0.3 million and owes an annual maintenance fee of \$50,000 on each anniversary of the license until our achievement of regulatory approval of a licensed product using the CD20 Technology. Additional payments are due for the achievement of development milestones totaling \$39.1 million. Royalty payments in the mid-single digits are due on net sales of licensed products.

CD20 CTA (NHL and CLL)

Also, on July 3, 2017, in conjunction with the CD20 Technology License from Fred Hutch, we entered into an investigator-initiated clinical trial agreement (the “CD20 CTA”) to provide partial funding for a Phase 1/2 clinical trial at Fred Hutch evaluating the safety and efficacy of the CD20 Technology in patients with relapsed or refractory B-cell non-Hodgkin lymphomas (“NHLs”). In connection with the CD20 CTA, we agreed to fund up to \$5.3 million of costs associated with the clinical trial, which commenced during the fourth quarter of 2017.

In November 2020, the CD20 CTA was amended to include additional funding of approximately \$1.8 million, and in January 2022, the CTA was amended to increase funding by approximately \$2.2 million for the treatment of additional patients.

Nationwide Children’s Hospital License

On February 20, 2019, we entered into an exclusive worldwide license agreement with Nationwide for the development of an oncolytic virus (referred to by Nationwide as C134; now referred to by us as MB-108) for the treatment of glioblastoma multiforme. We paid \$0.2 million in consideration for the exclusive license. Nationwide is eligible to receive additional payments totaling \$77.5 million upon the achievement of development and commercialization milestones. Royalty payments in the low-single digits are due on net sales of licensed products.

COMPETITION

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same conditions that we are targeting. Other companies have products or product candidates in various stages of pre-clinical or clinical development, or with marketing approvals, to treat conditions for which we are also seeking to discover and develop product candidates. Some of these potential competing drugs are further advanced in development than our product candidates and may be commercialized earlier.

The field of CAR T therapy is extremely active. Companies and partnerships currently engaged in clinical trials with CAR T modalities include Bristol Myers Squibb, Novartis, AstraZeneca, Janssen Pharmaceutical Company, Legend Biotech, Gilead Sciences, Arcellx, Galapagos NV, Autolus Therapeutics, 2seventy bio, Kyverna Therapeutics, CARGO Therapeutics, ImmPACT Bio, and Cabaletta Bio.

EMPLOYEES

As of January 10, 2025, we had 6 full-time employees. None of our employees are represented by a labor union or covered under a collective bargaining agreement, and we consider our employee relations to be good. Employees of Fortress also make valuable financial, legal, scientific and other strategic contributions to our Company on a regular basis.

SUPPLY AND MANUFACTURING

As an early-stage development company, we rely on our research partners to manufacture or have manufactured all LV vectors used in the clinical development programs currently in progress at COH and Fred Hutch under the IND applications filed by these institutions. In addition, we rely on the NIH to produce oncolytic virus for UAB, the clinical trial site for the Phase 1 trial of Nationwide’s herpes simplex virus type 1 oncolytic virus (MB-108).

Pursuant to the March 2015 Licensing Agreement with COH, we have the right to make and have made the cellular products, and we have negotiated Investigator-Initiated Clinical Research Support Agreements with COH and Fred Hutch which specify the cell processing costs and numbers of patients which will be supplied under filed protocols. Our research partners have extensive experience manufacturing clinical materials for development studies, but we are currently dependent on both their capacity limitations and continued operating success to manufacture LV vector and to process cells for all CAR T clinical trials for which these partners hold the INDs, as well as to have manufactured oncolytic virus for the MB-108 investigator-IND clinical trial being conducted at UAB.

We have limited experience in processing cells for clinical or commercial purposes. In 2018, we opened our own cell processing facility in Worcester, Massachusetts, in order to manufacture and supply cellular product candidates for all clinical trials that will be conducted under IND applications to be filed by us. In May 2023, we entered into an Asset Purchase Agreement (the “Prior Asset Purchase Agreement”) with uBriGene (Boston) Biosciences, Inc. (“uBriGene”), pursuant to which we agreed to sell our leasehold interests in our cell processing facility and associated assets relating to the manufacturing and production of cell and gene therapies. On July 28, 2023, we completed the sale of all of our assets relating to our operations primarily relating to the manufacturing and production of cell and gene therapies. In June 2024, we entered into an Asset Purchase Agreement with uBriGene to repurchase the assets, properties and rights previously transferred by the Company to uBriGene under the Prior Asset Purchase Agreement, excluding any inventory transferred under the Prior Asset Purchase Agreement that has been consumed or transferred to a third party by uBriGene since the closing of the Prior Asset Purchase Agreement. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments” for additional information.

We expect to rely on contract manufacturing relationships for LV vectors and for the MB-108 oncolytic virus, as well as for any non-CAR T products that we may in-license or acquire in the future for co-administration with our CAR T products. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers for these current and potential future non-CAR T products would be subject to ongoing periodic and unannounced inspections by the FDA, and corresponding state agencies, to ensure strict compliance with the current Good Manufacturing Practice regulations (“cGMP”) and other state and federal regulations. Our contractors, if any, in Europe would face similar challenges from the numerous EU and member state regulatory agencies and authorized bodies. We do not have control over third-party manufacturers’ compliance with these regulations and standards, other than through contractual obligations. If they are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers for these current and potential future non-CAR T products after commercialization, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

GOVERNMENT AND INDUSTRY REGULATIONS

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and, if approved, marketing of our product candidates, as well as our ongoing research and development activities. None of our product candidates has been approved for sale in any market. Before marketing in the U.S., any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, and the sale and distribution of biopharmaceutical products.

U.S. Drug Development

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive preclinical and clinical data and supporting information to the FDA for each indication or use to establish a product candidate's safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, preclinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial. Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

FDA Expedited Review and Approval Programs

FDA has various programs, including fast track designation, regenerative medicine advanced therapy (RMAT) designation, breakthrough therapy designation (BTD), accelerated approval, and priority review that are intended to expedite the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address existing unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for fast track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition and based on preclinical or preliminary clinical data that demonstrates the potential to address an unmet medical need in the intended patient population. The FDA will determine that a product will fulfill an unmet medical need if it will provide a therapy where either none exists or provide a therapy that may be potentially superior to an existing therapy based on efficacy or safety factors.

A drug is eligible for RMAT designation if it is a regenerative medicine therapy which is defined as either a cell therapy, therapeutic tissue engineered product, human cell and tissue product, or a combination therapy using any such therapies or products, it is intended to treat, modify, reverse, or cure a serious condition; and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address the unmet medical needs for such conditions. Advantages of RMAT designation include all the benefits of the fast track designation, including early interactions with FDA. The FDA must respond to a request for RMAT designation within 60 calendar days of receipt of the request. As with other expedited development programs, if RMAT designation has been granted but, later in development, the product no longer meets the qualifying criteria, then CBER may rescind the RMAT designation.

Moreover, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval, of a breakthrough therapy.

The FDA may give a priority review designation within 60 days of submission of a BLA or NDA to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. If granted, a priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Products that are eligible for fast track, RMAT or breakthrough therapy designation may be eligible to receive a priority review if the criteria for priority review are met at the time of the BLA or NDA submission.

In addition, drugs studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Approval is determined on the basis of adequate and well-controlled clinical trials that establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint and under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation, do not change the standards for approval and may not ultimately expedite the development or approval process.

Clinical Trials

To support a new drug application (“NDA”) or biologics license application (“BLA”) approval, clinical trials are typically conducted in the following sequential phases:

- *Phase 1:* The drug is administered to a small group of humans, either healthy volunteers or patients, for the first time to test for safety, dosage tolerance, absorption, metabolism, excretion and clinical pharmacology.
- *Phase 2:* Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.
- *Phase 3:* Studies establish safety and efficacy in an expanded patient population.
- *Phase 4:* The FDA may request phase 4 post-marketing studies to find out more about the drug’s long-term risks, benefits, and optimal use, or to test the drug in different patient populations.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

- slow patient enrollment 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;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site’s review board;
- longer treatment time required to demonstrate efficacy or determine the appropriate product dose;
- insufficient supply of the product candidates;
- adverse medical events or side effects in treated patients; and
- ineffectiveness of the product candidates.

In addition, the FDA, or equivalent foreign regulatory authority, or a data safety monitoring committee for a clinical trial may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk, or for futility. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a product candidate, known as toxicological studies, or clinical trials of product candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our product candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Sponsors of drugs may apply for a special protocol assessment (“SPA”) from the FDA for studies intended to form the primary basis of an efficacy claim. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for an NDA or BLA. However, final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the pivotal clinical trial. Once approved, the SPA may only be changed through a written agreement between the sponsor and the FDA, or in rare cases if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy the SPA can be rescinded.

The FDA has established the Office of Tissues and Advanced Therapies, formerly called the Office of Therapeutic Proteins, which is a super office within the Center for Biologics Evaluation and Research, or CBER, to consolidate the review of cell and gene therapies and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review, if requested by FDA. The FDA is not bound by the recommendations of an Advisory Committee, but it considers them carefully when making decisions. There are a number of additional requirements that apply exclusively to clinical trials involving this class of products. The FDA has issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider at each of the above stages of development. These guidelines relate to, among other things: preclinical evaluation of gene therapies, design of clinical studies, and the chemistry, manufacturing and control information that should be included in an initial IND application and throughout clinical development to support an NDA or BLA application. Measures to observe for delayed adverse effects in subjects who have been exposed to investigational gene therapies are required. Per the guidelines, FDA requires that sponsors observe subjects for potential gene therapy-related delayed adverse events which can be, dependent upon various factors, up to a period of 15 years post treatment.

FDA Review and Approval

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA or BLA containing the preclinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA or BLA for filing if certain content criteria are not met and, even after accepting an NDA or BLA, the FDA may require additional information, including clinical data, before approval for marketing a product.

Although uncommon, the FDA may request a Risk Evaluation and Mitigation Strategy, or REMS, as part of an NDA or BLA approval for products with serious safety concerns to help ensure that the benefits of the product outweigh the risks. The REMS plan may contain post-marketing obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and perhaps the conduct of Phase 4 follow-up studies and/or patient registries to ensure the continued safe use of the drug.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer’s quality control and manufacturing procedures conform to cGMP. Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or for us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies and as reflected in the approved labeling. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA or BLA. Certain changes to an approved NDA or BLA, including, with certain exceptions, any significant changes to labeling, may require prior approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will generally be limited to those specified in FDA approved labeling, and the advertising of our products will be subject to comprehensive monitoring and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding those contained in the approved labeling will constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes.

Post-Marketing Requirements

Following approval, we and the new product are subject to continuing regulation by the FDA, which include monitoring and recordkeeping activities, reporting of adverse experiences and complying with promotion and advertising requirements, which include prohibitions on the promotion of the drugs for unapproved, or “off-label” uses. Although physicians may prescribe legally available drugs for off-label treatments, manufacturers may not promote such non-FDA approved uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use and an on-going basis. Further, if there are any modifications to the drug, including changes to indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a supplemental NDA/BLA or new NDA/BLA, which may require the applicant to develop additional data or conduct additional preclinical studies or clinical trials.

The FDA regulations require that products be manufactured in specific approved facilities and in accordance with current Good Manufacturing Practices (“CGMPs”). These regulations require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from CGMPs. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic, inspections by the FDA and certain state agencies for compliance with CGMPs and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with CGMPs. The discovery of violative conditions, including failure to conform to CGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including voluntary recalls and product seizures.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrections to advertising or communications to doctors and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product’s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. New government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could delay or prevent regulatory approval of our product candidates under development.

Pediatric Information

Under the Pediatric Research Equity Act (“PREA”), an NDA or BLA or supplement to an NDA or BLA may need to contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation in which the product is safe and effective. The FDA may however grant deferrals for submission of pediatric data or full or partial waivers. Non-oncology drugs are exempt from PREA if they were granted an orphan drug designation.

The Food and Drug Administration Safety and Innovation Act (“FDASIA”), requires that a sponsor who is planning to submit an NDA or BLA, or a supplement to an approved NDA or BLA, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (“iPSP”), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 trial. In the event a Phase 3 study is not planned the iPSP must be submitted no later than 210 calendar days before the planned NDA or BLA submission. Oncology products intended to treat adult cancers is also required to submit an iPSP including those products which were granted an orphan drug designation. The initial PSP must include an outline of the pediatric trial(s) that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such information and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric trials. The FDA and the sponsor must reach an agreement on the PSP, but the sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and other clinical development programs. A sponsor should not submit an NDA or BLA until the FDA confirms agreement on the iPSP.

In the EU, a pediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorization of a medicine for children. All applications for marketing authorization for new medicines have to include the results of studies as described in an agreed upon PIP, unless there is a deferral or waiver.

Orphan Drug Designation and Exclusivity

The FDA may grant orphan drug designation (“ODD”) to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing and marketing the drug for this type of disease or condition will be recovered from sales in the U.S. In the EU, the European Commission, after receiving the opinion of the EMA’s Committee for Orphan Medicinal Products (“COMP”), grants orphan medicinal product designation in respect of products that are intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. In addition, designation may be granted for products intended for the diagnosis, prevention or treatment of a life threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product. In each case, there must be no satisfactory method of diagnosis, prevention or treatment of the applicable condition authorized for marketing in the EU, or, if such a method exists, the sponsor must establish that its product would be of significant benefit to those affected by the condition.

In the U.S., orphan drug status, which is granted following the approval of the NDA or BLA, entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

In the EU, orphan medicinal product designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following drug or biological product approval. This period may be reduced to six years if, at the end of the fifth year, it is established that the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting an application (NDA/BLA) for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Other Healthcare Laws and Compliance Requirements

Manufacturing, sales, promotion and other activities following product candidate approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the U.S. Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

We will also be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- 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 health care 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 health care benefit program through false representations or knowingly and willingly 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 (“HITECH”), 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.

Pharmaceutical Coverage, Pricing and Reimbursement

The ability to successfully commercialize any product candidate which receives marketing authorization depends in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the healthcare industry in the United States and elsewhere is cost containment.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. In the United States, the Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act.

Changes to and under the Affordable Care Act remain possible but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. We also expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that can be charged for drug products. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers.

The Inflation Reduction Act of 2022 (the “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. Orphan drugs that treat only one rare disease are exempt from the IRA’s drug negotiation program. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA.

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. 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 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 product or future product candidate. 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 products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. It is uncertain whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such may be. In addition, increased Congressional scrutiny of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject the industry to more stringent product labeling and post-marketing testing and other requirements. It is also unclear what impact any changes made by the new presidential administration will have on the industry. Such actions may impact the development and commercialization of drug products.

International Regulation

In addition to regulations in the U.S., there are a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

MANAGEMENT

Our Board of Directors

Our Bylaws provide that our board of directors shall consist of between one and nine directors, and such number of directors within this range may be determined from time to time by resolution of our board of directors or our stockholders. Currently, we have seven directors.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>	<u>Director Since</u>
Manuel Litchman, M.D.	70	President, Chief Executive Officer, Interim Chief Financial Officer and Director	2017
Michael S. Weiss	58	Chairman of the Board of Directors and Executive Chairman	2015
Adam J. Chill	56	Director	2017
Neil Herskowitz	67	Director	2015
David Jin	34	Director	2024
Lindsay A. Rosenwald, M.D.	69	Director	2015
Michael J. Zelefsky, M.D.	64	Director	2017

The board of directors does not have a formal policy regarding the separation of the roles of Chief Executive Officer and Chairman of the board of directors, as the board of directors believes that it is in the best interests of the Company to make that determination based on the direction of the Company and the current membership of the board of directors. The board of directors has determined that having a director who is also the chief executive officer serve as the Chairman is not in the best interest of the Company's stockholders at this time.

Mustang has a risk management program overseen by Manuel Litchman, M.D., our President and Chief Executive Officer. Dr. Litchman and management identify material risks and prioritize them for our board of directors. Our board of directors regularly reviews information regarding our credit, liquidity, operations, and compliance as well as the risks associated with each.

The following biographies set forth the names of our directors, their ages, the year in which they first became directors, their positions with us, their principal occupations and employers for at least the past five years, any other directorships held by them during the past five years in companies that are subject to the reporting requirements of the Exchange Act, or any company registered as an investment company under the Investment Company Act of 1940, as well as additional information, all of which we believe sets forth each director's qualifications to serve on the Board. There is no family relationship between and among any of our executive officers or directors.

On April 7, 2017, we entered into an Executive Employment Agreement with Dr. Litchman, pursuant to which, among other things, the Company agreed to use its best efforts to cause Dr. Litchman to be nominated and reelected to the board of directors. Except as described herein, there are no arrangements or understandings between any of our executive officers or directors and any other person pursuant to which any of them are elected as an officer or director.

Mustang adheres to the corporate governance standards adopted by Nasdaq. Nasdaq rules require our board of directors to make an affirmative determination as to the independence of each director. Consistent with these rules, our board of directors completed its annual review of director independence and considered relationships and transactions between each director or any member of his immediate family, on the one hand, and the Company and our subsidiaries and affiliates, on the other hand. The purpose of this review was to determine whether any such relationships or transactions were inconsistent with a determination that the director is independent. Based on this review, our board of directors determined that Adam Chill, Neil Herskowitz, and Michael Zelefsky, M.D. are independent under the criteria established by Nasdaq and our board of directors.

Fortress beneficially owns capital stock representing more than 50% of the voting power of our outstanding voting stock eligible to vote in the election of directors. As a result, we qualify as a "controlled company" and avail ourselves of certain "controlled company" exemptions under Nasdaq's corporate governance rules. As a controlled company, we are not required to have a majority of "independent directors" on our board of directors as defined under Nasdaq rules, or have a compensation, nominating or governance committee composed entirely of independent directors. Despite qualifying as a controlled company, we have a separately constituted Compensation Committee consisting entirely of independent directors.

Executive Officers

Manuel Litchman, M.D. - President, Chief Executive Officer, Interim Chief Financial Officer and Director

Dr. Litchman has served as our President and Chief Executive Officer, and as a member of our board of directors since April 2017. In November 2024, Dr. Litchman was appointed our Interim Chief Financial Officer. Dr. Litchman joined us from Arvinas, LLC, where he served as President and Chief Executive Officer. While at Arvinas, Dr. Litchman oversaw the advancement of the company's pipeline of protein-degradation therapeutics for the treatment of cancers and other diseases toward Investigational New Drug applications and secured multi-target discovery collaborations with Merck and Genentech. Prior to Arvinas, Dr. Litchman spent more than 18 years with Novartis Pharmaceuticals Corporation, where he held positions of increasing responsibility related to the development of Novartis' oncology pipeline. Most recently, Dr. Litchman served as Senior Vice President and Executive Global Program Head, CTL019, Cell & Gene Therapies Unit, where he led a collaboration with the University of Pennsylvania investigating chimeric antigen receptor modified T cells ("CAR Ts") directed against CD19 on B cell malignancies. Prior to the CTL019 collaboration, Dr. Litchman served as Novartis' Vice President and Head, Oncology Business Development & Licensing. Earlier in his career, Dr. Litchman was a senior equity analyst at Ursus Capital and directed oncology/immunology clinical research at Hoffmann-La Roche Inc. Dr. Litchman received his M.D. from Yale University School of Medicine, and his B.A. from Princeton University. He completed his internal medicine residency and hematology-oncology fellowship at New York-Presbyterian/Weill Cornell Medical Center. Based on Dr. Litchman's biotechnology and pharmaceutical industry experience and in-depth understanding of our business, we believe that Dr. Litchman has the appropriate set of skills to serve as a member of the Board.

Non-Employee Directors

Michael S. Weiss - Chairman of the Board of Directors and Executive Chairman

Mr. Weiss has served as Chairman of our board of directors since May 2015 and has also served as our Executive Chairman since January 2017. He previously served as our interim President & Chief Executive Officer from March 2015 to April 2017. He is also a board member and the Executive Vice Chairman, Strategic Development of Fortress Biotech, Inc., a position he has held since February 2014, and the Chairman of the board of directors of Checkpoint Therapeutics, Inc., where he previously served as interim President & Chief Executive Officer from March 2015 to December 2016. Mr. Weiss was also a board member of Avenue Therapeutics, Inc. from March 2015 to February 2018 and the Chairman of the Board of National Holdings Corporation from September 2016 to June 2018. Since December 2011, Mr. Weiss has served in multiple capacities at TG Therapeutics, Inc., and is currently its Executive Chairman, Chief Executive Officer and President. Mr. Weiss earned his J.D. from Columbia Law School and his B.S. in Finance from The University at Albany. He began his professional career as a lawyer with Cravath, Swaine & Moore LLP. In 1999, Mr. Weiss founded Access Oncology, which was later acquired by Keryx Biopharmaceuticals in 2004. Following the merger, Mr. Weiss remained as Chief Executive Officer of Keryx. Based on Mr. Weiss's biotechnology and pharmaceutical industry experience, as well as his extensive management experience, we believe that Mr. Weiss has the appropriate set of skills to serve as a member of the Board in light of our business and structure.

Effective January 1, 2017, our board of directors approved and authorized the execution of a Board Advisory Agreement with Caribe BioAdvisors, LLC (the "Advisor"), which is owned by Michael S. Weiss, to provide the Board with the advisory services of Mr. Weiss as Chairman of the Board and Executive Chairman. Pursuant to the Advisory Agreement, the Advisor is paid an annual cash fee of \$60,000, in addition to any and all annual equity incentive grants paid to members of the Board.

Adam J. Chill - Director

Mr. Chill has served as a member of our board of directors since June 2017. Mr. Chill is the President of and a Portfolio Manager at Kingsbrook Partners LP, an alternative asset management firm he co-founded in March 2009. From February 2001 to March 2009, Mr. Chill was a Portfolio Manager and Managing Director at Highbridge Capital Management, LLC, an alternative asset management firm owned by J.P. Morgan Asset Management. At Highbridge, Mr. Chill was responsible for structuring, negotiating and monitoring Highbridge's portfolio of structured investments in public and private companies worldwide. From April 2000 to February 2001, Mr. Chill worked at Angelo, Gordon & Co., an alternative asset management firm. From October 1992 to April 2000, Mr. Chill was a corporate attorney specializing in securities and mergers and acquisitions at Stroock & Stroock & Lavan LLP. Mr. Chill is a co-founder of the Bayit Association of New Jersey. Mr. Chill received his B.A., magna cum laude, from Yeshiva University and his J.D. from Columbia University School of Law, where he was a Harlan Fiske Stone Scholar. Based on Mr. Chill's extensive investment experience and knowledge of the biotechnology industry, we believe that Mr. Chill has the appropriate set of skills to serve as a member of the Board.

Neil Herskowitz - Director

Mr. Herskowitz has served as a member of our board of directors since August 2015. Mr. Herskowitz has served as the managing member of the ReGen Group of companies, located in New York, since 1998, which include ReGen Capital Investments LLC and Riverside Claims Investments LLC. He has also served as the President of its affiliate, Riverside Claims LLC, since June 2004. Mr. Herskowitz serves as a member of the board of directors for two of our affiliates, Checkpoint Therapeutics, Inc. and Avenue Therapeutics, Inc. Mr. Herskowitz received a B.B.A. in Finance from Bernard M. Baruch College in 1978. Based on Mr. Herskowitz's financial industry experience and in-depth understanding of our business, we believe that Mr. Herskowitz has the appropriate set of skills to serve as a member of the Board.

David Jin - Director

Mr. Jin has served as a member of our board of directors since October 2024. Mr. Jin has served as the Chief Financial Officer since August 2022 and Head of Corporate Development since May 2020 of Fortress. He also serves as Interim Chief Operating Officer, Chief Financial Officer and Corporate Secretary of Avenue Therapeutics, Inc. (a Fortress partner company). Since August 2022, Mr. Jin has served as Treasurer of Fortress' private subsidiaries, including Cyprium Therapeutics, Urica Therapeutics, Helocyte, and Cellvation. From March 2022 to August 2022, he served as Interim Chief Executive Officer at Avenue Therapeutics Inc. Prior to joining Fortress, Mr. Jin was a member of the Private Equity group at Barings focused on control equity and asset-based investments in pharma and biotech. Prior to that, he was Director of Corporate Development at Sorrento Therapeutics, and Vice President of Healthcare Investment Banking at FBR & Co. Mr. Jin began his career in management consulting at IMS Health (now IQVIA). Mr. Jin has a Bachelor of Science degree in Industrial Engineering & Management Sciences with a double-major in Mathematical Methods in the Social Sciences from Northwestern University. Based on Mr. Jin's financial experience and knowledge of the biotechnology industry, we believe that Mr. Jin has the appropriate set of skills to serve as a member of the board of directors.

Lindsay A. Rosenwald, M.D. - Director

Dr. Rosenwald has served as a member of our board of directors since our inception. Dr. Rosenwald has been a member of the board of directors of Fortress Biotech, Inc. since October 2009 and has served as its Chairman, President and Chief Executive Officer since December 2013. From November 2014 to August 2015, Dr. Rosenwald served as Interim President and CEO of Checkpoint Therapeutics, Inc. and remains on that company's board of directors. He also serves on the board of directors of Avenue Therapeutics, Inc. and Journey Medical Corporation. Prior to that, from 1991 to 2008, he served as the Chairman of Paramount BioCapital, Inc. Over the last 30 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and has been involved in the founding and recapitalization of numerous public and private biotechnology and life sciences companies. Dr. Rosenwald received his B.S. in finance from Pennsylvania State University and his M.D. from Temple University School of Medicine. We believe that Dr. Rosenwald's extensive biotechnology, pharmaceutical and finance expertise, as well as his medical background and in-depth understanding of our businesses, makes him an exemplary candidate to continue serving on our board of directors.

Michael J. Zelefsky, M.D. - Director

Dr. Zelefsky has served as a member of our board of directors since June 2017. Dr. Zelefsky has served as a Member at NYU Langone since 2023 and before that was a Member at the Memorial Sloan-Kettering Cancer Center Department of Radiation Oncology since 2005. He has served as Chief of Memorial Sloan-Kettering's Brachytherapy Services since 2000 and has been a Professor of Radiation Oncology at Weill Cornell Medical College, Cornell University since 1994. He is a recognized expert in radiation therapy and has helped develop and enhance Memorial Sloan-Kettering's prostate brachytherapy program during his tenure. Dr. Zelefsky received a Bachelor of Arts in Biology (summa cum laude) from Yeshiva University in 1982 and a Medical Doctor degree from Albert Einstein College of Medicine in 1986. Dr. Zelefsky is currently Editor-in-Chief of *Brachytherapy* and has previously served as president of the American Brachytherapy Society. Based on Dr. Zelefsky's extensive experience and background in oncology, we believe that Dr. Zelefsky has the appropriate set of skills to serve as a member of the Board.

Board Committees

Our board of directors has established an audit committee, and a compensation committee, each of which will have the composition and responsibilities described below. Our board of directors may establish other committees to facilitate the management of our business. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has adopted a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq rules.

Audit Committee

The Audit Committee currently consists of Adam J. Chill, Neil Herskowitz, and Michael J. Zelefsky, M.D. Mr. Chill chairs the Audit Committee.

The duties and responsibilities of the Audit Committee are set forth in the Charter of the Audit Committee which was recently reviewed by our Audit Committee. A copy of the Charter of the Audit Committee is available on our website, located at ir.mustangbio.com. Among other things, the duties and responsibilities of the Audit Committee include reviewing and monitoring our financial statements and internal accounting procedures, the selection of, consultation with and review of the services provided by our independent registered public accounting and identifying and assessing any related party transactions in collaboration with counsel, accountants and management. Our Audit Committee has sole discretion over the retention, compensation, evaluation and oversight of our independent registered public accounting firm.

The SEC and Nasdaq have established rules and regulations regarding the composition of audit committees and the qualifications of audit committee members. Our board of directors has examined the composition of our Audit Committee and the qualifications of our Audit Committee members in light of the current rules and regulations governing audit committees. Based upon this examination, our board of directors has determined that each member of our Audit Committee is independent and is otherwise qualified to be a member of our Audit Committee in accordance with the rules of the SEC and Nasdaq.

Additionally, the SEC requires that at least one member of the Audit Committee have a "heightened" level of financial and accounting sophistication. Such a person is known as the "audit committee financial expert" under the SEC's rules. Our board of directors has determined that Mr. Chill is an "audit committee financial expert," as the SEC defines that term, and is an independent member of our board of directors and our Audit Committee. Please see Mr. Chill's biography above for a description of his relevant experience.

Compensation Committee

The Compensation Committee currently consists of Adam J. Chill, Neil Herskowitz and Michael J. Zelefsky, M.D. Mr. Herskowitz chairs the Compensation Committee.

The duties and responsibilities of the Compensation Committee are set forth in the Charter of the Compensation Committee which was recently reviewed by our Compensation Committee. A copy of the Charter of the Compensation Committee is available on our website, located at *ir.mustangbio.com*. As discussed in its Charter, among other things, the duties and responsibilities of the Compensation Committee include approving any corporate goals and objectives relating to the compensation of our executive officers, evaluating the performance of our executive officers, and administering all of our executive compensation programs, including, but not limited to, our incentive and equity-based plans. The Compensation Committee evaluates the performance of all of our executive officers on an annual basis and reviews and approves on an annual basis all compensation programs and awards relating to such officers. The Compensation Committee applies discretion in the determination of individual executive compensation packages to ensure compliance with our compensation philosophy. Our Chief Executive Officer makes recommendations to the Compensation Committee with respect to the compensation packages for officers other than himself.

Nasdaq has established rules and regulations regarding the composition of compensation committees and the qualifications of compensation committee members. Our board of directors has examined the composition of our Compensation Committee and the qualifications of our Compensation Committee members in light of the current rules and regulations governing compensation committees. Based upon this examination, our board of directors has determined that each member of our Compensation Committee is independent and is otherwise qualified to be a member of our Compensation Committee in accordance with such rules.

Nominating Process

We do not currently have a nominating committee or any other committee serving a similar function. Although we do not have a written charter in place to select director nominees, our board of directors has adopted resolutions regarding the director nomination process. We believe that the current process in place functions effectively to select director nominees who will be valuable members of our board of directors.

We identify potential nominees to serve as directors through a variety of business contacts, including current executive officers, directors, community leaders and stockholders. We may, to the extent deemed appropriate by the board of directors, retain a professional search firm and other advisors to identify potential nominees.

We will also consider candidates recommended by stockholders for nomination to our board of directors. A stockholder who wishes to recommend a candidate for nomination to our board of directors must submit such recommendation to our Corporate Secretary at our offices located at 377 Plantation Street, Worcester, Massachusetts 01605. Pursuant to our Bylaws, any recommendation must be received not less than 50 calendar days nor more than 90 calendar days before the anniversary date of the previous year's annual meeting.

We believe that our board of directors as a whole should encompass a range of talent, skill, and expertise enabling it to provide sound guidance with respect to our operations and interests. Our independent directors evaluate all candidates to our board of directors by reviewing their biographical information and qualifications. If the directors determine that a candidate is qualified to serve on our board of directors, such candidate is interviewed by at least one of the directors and our Chief Executive Officer. Other members of the board of directors also have an opportunity to interview qualified candidates. The directors then determine, based on the background information and the information obtained in the interviews, whether to recommend to board of directors that the candidate be nominated for approval by the stockholders to fill a directorship. With respect to an incumbent director whom the directors are considering as a potential nominee for re-election, the directors review and consider the incumbent director's service during his or her term, including the number of meetings attended, level of participation, and overall contribution to board of directors. The manner in which the directors evaluate a potential nominee will not differ based on whether the candidate is recommended by our directors or stockholders.

We consider the following qualifications, among others, when making a determination as to whether a person should be nominated to our board of directors: the independence of the director nominee; the nominee's character and integrity; financial literacy; level of education and business experience, including experience relating to biopharmaceutical companies; whether the nominee has sufficient time to devote to our board of directors; and the nominee's commitment to represent the long-term interests of our stockholders. We review candidates in the context of the current composition of the board of directors and the evolving needs of our business. We believe that each of the current members of our board of directors (who are also our director nominees) has the requisite business, biopharmaceutical, financial or managerial experience to serve as a member of the board of directors, as described above. We also believe that each of the current members of our board of directors has other key attributes that are important to an effective board, including integrity, high ethical standards, sound judgment, analytical skills, and the commitment to devote significant time and energy to service on the board of directors and its committees.

We do not have a formal policy in place with regard to diversity in considering candidates for our board of directors, but the board of directors strives to nominate candidates with a variety of complementary skills so that, as a group, the board of directors will possess the appropriate talent, skills and expertise to oversee our business.

Code of Business Conduct and Ethics

We adopted a Code of Ethics (the “Code”), which applies to all of our directors and employees, including our principal executive officer and principal financial officer. The Code includes guidelines dealing with the ethical handling of conflicts of interest, compliance with federal and state laws, financial reporting, and our proprietary information. The Code also contains procedures for dealing with and reporting violations of the Code. The Code is disclosed, and any amendments thereto, or any waivers of its requirements will be disclosed, on our website at www.mustangbio.com.

Policy Prohibiting Hedging and Speculative Trading

Pursuant to our Insider Trading Policy, our officers, directors, and employees are prohibited from engaging in speculative trading, including hedging transactions or short sale transactions with respect to Company securities.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws each limit our directors’ liability and may indemnify our directors and officers to the fullest extent permitted under the General Corporation Law of the State of Delaware (the “DGCL”). The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for:

- any breach of the director’s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payment of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper benefit.

The DGCL and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law.

We have entered or intend to enter into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys’ fees, judgments, penalties, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors, officers and key employees for the defense of any action for which indemnification is required or permitted.

We maintain a directors’ and officers’ insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our amended and restated certificate of incorporation, as amended, and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation, as amended, and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder’s investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

As determined in accordance with SEC rules, our named executive officers (“NEOs”) set forth below, which includes all executive officers serving during 2024. The following table sets forth information concerning compensation paid by us to our NEOs for their services rendered to us in all capacities during the years ended December 31, 2024 and 2023.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Stock Awards ⁽¹⁾ (\$)</u>	<u>Option Awards (\$)</u>	<u>Non-Equity Incentive Plan Compensation (\$)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Manuel Litchman, M.D. ⁽³⁾	2024	\$ 501,704	\$ — ⁽²⁾	\$ —	\$ —	\$ —	\$ —	\$ 501,704
<i>President, Chief Executive Officer and Interim Chief Financial Officer</i>	2023	\$ 480,788	\$ — ⁽²⁾	21,050	—	—	—	501,838
James Murphy ⁽⁴⁾	2024	—	—	—	—	—	199,485	199,485
<i>Interim Chief Financial Officer</i>								
Eliot Lurier ⁽⁵⁾	2023	—	—	—	—	—	244,283	244,283
<i>Interim Chief Financial Officer</i>								

(1) The amounts in the “Stock Awards” column reflect the aggregate grant date fair value of restricted stock units granted during the year computed in accordance with the provisions of FASB ASC Topic 718. The assumptions used in calculating these amounts are set forth in Note 9 to our financial statements for the year ended December 31, 2023 included elsewhere in this prospectus.

(2) On October 23, 2024, the Compensation Committee elected to forgo payments for the 2023 and 2024 annual cash incentive bonuses.

(3) Dr. Litchman was appointed Interim Chief Financial Officer as of November 15, 2024.

(4) Effective January 19, 2024, Mr. Murphy was appointed as our Interim Chief Financial Officer, although he remained a consultant employed by Danforth Advisors, LLC (“Danforth”) and was contracted to work for us on a part time basis, as described under “Narrative to Summary Compensation Table” below. The amount shown represents fees and expenses payable to Danforth in connection with the Chief Financial Officer services provided by Mr. Murphy based on a negotiated hourly rate. On November 12, 2024, Mr. Murphy resigned as our Interim Chief Financial Officer. Mr. Murphy’s resignation was not a result of any disagreement on any matter relating to the our operations, policies or practices.

(5) Effective April 18, 2022, Mr. Lurier was appointed as our Interim Chief Financial Officer, although he remained a consultant employed by Danforth and was contracted to work for us on a part time basis, as described under “Narrative to Summary Compensation Table” below. The amount shown represents fees and expenses payable to Danforth in connection with the Chief Financial Officer services provided by Mr. Lurier based on a negotiated hourly rate. On December 8, 2023, Mr. Lurier passed away unexpectedly.

Narrative to Summary Compensation Table

Employment Agreements

Dr. Litchman

In April 2017, we entered into an employment agreement with Dr. Litchman, our President and Chief Executive Officer, pursuant to which he received an initial annual base salary of \$395,000. As part of his annual review in January 2023, the board of directors increased Dr. Litchman's annual base salary to \$485,500 effective as of April 1, 2023. The employment agreement further provides eligibility for an incentive bonus linked to the realization of certain corporate milestones to be established annually by the board of directors or the Compensation Committee. Dr. Litchman's target annual bonus is equal to fifty percent (50%) of his annual salary, and the board of directors or the Compensation Committee will determine the actual payout amount each year. Dr. Litchman's annual bonus for 2023 is described under "Annual Incentive Bonus" below. The employment agreement provides that if we terminate Dr. Litchman without cause or if he resigns for good reason, as those terms are defined in the employment agreement, he will be entitled to: (i) severance payments at a rate equal to his base salary then in effect for a period of 12 months following his termination date; (ii) a pro-rata share of the annual incentive bonus for the year in which the termination occurred, to be paid when and if such bonus would have been paid under the employment agreement; (iii) accelerated partial vesting of all unvested time-based equity awards with respect to the same number of shares that would have vested if Dr. Litchman had continued in employment for one year following the termination date; and (iv) if Dr. Litchman timely elects continued health insurance coverage under COBRA, the entire premium necessary to continue such coverage for Dr. Litchman and Dr. Litchman's eligible dependents until the conclusion of the time when Dr. Litchman is receiving continuation of base salary payments or until Dr. Litchman becomes eligible for group health insurance coverage under another employer's plan, whichever occurs first, provided however that we have the right to terminate such payment of COBRA premiums on behalf of Dr. Litchman and instead pay him a lump sum amount equal to the COBRA premium times the number of months remaining in the specified period if we determine in our discretion that continued payment of COBRA premiums is or may be discriminatory under Section 105(h) of the Internal Revenue Code. In addition, if Dr. Litchman is terminated without cause or resigns for good reason within twelve months following a change in control, he will be entitled to the severance benefits described in (i), (ii) and (iv) of the immediately preceding sentence, as well as 100% accelerated vesting of the options and other equity awards granted to him. In the event Dr. Litchman's employment is terminated due to his death or disability, he or his estate will receive continuing salary payments for ninety days and a pro-rata share of the annual incentive bonus for the year in which the termination occurred, to be paid when and if such bonus would have been paid under the employment agreement. In each case, the severance benefits are conditioned upon Dr. Litchman's execution and non-revocation of a release of claims against us and compliance with certain non-solicitation and non-competition covenants during his employment and for a period of six months thereafter. Also, the severance benefits are subject to reduction to avoid the imposition of excise taxes under Sections 280G and 4999 of the Code, provided that such reduction would result in a better after-tax result for Dr. Litchman.

Mr. Murphy and Mr. Lurier

Mr. Murphy and Mr. Lurier provided consulting services to us pursuant to a consulting agreement between us and Danforth Advisors, LLC and received no compensation directly from us.

Annual Incentive Bonus

In 2024, Dr. Litchman was eligible to earn a target annual cash incentive equal to 50% of his base salary per the terms of his Employment Agreement.

Dr. Litchman's annual cash incentive bonus is based upon our performance against pre-established corporate goals and objectives, which include a combination of clinical and nonclinical goals related to our products as well as other corporate development goals, and his individual performance based upon subjective performance reviews. On October 23, 2024, the Compensation Committee elected to forgo payments for the 2023 and 2024 annual cash incentive bonuses. The actual amounts paid to Dr. Litchman pursuant to his annual cash incentive award is reported in the "Summary Compensation Table" as non-equity incentive plan compensation.

Equity Awards

The Compensation Committee has granted Dr. Litchman equity awards under our Mustang Bio, Inc. 2016 Incentive Plan (the “2016 Plan”). In 2017, Dr. Litchman received an option to purchase 69,445 shares, and he received awards of 5,000 restricted stock units in 2023, which vest as described in footnotes (2) and (3), respectively, to the Outstanding Equity Awards table below. No awards of restricted stock units were granted in 2024.

Outstanding Equity Awards at Fiscal Year-End 2024

Name	Option Awards				Stock Awards	
	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ⁽¹⁾ (\$)
Manuel Litchman M.D.	43,403 ⁽²⁾	26,042 ⁽²⁾	\$ 85.95	4/24/2027	6,801 ⁽³⁾	\$ 1,204

(1) Market value is based on \$0.177 per share, the closing price of our common stock on the Nasdaq Capital Market on December 31, 2024, the last trading day of the fiscal year.

(2) The option vests as follows: (i) one half of the option will vest over time, with 25% of such shares vesting after twelve months of employment, and the remaining shares vesting in twelve equal quarterly installments thereafter, subject to Dr. Litchman’s “continuous service” (as defined in the 2016 Plan) to the Company on each vesting date; (ii) the remaining one half of the option will vest and become exercisable upon the occurrence of the following milestones being achieved, in each case subject to Dr. Litchman’s continuous service to the Company on the date of such occurrences: (A) 25% of such shares will vest upon the dosing of the first patient in the first Phase 2 clinical trial of any Company product candidate; (B) 25% of such shares will vest upon the dosing of the first patient in the first Phase 2 clinical trial of a second Company product candidate; (C) 25% of such shares will vest upon our achievement of a fully-diluted market capitalization of \$500,000,000; and (D) 25% of such shares will vest upon our achievement of a fully-diluted market capitalization of \$1 billion. Notwithstanding the foregoing, in the event that a Phase 2 clinical trial for either of the Company product candidates referenced in subsections (i) or (ii) of this paragraph is bypassed, the corresponding percentage of the Performance Option grant that would have otherwise vested pursuant to subsections (i) or (ii) of this paragraph will vest upon the earlier of (x) the dosing of the first patient in the first Phase 3 clinical trial for that Company product candidate, or (y) the filing of a Biologics License Application or New Drug Application with the U.S. Food and Drug Administration, or alternatively the filing of an equivalent regulatory filing with a foreign regulatory agency, with respect to that Company product candidate.

(3) Subject to Dr. Litchman’s continuous service, the restricted stock units vest as follows: (i) 3,284 shares will vest on April 24, 2025; (ii) 2,267 shares will vest on April 24, 2026; and (iii) 1,250 shares will vest on April 24, 2027.

Director Compensation

Director Compensation Program

In January 2016, our board of directors adopted a Non-Employee Directors Compensation Plan for our non-employee directors, which determines the cash and equity compensation payable to our non-employee directors. The Non-Employee Directors Compensation Plan provides for our non-employee directors to receive the following compensation:

Cash Compensation:

- \$50,000 annual retainer; and
- \$10,000 additional annual retainer for the Audit Committee Chair.

However, for Mr. Weiss, in lieu of the cash compensation described above, \$60,000 of annual cash compensation is paid to the Advisor according to the Advisory Agreement

Equity Compensation:

- Initial Equity Grant: 50,000 shares of restricted stock, which shares shall vest and become non-forfeitable in equal annual installments over three years, beginning on the third (3rd) anniversary of the grant date, subject to the director's continued service on the board of directors on such date.
- Re-Election Equity Grant: The greater of (i) a number of shares of restricted stock having a fair market value on the grant date of \$50,000, or (ii) 10,000 shares of restricted stock, which shares shall vest and become non-forfeitable on the third (3rd) anniversary of the grant date, subject to the director's continued service on the board of directors on such date.

In addition, each non-employee director receives reimbursement for reasonable travel expenses incurred in attending meetings of our board of directors and meetings of committees of our board of directors.

Director Compensation Table

The following table sets forth the cash and other compensation we paid to the non-employee members of our board of directors for all services in all capacities during 2024.

Name	Fees Earned or Paid in Cash (\$) ⁽¹⁾	Stock Awards (\$) ⁽²⁾	Total (\$)
Neil Herskowitz	\$ 50,000	\$ —	\$ 50,000
Lindsay A. Rosenwald, M.D.	\$ 50,000	—	50,000
Michael S. Weiss ⁽³⁾	\$ 60,000	—	60,000
Adam J. Chill	\$ 60,000	—	60,000
Michael J. Zelefsky, M.D.	\$ 50,000	—	50,000
David Jin	\$ 12,500	—	12,500

(1) Represents the cash retainer for serving on our board of directors and committees thereof.

(2) No stock awards were granted in 2024. As of December 31, 2024, each of Mr. Herskowitz, Dr. Rosenwald, Mr. Weiss, Mr. Chill and Dr. Zelefsky had 12,691 shares of unvested restricted stock pursuant to prior awards.

(3) Pursuant to the Advisory Agreement, the Advisor is paid an annual cash fee of \$60,000, for the services of Mr. Weiss as Chairman of the board of directors and Executive Chairman in addition to any and all annual equity incentive grants paid to members of the board of directors.

Mustang Bio, Inc. 2016 Incentive Plan

The material terms of the Mustang Bio, Inc. 2016 Incentive Plan (the “Plan”) are described below. The following summary is qualified in its entirety by reference to the complete text of the Plan which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Purpose. The purpose of Plan is to promote the success, and enhance the value, of Mustang Bio, Inc. by linking the personal interests of employees, officers, directors and consultants of the Company or any its Affiliates (defined below) to those of Company stockholders and by providing such persons with an incentive for outstanding performance. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of employees, officers, directors and consultants upon whose judgment, interest, and special effort the successful conduct of the Company’s operation is largely dependent. Accordingly, the Plan permits the grant of incentive awards from time to time to selected employees, officers, directors and consultants of the Company and its Affiliates. “Affiliate” means (i) any Subsidiary or Parent, or (ii) an entity that directly or through one or more intermediaries controls, is controlled by or is under common control with, the Company, as determined by the Committee.

Permissible Awards. The Plan authorizes the board of directors (or the Compensation Committee) to grant awards in any of the following forms:

- options to purchase shares of our common stock, which may be nonstatutory stock options or incentive stock options under the Internal Revenue Code of 1986, as amended (the “Code”). The exercise price of an option granted under the Plan may not be less than the fair market value of our common stock on the date of grant. Stock options granted to U.S. participants under the Plan may not have a term longer than ten (10) years;
- stock appreciation rights, or SARs, which give the holder the right to receive the excess, if any, of the fair market value of one (1) share of our common stock on the date of exercise, over the base price of the stock appreciation right. The base price of a SAR may not be less than the fair market value of our common stock on the date of grant. SARs granted to U.S. participants under the Plan may not have a term longer than ten (10) years;
- restricted stock, which is subject to restrictions on transferability and subject to forfeiture on terms set by the Compensation Committee;
- restricted stock units, which represent the right to receive shares of our common stock (or an equivalent value in cash or other property) in the future, based upon the attainment of stated vesting or performance goals set by the Compensation Committee;
- deferred stock units, which represent the right to receive shares of our common stock (or an equivalent value in cash or other property) in the future, generally without any vesting or performance restrictions;
- performance awards, which may be stock-based or cash-based Awards with performance-based vesting criteria, on such terms and conditions as may be selected by the Committee;
- other stock-based awards in the discretion of the Compensation Committee, including unrestricted stock grants; and
- cash-based awards in the discretion of the Compensation Committee, including cash-based performance awards.

All awards will be evidenced by a written award certificate between us and the participant, which will include such provisions as may be specified by the Compensation Committee or the independent members of our board of directors. Dividend equivalent rights, which entitle the participant to payments in cash or property calculated by reference to the amount of dividends paid on the shares of stock underlying an award, may be granted with respect to awards other than options or SARs.

Awards to Non-Employee Directors. Awards granted under the Plan to our non-employee directors will be made only in accordance with the terms, conditions and parameters of a plan, program or policy for the compensation of non-employee directors as in effect from time to time. The Compensation Committee may not make discretionary grants under the Plan to non-employee directors. The maximum aggregate number of shares associated with any award granted under the Plan in any calendar year to any one non-employee director is 100,000.

Shares Available for Awards; Adjustments. Subject to adjustment as provided in the Plan, the aggregate number of shares of our common stock reserved and available for issuance pursuant to awards granted under the Plan is 733,333. Shares subject to awards that are canceled, terminated, forfeited, settled in cash, withheld to satisfy exercise prices or tax withholding obligations or otherwise not issued for any reason, including by reason of failure to achieve maximum performance goals, will again be available for awards under the Plan. In the event of a nonreciprocal transaction between us and our stockholders that causes the per share value of our common stock to change (including, without limitation, any stock dividend, stock split, spin-off, rights offering, or large nonrecurring cash dividend), the share authorization limits under the Plan will be adjusted proportionately, and the Compensation Committee must make such adjustments to the Plan and awards as it deems necessary, in its sole discretion, to prevent dilution or enlargement of rights immediately resulting from such transaction.

Administration. The Plan is administered by the Compensation Committee or, at the discretion of the Board from time to time, the Plan may be administered by the Board. It is intended that at least two of the directors appointed to serve on the Committee shall be Independent Directors and that any members of the Committee who do not so qualify shall abstain from participating in any decision to make or administer Awards that are made to Eligible Participants who at the time of consideration for such Award are persons subject to the short-swing profit rules of Section 16 of the 1934 Act. However, the mere fact that a Committee member shall fail to qualify as an Independent Director or shall fail to abstain from such action shall not invalidate any Award made by the Committee which Award is otherwise validly made under the Plan. The members of the Committee shall be appointed by, and may be changed at any time and from time to time in the discretion of, the Board. Unless and until changed by the Board, the Compensation Committee of the Board is designated as the Committee to administer the Plan. The Board may reserve to itself any or all of the authority and responsibility of the Committee under the Plan or may act as administrator of the Plan for any and all purposes. To the extent the Board has reserved any authority and responsibility or during any time that the Board is acting as administrator of the Plan, it shall have all the powers and protections of the Committee hereunder, and any reference herein to the Committee (other than in this Section 4.1) shall include the Board. To the extent any action of the Board under the Plan conflicts with actions taken by the Committee, the actions of the Board shall control.

Limitations on Transfer; Beneficiaries. No right or interest of a Participant in any unexercised or restricted Award may be pledged, encumbered, or hypothecated to or in favor of any party other than the Company or an Affiliate, or shall be subject to any lien, obligation, or liability of such Participant to any other party other than the Company or an Affiliate. No unexercised or restricted Award shall be assignable or transferable by a Participant other than by will or the laws of descent and distribution; provided, however, that Nonstatutory Stock Options may be transferred without consideration to members of a Participant's immediate family ("Immediate Family Members"), to trusts in which such Immediate Family Members have more than fifty percent (50%) of the beneficial interest, to foundations in which such Immediate Family Members (or the Participant) control the management of assets, and to any other entity (including limited partnerships and limited liability companies) in which the Immediate Family Members (or the Participant) own more than fifty percent (50%) of the voting interest; and, provided, further, that the Committee may (but need not) permit other transfers (other than transfers for value) where the Committee concludes that such transferability (i) does not result in accelerated taxation, (ii) does not cause any Option intended to be an Incentive Stock Option to fail to be described in Code Section 422(b), and (iii) is otherwise appropriate and desirable, taking into account any factors deemed relevant, including without limitation, state or federal tax or securities laws applicable to transferable Awards.

Treatment of Awards upon a Change in Control. Upon the occurrence of a Change in Control: (i) outstanding Options, SARs, and other Awards in the nature of rights that may be exercised shall become fully exercisable, (ii) time-based vesting restrictions on outstanding Awards shall lapse, and (iii) the target payout opportunities attainable under outstanding performance-based Awards shall be deemed to have been fully earned as of the effective date of the Change in Control based upon an assumed achievement of all relevant performance goals at the "target" level, and there shall be a pro rata payout to Participants within sixty (60) days following the Change in Control (unless a later date is required by Section 16.3 hereof), based upon the length of time within the performance period that has elapsed prior to the Change in Control. Any Awards shall thereafter continue or lapse in accordance with the other provisions of the Plan and the Award Certificate. To the extent that this provision causes Incentive Stock Options to exceed the dollar limitation set forth in Code Section 422(d), the excess Options shall be deemed to be Nonstatutory Stock Options.

Discretionary Acceleration. The Compensation Committee may, in its discretion, accelerate the vesting and/or payment of any awards for any reason, subject to certain limitations under Section 409A of the Internal Revenue Code. The Compensation Committee may discriminate among participants or among awards in exercising such discretion.

Certain Transactions. Upon the occurrence or in anticipation of certain corporate events or extraordinary transactions, the Compensation Committee may also make discretionary adjustments to awards, including settling awards for cash, providing that awards will become fully vested and exercisable, providing for awards to be assumed or substituted, or modifying performance targets or periods for awards.

Termination and Amendment. Unless earlier terminated as provided in the Plan, the Plan will terminate on the tenth (10) anniversary of its adoption, or, if the stockholders approve this proposal three, the tenth (10) anniversary of the date of such approval, unless earlier terminated by our Board of Directors or Compensation Committee.

The Board or the Committee may, at any time and from time to time, amend, modify or terminate the Plan without stockholder approval; however, if an amendment to the Plan would, in the reasonable opinion of the Board or the Committee, constitute a material change requiring stockholder approval under applicable laws, policies or regulations or the applicable listing or other requirements of an Exchange, then such amendment shall be subject to stockholder approval; and provided, further, that the Board or Committee may condition any other amendment or modification on the approval of stockholders of the Company for any reason, including by reason of such approval being necessary or deemed advisable (i) to comply with the listing or other requirements of an Exchange, or (ii) to satisfy any other tax, securities or other applicable laws, policies or regulations. Except for any mandatory adjustments to the Plan and Awards required under the Plan, without the prior approval of the stockholders of the Company, the Plan may not be amended to permit: (i) the exercise price or base price of an Option or SAR to be reduced, directly or indirectly, (ii) an Option or SAR to be cancelled in exchange for cash, other Awards, or Options or SARs with an exercise or base price that is less than the exercise price or base price of the original Option or SAR, or otherwise, or (iii) the Company to repurchase an Option or SAR for value (in cash or otherwise) from a Participant if the current Fair Market Value of the Shares underlying the Option or SAR is lower than the exercise price or base price per share of the Option or SAR.

Prohibition on Repricing. As indicated above under “Termination and Amendment,” outstanding stock options and SARs cannot be repriced, directly or indirectly, without the prior consent of our stockholders. The exchange of an “underwater” option or stock appreciation right (i.e., an option or stock appreciation right having an exercise price or base price in excess of the current market value of the underlying stock) for cash or for another award would be considered an indirect repricing and would, therefore, require the prior consent of our stockholders.

Mustang Bio, Inc. 2019 Employee Stock Purchase Plan (“ESPP”)

The ESPP is intended to qualify as an “employee stock purchase plan” under Section 423 of the Code. There are currently 466,667 shares reserved for issuance under the ESPP. The purpose of the ESPP is to attract, retain and motivate employees of the Company by permitting them to participate in the ownership of the Company.

Administration of the Plan

The ESPP is administered by our Board and/or by a committee of our Board having such power as shall be specified by our Board. Generally, each offering of common stock under the ESPP (an “Offering”) is for a period of approximately six (6) months duration (“Offering Period”). Our Board may adjust the Offering Periods, subject to certain limitations. The ESPP will continue until terminated by our Board or until all of the Shares reserved for issuance under the ESPP have been issued.

Eligibility

Participation in the ESPP is limited to eligible employees of the Company and any parent or subsidiary corporation of the Company designated by our Board for inclusion in the ESPP (individually, a “Participating Company”) who authorize payroll deductions. Payroll deductions may not exceed 10% of compensation. No person who owns Shares or holds options to purchase, or who as a result of participation in the ESPP would own Shares or hold options to purchase, 5% or more of the total combined voting power or value of all classes of stock of the Company is entitled to participate in the ESPP. In addition, employees (1) who customarily work fewer than 20 hours per week or (2) who customarily work not more than five months in any calendar year are not eligible to participate. Once an employee becomes a participant in the ESPP (a “Participant”), the employee will automatically participate in each successive Offering until such time as the employee either ceases to be an eligible employee, withdraws from the ESPP or terminates employment.

Generally, Offerings will be six months in duration and will commence on September 1 and end on February 28 (or 29 in the case of a leap year) and then commence on March 1 and end on August 31.

Purchase of and Payment for Securities Offered

Each Offering Period shall consist of one purchase period of approximately six months duration (individually, a “Purchase Period”). On the last day of each Purchase Period (the “Purchase Date”), Shares are purchased based on accumulated payroll deductions. The purchase price per share at which the Shares are sold under the ESPP generally will be 85% of the lesser of the fair market value of the Shares on the first day of the Offering or the Purchase Date.

The number of Shares a Participant purchases in each Offering is determined by dividing the total amount of payroll deductions withheld from the Participant’s compensation by the purchase price. Subject to certain limitations, during an Offering each Participant has a “Purchase Right” consisting of the right to purchase up to 5,000 shares. However, Participants may not purchase shares under the ESPP or any other employee stock purchase plan under Section 423 of the Code having a fair market value exceeding \$25,000 (as determined for purposes of the Code as of the Offering date for each Offering) in any calendar year in which such Participant’s Purchase Right with respect to such Offering remains outstanding. Any cash balance remaining in the Participant’s account is refunded to the Participant as soon as practicable after the Purchase Date. If the refund is less than the amount necessary to purchase a whole Share, the Company may maintain the cash in the Participant’s account and apply it toward the purchase of shares in the subsequent Purchase Period or Offering.

A Participant may withdraw from an Offering at any time without affecting his or her eligibility to participate in future Offerings. In effect therefore, a Participant is given an option which he or she may or may not exercise at the end of a Purchase Period. However, once a Participant withdraws from an Offering, that Participant may not again participate in the same Offering.

In the event of a Transfer of Control of the Company (as defined in the ESPP), the Board, in its sole discretion, may arrange with the surviving, continuing, successor, or purchasing corporation or parent corporation thereof (the “Acquiring Corporation”) to assume the Company’s rights and obligations under the ESPP. Purchase Rights which are neither assumed by the Acquiring Corporation nor exercised as of the Transfer of Control terminate as of the date of the Transfer of Control.

The Board may amend or terminate the ESPP but may not affect Purchase Rights previously granted under the ESPP or adversely affect the right of any Participant except as permitted by the ESPP, as necessary to qualify the ESPP as an employee stock purchase plan pursuant to Section 423 of the Code or to obtain qualification or registration of the shares under applicable foreign, federal or state securities laws. The stockholders must approve any amendment changing the number of shares reserved under the ESPP or changing the definition of the employees (or class of employees) eligible for participation in the ESPP or the definition of a corporation that may be designated by the Board as a Participating Company within 12 months of the adoption of such amendment.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Except as set forth below, since January 1, 2023, we have not been a party to any transaction in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, NEOs, or beneficial owners of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, and other than compensation, termination, and change-in-control arrangements.

The written charter of the Audit Committee authorizes, and Nasdaq rules require, the Audit Committee to review and approve related-party transactions. In reviewing related-party transactions, the Audit Committee applies the basic standard that transactions with affiliates should be made on terms no less favorable to us than could have been obtained from unaffiliated parties. Therefore, the Audit Committee reviews the benefits of the transactions, terms of the transactions and the terms available from unrelated third parties, as applicable. All transactions other than compensatory arrangements between us and our officers, directors, principal stockholders and their affiliates will be approved by the Audit Committee or a majority of the disinterested directors and will continue to be on terms no less favorable to us than could be obtained from unaffiliated third parties.

The following is a summary of each transaction or series of similar transactions since the inception of Mustang to which it was or is a party and that:

- the amount involved exceeded or exceeds \$120,000 or is greater than 1% of our total assets; and
- any of our directors or executive officers, any holder of 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest.

Founders Agreement and Management Services Agreement with Fortress

Effective March 13, 2015, we entered a Founders Agreement with Fortress, which was amended and restated on May 17, 2016, and again on July 26, 2016 (the “Mustang Founders Agreement”). The Mustang Founders Agreement provides that, in exchange for the time and capital expended in the formation of our company and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Fortress loaned \$2.0 million, representing the up-front fee required to acquire our license agreement with COH. The Mustang Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Fortress and the Company or a Change in Control (as defined in the Mustang Founders Agreement) occurs. Concurrently with the second amendment on July 26, 2016, to the Mustang Founders Agreement, Fortress entered into an Exchange Agreement whereby Fortress exchanged its 7.25 million Class B Common shares for 466,667 common shares and 250,000 Class A Preferred shares. Class A Preferred Stock is identical to common stock other than as to voting rights, conversion rights and the Annual Stock Dividend right (as described below). Each share of Class A Preferred Stock is entitled to vote 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 our outstanding common stock and (B) the whole shares of our common stock into which the shares of outstanding Class A common stock and Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Each share of Class A Preferred Stock is convertible, at Fortress’ option, into one fully paid and nonassessable share of our common stock, subject to certain adjustments. As holders of Class A Preferred Stock, Fortress will receive on each January 1 (each a “Annual Stock Dividend Payment Date”) until the date all outstanding Class A Preferred Stock is converted into common stock, pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock (“Annual Stock Dividends”) such that the aggregate number of shares of common stock issued pursuant to such Annual Stock Dividend is equal to two and one-half percent (2.5%) of our fully-diluted outstanding capitalization on the date that is one (1) business day prior to any Annual Stock Dividend Payment Date.

As additional consideration under the Mustang Founders Agreement, we are required to: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing that occurs after the effective date of the Mustang Founders Agreement and ending on the date when Fortress no longer has majority voting control in our voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of our annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, we will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%).

Effective as of March 13, 2015, we entered into a Management Services Agreement (the “MSA”) with Fortress, pursuant to which Fortress renders advisory and consulting services to us. The MSA has an initial term of five years and is automatically renewed for successive five-year terms unless terminated in accordance with its provisions. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of our operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on our behalf with accountants, attorneys, financial advisors and other professionals (collectively, the “Services”). We are obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices.

However, we are not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of its actions or inactions based upon their advice. Pursuant to the MSA and our amended and restated certificate of incorporation, as amended, Fortress and its affiliates, including all members of our board of directors, will have no fiduciary or other duty to communicate or present any corporate opportunities to us or to refrain from engaging in business that is similar to that of our company. In consideration for the Services, we pay Fortress an annual consulting fee of \$0.5 million (the “Annual Consulting Fee”), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to \$1.0 million for each calendar year in which we have net assets in excess of \$100 million at the beginning of the calendar year. We record fifty percent of the Annual Consulting Fee in research and development expense and fifty percent in general and administrative expense in the Statement of Operations. For the years ended December 31, 2023 and 2022, we recorded expense of \$0.5 million and \$1.0 million, respectively, related to this agreement.

For the year ended December 31, 2023, we issued zero shares of common stock and recorded 66,003 shares issuable to Fortress, which equaled 2.5% of the gross proceeds of \$0.2 million from the sale of shares of common stock under our At-the-Market Offering and \$4.4 million gross proceeds on the Registered Direct Offering. We recorded an expense of approximately \$0.1 million in general and administrative expenses related to these shares for the year ended December 31, 2023.

For the year ended December 31, 2022, we issued 13,131 shares of common stock and recorded zero shares issuable to Fortress, which equaled 2.5% of the gross proceeds of \$6.6 million from the sale of shares of common stock under the Mustang ATM. We recorded an expense of approximately \$0.2 million in general and administrative expenses related to these shares for the year ended December 31, 2022.

Payables and Accrued Expenses Related Party

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

Director Compensation

Dr. Rosenwald and Mr. Jin

Pursuant to the terms of our Non-Employee Directors Compensation Plan, Dr. Rosenwald and Mr. Jin will receive a cash fee of \$50,000 per year paid quarterly and an annual stock award of the greater of (i) a number of shares of common stock having a fair market value on the grant date of \$50,000 or (ii) 10,000 shares of common stock, which shares shall vest and become non-forfeitable on the third anniversary of the grant date, subject to continued service on the board of directors on such date. Dr. Rosenwald is Chairman, President and Chief Executive Officer of Fortress and Mr. Jin is Chief Financial Officer and Head of Corporate Development of Fortress. We are a controlled subsidiary of Fortress.

For the year ended December 31, 2024, we recognized \$50,000 and \$12,000 for Dr. Rosenwald and Mr. Jin, respectively, in expense related to the director compensation. For the year ended December 31, 2023, we recognized \$100,000 in expense in our Statements of Operations related to the director compensation, including approximately \$50,000 in expense related to equity incentive grants. We issued Dr. Rosenwald 7,246 restricted stock awards for the year ended December 31, 2023. No restricted stock awards were granted in 2024. We have not yet paid a cash fee or granted any equity awards to Mr. Jin.

Mr. Weiss - Advisory Agreement with Caribe BioAdvisors, LLC

The board of directors approved and authorized our entrance into an advisory agreement, dated January 1, 2017 (the “Advisory Agreement”), with Caribe BioAdvisors, LLC (the “Advisor”), owned by Michael S. Weiss, the Chairman of the board of directors, to provide the board advisory services of Mr. Weiss as Chairman of the board of directors. Pursuant to the Advisory Agreement, the Advisor will be paid an annual cash fee of \$60,000, paid quarterly and an annual stock award of the greater of (i) a number of shares of common stock having a fair market value on the grant date of \$50,000 or (ii) 10,000 shares of common stock, which shares shall vest and become non-forfeitable on the third anniversary of the grant date, subject to continued service on the board of directors on such date.

For the year ended December 31, 2024, we recognized \$60,000 in expense related to the advisory agreement. For the year ended December 31, 2023, we recognized \$110,000 in expense in our Statements of Operations related to the advisory agreement, including approximately \$50,000 in expense related to equity incentive grants. We issued Mr. Weiss 7,246 shares of restricted stock for the year ended December 31, 2023. No restricted stock awards were granted in 2024.

PRINCIPAL STOCKHOLDERS

The following table sets forth, as of January 10, 2025, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our NEOs;
- each of our directors; and
- all of our executive officers and directors as a group.

As of January 10, 2025, there were 64,768,830 shares of our common stock, 845,385 shares of our Class A Common Stock, and 250,000 shares of our Class A Preferred Stock outstanding. In order to calculate a stockholder’s percentage of beneficial ownership, we include in the calculation those shares underlying options or warrants beneficially owned by that stockholder that are vested or that will vest within 60 days of January 10, 2025. Shares of restricted stock are deemed to be outstanding. Options or warrants held by other stockholders that are not attributed to the named beneficial owner are disregarded in this calculation. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares of our common stock. Unless we have indicated otherwise, each person named in the table below has sole voting power and investment power for the shares listed opposite such person’s name, except to the extent authority is shared by spouses under community property laws.

Name of Beneficial Owner (1)	Shares owned	Shares Under Exercisable Options and Unvested Restricted Stock Units (2)	Total Shares Beneficially Owned	% of total CS
Michael S. Weiss (3)	49,637	—	49,637	* %
Manuel Litchman, M.D	76,223	50,024	126,427	* %
Lindsay A. Rosenwald, M.D (3)	60,525	—	60,525	* %
Neil Herskowitz	19,703	—	19,703	* %
David Jin	1,994	—	1,994	* %
Adam J. Chill	19,170	—	19,170	* %
Michael J. Zelefsky, M.D	18,970	—	18,970	* %
All current executive officers and directors as a group (7 persons)	246,222	50,204	296,426	* %
5% or Greater Stockholders:				
Fortress Biotech, Inc (4)	6,552,781	—	6,552,781	10.1 %

* Less than 1% of our common stock outstanding

- (1) The address of each of the directors and executive officers is c/o Mustang Bio, Inc., 377 Plantation Street, Worcester, Massachusetts 01605, and the address of Fortress Biotech, Inc. is c/o Fortress Biotech, Inc., 1111 Kane Concourse, Suite 301, Bay Harbor Island, FL 33154.
- (2) Includes only options exercisable within 60 days of January 10, 2025 and unvested restricted stock units.
- (3) Includes 33,334 warrants issued by Fortress to each of Mr. Weiss and Dr. Rosenwald that cover shares of our common stock that are owned by Fortress. These do not represent equity compensation by us to either Mr. Weiss or Dr. Rosenwald.
- (4) Includes shares underlying 33,334 warrants issued to each of Mr. Weiss and Dr. Rosenwald, and excludes 250,000 of Class A Preferred Stock, which are convertible into 16,666 shares of common stock.

Name and Address of Beneficial Owner⁽¹⁾	Class A Common Stock Beneficially Owned	
	Number of Shares and Nature of Beneficial Ownership	Percentage of Total Class A Common Stock
City of Hope National Medical Center	845,385	100%

(1) The address of City of Hope National Medical Center is 1500 East Duarte Road, Duarte, California 91010.

Name and Address of Beneficial Owner⁽¹⁾	Class A Preferred Stock Beneficially Owned	
	Number of Shares and Nature of Beneficial Ownership	Percentage of Total Class A Preferred Stock
Fortress Biotech, Inc.	250,000	100%

(1) The address of Fortress Biotech Inc. is c/o Fortress Biotech, Inc., 1111 Kane Concourse, Suite 301, Bay Harbor Islands, Florida 33154.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following discussion is a summary of certain material U.S. federal income tax consequences of the purchase, ownership and disposition of the shares of common stock and pre-funded warrants and accompanying Warrants or components thereof, which we refer to collectively as the “Securities,” issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended (the “Code”), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the “IRS”) in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a holder of the Securities. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of the Securities.

This discussion is limited to holders that hold the Securities as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a holder’s particular circumstances, including the impact of the alternative minimum tax or the unearned income Medicare contribution tax. In addition, it does not address consequences relevant to holders subject to particular rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons holding the Securities as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;

- persons deemed to sell the Securities under the constructive sale provisions of the Code;
- persons for whom our stock and pre-funded warrants constitutes “qualified small business stock” within the meaning of Section 1202 of the Code;
- persons who hold or receive the Securities pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into account in an “applicable financial statement” (as defined in the Code);
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- tax-qualified retirement plans.

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds the Securities, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding the Securities and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS LEGAL OR TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF THE SECURITIES ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Allocation of Purchase Price

Each share of common stock or pre-funded warrant, as applicable, and accompanying Warrants will be treated for U.S. federal income tax purposes as an investment unit consisting of one share of our common stock or pre-funded warrant, as applicable, and accompanying Warrants to purchase our common stock. In determining their tax basis for the common stock or pre-funded warrant and the Warrants constituting an investment unit, holders of Securities should allocate their purchase price for the investment unit between the common stock or pre-funded warrant, as applicable, and the Warrants on the basis of their relative fair market values at the time of issuance. We do not intend to advise holders of the Securities with respect to this determination, and holders of the Securities are advised to consult their tax and financial advisors with respect to the relative fair market values of the common stock or pre-funded warrant, as applicable, and the Warrants for U.S. federal income tax purposes.

Treatment of Pre-Funded Warrants

Although not free from doubt, a pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes, and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock, as described below. Accordingly, no gain or loss should be recognized (other than with respect to cash paid in lieu of a fractional share) upon the exercise of a pre-funded warrant (except in the case of a cashless exercise, the treatment of which for U.S. federal income tax purposes is not clear) and, upon exercise, the holding period of a pre-funded warrant should carry over to the share of common stock received. Similarly, the tax basis of the pre-funded warrant should carry over to the share of common stock received upon exercise, increased by the exercise price of \$0.0001. The discussion below assumes the characterization described above is respected for U.S. federal income tax purposes. Holders should consult their tax advisors regarding the risks associated with the acquisition of pre-funded warrants pursuant to this offering (including alternative characterizations).

Tax Considerations Applicable to U.S. Holders

Definition of a U.S. Holder

For purposes of this discussion, a “U.S. holder” is any beneficial owner of the Securities that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more United States persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled “Dividend Policy,” we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock or pre-funded warrants (other than certain distributions of common stock), such distributions will constitute dividends to the extent paid out of our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. Dividends received by a corporate U.S. holder may be eligible for a dividends received deduction, subject to applicable limitations. Dividends received by certain non-corporate U.S. holders, including individuals, are generally taxed at the lower applicable capital gains rate provided certain holding period and other requirements are satisfied. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital and first be applied against and reduce a U.S. holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our common stock or pre-funded warrants, as applicable.

Sale or Other Taxable Disposition of Common Stock or Pre-Funded Warrants

Upon the sale, exchange or other taxable disposition of the common stock or pre-funded warrants, a U.S. holder generally will recognize capital gain or loss equal to the difference between (i) the amount of cash and the fair market value of any property received upon the sale, exchange or other taxable disposition and (ii) such U.S. holder's adjusted tax basis in the common stock or pre-funded warrant. Such capital gain or loss will be long-term capital gain or loss if the U.S. holder's holding period in such common stock or pre-funded warrant is more than one year at the time of the sale, exchange or other taxable disposition. Long-term capital gains recognized by certain non-corporate U.S. holders, including individuals, generally will be subject to reduced rates of U.S. federal income tax. The deductibility of capital losses is subject to certain limitations.

Sale or Other Disposition, Exercise or Expiration of the Warrants

Upon the sale or other disposition of Warrants (other than by exercise), a U.S. holder will generally recognize capital gain or loss equal to the difference between the amount realized on the sale or other disposition and the U.S. holder's tax basis in the Warrants. This capital gain or loss will be long-term capital gain or loss if the U.S. holder's holding period in such Warrant is more than one year at the time of the sale or other disposition. The deductibility of capital losses is subject to certain limitations.

In general, a U.S. holder will not be required to recognize income, gain or loss upon exercise of the Warrants for their exercise prices (except to the extent the U.S. holder receives a cash payment for a such fractional share that would otherwise have been issuable upon exercise of the Warrants, which will be treated as a sale as described above under "Sale or Other Taxable Disposition of Common Stock or Pre-Funded Warrants"). A U.S. holder's tax basis in a share of common stock received upon exercise of the Warrants will be equal to the sum of (i) the U.S. holder's tax basis in the Warrants exchanged therefor and (ii) the exercise price of such Warrants. A U.S. holder's holding period in the shares of common stock received upon exercise will commence on the day after such U.S. holder exercises the Warrants. U.S. holders are urged to consult their tax advisors as to the consequences of an exercise of the Warrants on a cashless basis, including with respect to their holding period and tax basis in the common stock received.

If a Warrant expires without being exercised, a U.S. holder will recognize a capital loss in an amount equal to such holder's tax basis in such Warrant. Such loss will be long-term capital loss if, at the time of the expiration, the U.S. holder's holding period in such Warrant is more than one year. The deductibility of capital losses is subject to certain limitations.

Constructive Dividends on Common Warrants or Pre-Funded Warrants

As described in the section entitled "Dividend Policy," we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if at any time during the period in which a U.S. holder holds Warrants or pre-funded warrants, we were to pay a taxable dividend to our stockholders and, in accordance with an anti-dilution provisions of the Warrants or pre-funded warrants, the exercise price thereof were decreased, that decrease would be deemed to be the payment of a taxable dividend to a U.S. holder of the Warrants or pre-funded warrants, as applicable, to the extent of our earnings and profits, notwithstanding the fact that such holder will not receive a cash payment. If the exercise price is adjusted in certain other circumstances or other adjustments are made (or in certain circumstances, there is a failure to make adjustments), such adjustments may also result in the deemed payment of a taxable dividend to a U.S. holder. In addition, a holder of a Warrant or pre-funded warrant may, in some circumstances, be deemed to have received a distribution subject to U.S. federal income tax as a result of an adjustment or the non-occurrence of an adjustment to the exercise price or number of shares of common stock issuable upon exercise of the Warrants or pre-funded warrant. U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the Warrants and pre-funded warrants.

We are currently required to report the amount of any deemed distributions on our website or to the IRS and to holders not exempt from reporting. The IRS has proposed regulations addressing the amount and timing of deemed distributions, as well as obligations of withholding agents and filing and notice obligations of issuers in respect of such deemed distributions. If adopted as proposed, the regulations would generally provide that (i) the amount of a deemed distribution is the excess of the fair market value of the right to acquire stock immediately after the exercise price adjustment over the fair market value of the right to acquire stock (after the exercise price adjustment) without the adjustment, (ii) the deemed distribution occurs at the earlier of the date the adjustment occurs under the terms of the instrument and the date of the distribution of cash or property that results in the deemed distribution and (iii) we are required to report the amount of any deemed distributions on our website or to the IRS and to all holders (including holders that would otherwise be exempt from reporting). The final regulations will be effective for deemed distributions occurring on or after the date of adoption, but holders and withholding agents may rely on them prior to that date under certain circumstances.

Information Reporting and Backup Withholding

A U.S. holder may be subject to information reporting and backup withholding when such holder receives payments on the common stock or pre-funded warrants or Warrants (including constructive dividends) or receives proceeds from the sale or other taxable disposition of common stock, pre-funded warrants, or Warrants. Certain U.S. holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the IRS that the holder previously failed to properly report payments of interest or dividends;
- or fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Tax Considerations Applicable to Non-U.S. Holders

For purposes of this discussion, a "non-U.S. holder" is a beneficial owner of the Securities that is neither a U.S. holder nor an entity treated as a partnership for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if we do make distributions of cash or property (other than certain distributions of common stock) on our common stock or pre-funded warrants, such will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock or pre-funded warrants, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of our common stock, pre-funded warrants or Warrants. Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of the withholding rules discussed below we or the applicable withholding agent may treat the entire distribution as a dividend.

Subject to the discussion below on backup withholding and foreign accounts, dividends paid to a non-U.S. holder of our common stock or pre-funded warrants that are not effectively connected with the non-U.S. holder's conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders will be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding our common stock or pre-funded warrants in connection with the conduct of a trade or business within the United States and dividends being effectively connected with that trade or business. To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) claiming an exemption from or reduction of the withholding tax under the benefit of an income tax treaty between the United States and the country in which the non-U.S. holder resides or is established, or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the United States, as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated U.S. federal income tax rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Exercise of Common Warrants or Pre-Funded Warrants

A non-U.S. holder generally will not be subject to U.S. federal income tax on the exercise of Warrants or pre-funded warrants into shares of common stock. Non-U.S. holders are urged to consult their tax advisors as to the consequences of an exercise of a Warrant on a cashless basis, including with respect to their holding period and tax basis in the common stock received.

Sale or Other Disposition of Common Stock, Pre-Funded Warrants or Common Warrants

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock, pre-funded warrants or Warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock, pre-funded warrants, or Warrants constitute U.S. real property interests ("USRPIs") by reason of our status as a U.S. real property holding corporation ("USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, however, there can be no assurance we are not a USRPHC or will not become one in the future.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Constructive Dividends on Common Warrants or Pre-Funded Warrants

As described in the section entitled “Dividend Policy,” we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if at any time during the period in which a non-U.S. holder holds Warrants or pre-funded warrants we were to pay a taxable dividend to our stockholders and, in accordance with the anti-dilution provisions of the Warrants or pre-funded warrants, the exercise price of the Warrants were decreased, that decrease would be deemed to be the payment of a taxable dividend to a non-U.S. holder to the extent of our earnings and profits, notwithstanding the fact that such holder will not receive a cash payment. If the exercise price is adjusted in certain other circumstances (or in certain circumstances, there is a failure to make adjustments), such adjustments may also result in the deemed payment of a taxable dividend to a non-U.S. holder. Any resulting withholding tax attributable to deemed dividends may be collected from other amounts payable or distributable to the non-U.S. holder. Non-U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the Warrants and pre-funded warrants.

Information Reporting and Backup Withholding

Subject to the discussion below on foreign accounts, a non-U.S. holder will not be subject to backup withholding with respect to distributions on our common stock or pre-funded warrants we make to the non-U.S. holder (including constructive dividends with respect to Warrants and pre-funded warrants), provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a United States person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable certification. However, information returns generally will be filed with the IRS in connection with any distributions (including deemed distributions) made on our common stock, pre-funded warrants and Warrants to the non-U.S. holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale or other taxable disposition of our common stock, pre-funded warrants or Warrants within the United States, and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale or other taxable disposition of our common stock, pre-funded warrants or Warrants outside the United States conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or W-8BEN-E, or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption. Proceeds of a disposition of our common stock, pre-funded warrants or Warrants conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder’s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act (“FATCA”)) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including deemed dividends) paid on our common stock, pre-funded warrants or Warrants, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of our common stock, pre-funded warrants or Warrants paid to a “foreign financial institution” or a “non-financial foreign entity” (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain “specified United States persons” or “United States-owned foreign entities” (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends (including deemed dividends). Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules we or the applicable withholding agent may treat the entire distribution as a dividend. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock, pre-funded warrants or Warrants on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISORS REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR SECURITIES, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws, which are attached as exhibits to the registration statement of which this prospectus forms a part. See "Where You Can Find More Information." For a complete description, you should refer to our amended and restated certificate of incorporation, as amended, and amended and restated bylaws, copies of which are attached as exhibits to the registration statement of which this prospectus forms a part.

Capital Stock

We are authorized to issue 200,000,000 shares of common stock, par value of \$0.0001 per share, of which 1,000,000 shares are designated as Class A common stock, and 2,000,000 of preferred stock, \$0.0001 par value per share, of which 250,000 are designated as Class A Preferred Stock.

Common Stock

The holders of common stock are entitled to one vote per share held.

As of January 10, 2025, there were 64,768,830 shares of our common stock outstanding held by 72 stockholders of record.

The undesignated preferred stock may be issued from time to time in one or more series. Our board of directors is authorized to determine or alter the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions, if any), the redemption price or prices, the liquidation preferences and other designations, powers, preferences and relative, participating, optional or other special rights, if any, and the qualifications, limitations and restrictions granted to or imposed upon any wholly unissued series of preferred stock, and to fix the number of shares of any series of preferred stock (but not below the number of shares of any such series then outstanding).

Class A Common Stock

The holders of Class A common stock are entitled to the number of votes equal to the number of whole shares of common stock into which the shares of Class A Common Shares held by such holder are convertible. For a period of ten years from issuance, the holders of the Class A common stock have the right to appoint one member of the Board of Directors of Mustang. To date, the holders of Class A common stock have not yet appointed such director.

Class A Preferred Stock

The Class A Preferred Stock is identical to undesignated common stock other than as to voting rights, conversion rights, and the PIK dividend right.

The holders of the outstanding shares of Class A Preferred Stock receive on each January 1 (each a "PIK Dividend Payment Date") after the original issuance date of the Class A Preferred Stock until the date all outstanding Class A Preferred Stock is converted into common stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and non-assessable shares of common stock such that the aggregate number of shares of common stock issued pursuant to such PIK dividend is equal to 2.5% of the Corporation's fully-diluted outstanding capitalization on the date that is one business day prior to any PIK Dividend Payment Date ("PIK Record Date"). In the event the Class A Preferred Stock converts into common stock, the holders shall receive all PIK dividends accrued through the date of such conversion. No dividend or other distribution shall be paid, or declared and set apart for payment (other than dividends payable solely in capital stock on the capital stock) on the shares of common stock until all PIK dividends on the Class A Preferred Stock shall have been paid or declared and set apart for payment. All dividends are non-cumulative.

On any matter presented to the stockholders for their action or consideration at any meeting of stockholders (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Class A Preferred Stock shall be entitled to cast for each share of Class A Preferred Stock held by such holder as of the record date for determining stockholders entitled to vote on such matter, 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 number of shares of outstanding common stock and (B) the whole shares of common stock in to which the shares of outstanding Class A common stock and the Class A Preferred Stock are convertible, and the denominator of which is number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority.

Each share of Class A Preferred Stock is convertible, at the option of the holder, into one fully paid and nonassessable share of common stock, subject to certain adjustments. If we, at any time effects a subdivision or combination of our outstanding common stock (by any stock split, stock dividend, recapitalization, reverse stock split or otherwise), the applicable conversion ratio in effect immediately before that subdivision is proportionately decreased or increased, as applicable, so that the number of shares of common stock issuable on conversion of each share of Class A Preferred Stock shall be increased or decreased, as applicable, in proportion to such increase or decrease in the aggregate number of shares of common stock outstanding. Additionally, if any reorganization, recapitalization, reclassification, consolidation or merger involving the Company occurs in which the common stock (but not the Class A Preferred Stock) is converted into or exchanged for securities, cash or other property, then each share of Class A Preferred Stock becomes convertible into the kind and amount of securities, cash or other property which a holder of the number of shares of our common stock issuable upon conversion of one share of the Class A Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction.

Additional Features

Other features of our capital stock include:

- *Dividend Rights.* The holders of outstanding shares of our common stock, including Class A common stock, are entitled to receive dividends out of funds legally available at the times and in the amounts that our Board of Directors may determine. All dividends are non-cumulative.
- *Voting Rights.* The holders of our common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our certificate of incorporation and bylaws do not provide for cumulative voting rights.
- *No Preemptive or Similar Rights.* The holders of our common stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock.
- *Right to Receive Liquidation Distributions.* Upon our liquidation, dissolution, or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock, including Class A common stock, outstanding at that time after payment of other claims of creditors, if any.
- *Fully Paid and Non-Assessable.* All of the outstanding shares of our common stock, including Class A common stock, and the Class A Preferred Stock are duly issued, fully paid and non-assessable.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering up to shares of common stock, Series C-1 Warrants to purchase up to shares of common stock, Series C-2 Warrants to purchase up to shares of common stock, and Series C-3 Warrants to purchase up to shares of common stock. We are also offering pre-funded warrants to purchase up to shares of common stock to those purchasers, whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each pre-funded warrant will be exercisable for one share of common stock. Each pre-funded warrant is being issued together with the same Warrants described above being issued with each share of common stock. The shares of common stock or pre-funded warrants, as the case may be, and the accompanying Warrants, can only be purchased together in this offering, but the shares of common stock and pre-funded warrants and accompanying Warrants are immediately separable and will be issued separately in this offering. We are also registering the shares of common stock issuable from time to time upon exercise of the pre-funded warrants and Warrants offered hereby.

Common Stock

The description of our common stock under the section “Description of Our Capital Stock” in this prospectus is incorporated herein by reference.

Warrants

The following summary of certain terms and provisions of the Warrants included with the shares of common stock and the pre-funded warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Warrants, the forms of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Warrant for a complete description of the terms and conditions of the warrants. The Series C-1 Warrant, Series C-2 Warrant, and Series C-3 Warrant are identical except with regard to their duration.

Duration and Exercise Price

Each Warrant offered hereby will have an exercise price of \$ per share and will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, the Warrants will be exercisable upon issuance (the “Initial Exercise Date”). The exercise price and number of shares of common stock issuable upon exercise of the warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Warrants will be issued separately from the common stock and pre-funded warrants and may be transferred separately immediately thereafter. The Warrants will be issued in certificated form only. The Series C-1 Warrants will expire on the five-year anniversary of the Initial Exercise Date. The Series C-2 Warrants will expire on the twenty-four-month anniversary of the Initial Exercise Date. The Series C-3 Warrants will expire on the nine-month anniversary of the Initial Exercise Date.

We intend to promptly, and in no event later than 90 days after the consummation of this offering, seek stockholder approval for the issuance of shares of common stock issuable upon exercise of the Warrants but we cannot assure you that such stockholder approval will be obtained, provided, however, that, if and only if the Pricing Conditions are satisfied, then we will not seek Warrant Stockholder Approval. We have agreed with the investors in this offering that, if we do not obtain stockholder approval for the issuance of the shares of common stock upon exercise of the Warrants at the first stockholder meeting for such purpose after this offering, we will call a stockholder meeting every 90 days thereafter until the earlier of the date we obtain such approval or the Warrants are no longer outstanding, provided, however, that, if and only if the Pricing Conditions are satisfied, then we will not seek Warrant Stockholder Approval.

Exercisability

The Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of the Warrants, 9.99%) of the outstanding common stock immediately after exercise. Following the issuance of the Warrants, upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding stock after exercising the holder's Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants and in accordance with the rules and regulations of the SEC, provided that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice to us.

Cashless Exercise

If, at the time a holder exercises its Warrants, a registration statement registering the issuance of the shares of common stock underlying the Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Warrants. Rather, the number of shares of common stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment equal to such fraction multiplied by the exercise price to the holder.

Transferability

Subject to applicable laws, the Warrants may be transferred at the option of the holder upon surrender of the Warrants to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Warrants will be extremely limited. The common stock issuable upon exercise of the Warrants is currently listed on the Nasdaq Capital Market.

Right as a Shareholder

Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding common stock, the holders of the Warrants will be entitled to receive upon exercise of the Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our board of directors, the holders of the Warrants have the right to require us or a successor entity to redeem the Warrants for cash in the amount of the Black-Scholes Value (as defined in the Warrants) of the unexercised portion of the Warrants on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our board of directors, the holders of the Warrants have the right to require us or a successor entity to redeem the Warrants for the consideration paid in the fundamental transaction in the amount of the Black-Scholes Value of the unexercised portion of the Warrants on the date of the consummation of the fundamental transaction.

Amendments

The Warrants may be modified or amended with the written consent of the holder of such Warrants and us.

Pre-Funded Warrants

The following summary of certain terms and provisions of the pre-funded warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.0001. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued separately from the accompanying Warrants, in certificated form only.

Exercisability

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of the pre-funded warrant, 9.99%) of the outstanding common stock immediately after exercise. Following the issuance of the pre-funded warrants, upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants and in accordance with the rules and regulations of the SEC. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock, provided that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice to us.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability

Subject to applicable law, pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment to such fraction multiplied by the exercise price to the holder.

Trading Market

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the pre-funded warrants will be extremely limited. The common stock issuable upon exercise of the pre-funded warrants is currently listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants. The pre-funded warrants will provide that holders have the right to participate in distributions or dividends paid on our common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Amendments

The pre-funded warrants may be modified or amended with the written consent of the holder of such pre-funded warrant and us.

Placement Agent Warrants

The following summary of certain terms and provisions of the Placement Agent Warrants that are being issued hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Placement Agent Warrants, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Placement Agent Warrant for a complete description of the terms and conditions of the Placement Agent Warrant.

Duration and Exercise Price

Each Placement Agent Warrant offered hereby will have an initial exercise price equal to \$ _____ per share of common stock. The Placement Agent Warrants will be exercisable beginning on the effective date of the Warrant Stockholder Approval, provided however, if the Pricing Conditions are met, such Placement Agent Warrants will be exercisable upon issuance and will expire five years from the commencement of sales in this offering. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability

The Placement Agent Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Placement Agent Warrant to the extent that the holder would own more than 4.99% (or, at the election of the purchaser prior to the issuance of such warrants, 9.99%) of the outstanding common stock immediately after exercise, except that upon notice from the holder to us, the holder may increase or decrease the amount of beneficial ownership of outstanding stock after exercising the holder's Placement Agent Warrant up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Placement Agent Warrants and in accordance with the rules and regulations of the SEC, provided that any increase in the beneficial ownership limitation shall not be effective until 61 days following notice to us.

Cashless Exercise

If, at the time a holder exercises its Placement Agent Warrants, a registration statement registering the issuance of the shares of common stock underlying the Placement Agent Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Placement Agent Warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Placement Agent Warrants. Rather, the number of shares of common stock to be issued will be rounded up to the next whole share or we will pay a cash adjustment equal to such fraction multiplied by the exercise price to the holder.

Transferability

Subject to applicable laws, a Placement Agent Warrant may be transferred at the option of the holder upon surrender of the Placement Agent Warrant to us together with the appropriate instruments of transfer.

Trading Market

There is no trading market available for the Placement Agent Warrants on any securities exchange or nationally recognized trading system, and we do not expect a trading market to develop. We do not intend to list the Placement Agent Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Placement Agent Warrants will be extremely limited. The common stock issuable upon exercise of the Placement Agent Warrants is currently listed on the Nasdaq Capital Market.

Right as a Shareholder

Except as otherwise provided in the Placement Agent Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Placement Agent Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Placement Agent Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Placement Agent Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of greater than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding common stock, the holders of the Placement Agent Warrants will be entitled to receive upon exercise of the Placement Agent Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Placement Agent Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our board of directors, the holders of the Placement Agent Warrants have the right to require us or a successor entity to redeem the Placement Agent Warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the Placement Agent Warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our board of directors, the holders of the Placement Agent Warrants have the right to require us or a successor entity to redeem the Placement Agent Warrants for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the Placement Agent Warrant on the date of the consummation of the fundamental transaction.

Amendments

The Placement Agent Warrants may be modified or amended with the written consent of the holder of such Placement Agent Warrants and us.

PLAN OF DISTRIBUTION

We have engaged (the “Placement Agent”) to act as our exclusive placement agent to solicit offers to purchase the securities offered pursuant to this prospectus on a reasonable best efforts basis. The engagement agreement does not give rise to any commitment by the Placement Agent to purchase any of our securities, and the Placement Agent will have no authority to bind us by virtue of the engagement agreement. The Placement Agent is not purchasing or selling any of the securities offered by us under this prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of securities. This is a “best efforts” offering and there is no minimum offering amount required as a condition to the closing of this offering. The Placement Agent has agreed to use reasonable best efforts to arrange for the sale of the securities by us. Therefore, we may not sell all of the shares of common stock, pre-funded warrants and Warrants being offered. The terms of this offering are subject to market conditions and negotiations between us, the Placement Agent and prospective investors. The Placement Agent does not guarantee that it will be able to raise new capital in any prospective offering. The Placement Agent may engage sub-agents or selected dealers to assist with the offering.

Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) a covenant to not enter into variable rate financings for a period of one year following the closing of the offering, subject to an exception; and (ii) a covenant to not enter into any equity financings for 45 days from closing of the offering, subject to certain exceptions. The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and
- covenants regarding matters such as registration of Warrant shares, no integration with other offerings, no stockholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of shares of common stock, and no subsequent equity sales for 45 days, subject to certain exceptions.

The securities will be offered at a fixed combined public offering price and are expected to be issued in a single closing. We expect this offering to be completed on or about , 2025, and we will deliver all securities to be issued in connection with this offering delivery versus payment/receipt versus payment upon receipt by us of investor funds. Accordingly, neither we nor the Placement Agent have made any arrangements to place investor funds in an escrow account or trust account since the Placement Agent will not receive investor funds in connection with the sale of the securities offered hereunder.

We expect to deliver the shares and securities to the purchasers in the offering on or about , 2025, subject to satisfaction of certain conditions

Fees and Expenses

The following table shows per share and accompanying Warrants and per pre-funded warrant and accompanying Warrants Placement Agent fees and total Placement Agent fees we will pay in connection with the sale of the securities in this offering, assuming the purchase of all of the securities we are offering.

Per share and accompanying Warrants Placement Agent cash fees	\$
Per pre-funded warrant and accompanying Warrants Placement Agent cash fees	\$
Total	\$

We have agreed to pay the Placement Agent a total cash fee equal to 7.0% of the gross proceeds of this offering and a management fee equal to 1.0% of the gross proceeds raised in this offering. We will also pay the Placement Agent a non-accountable expense allowance of \$25,000, \$15,950 for the expenses of its clearing firm, up to \$3,500 for road show expenses, and will reimburse the Placement Agent’s legal fees and expenses in an amount up to \$100,000. We estimate the total offering expenses of this offering that will be payable by us, excluding the Placement Agent’s fees and expenses, will be approximately \$ million. After deducting the Placement Agent’s fees and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$ million.

Placement Agent Warrants

We have agreed to grant Placement Agent Warrants to the Placement Agent to purchase a number of shares of our common stock equal to 6.0% of the aggregate number of shares of common stock and pre-funded warrants sold to the investors in this offering. The Placement Agent Warrants will have an exercise price of \$ (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 this offering. The Placement Agent Warrants are registered on the registration statement of which this prospectus is a part. The form of the Placement Agent Warrants is included as an exhibit to this registration statement of which this prospectus forms a part.

Right of First Refusal

We have granted the Placement Agent a right of first refusal for a period of 10 months following the closing of this offering to act as sole book-running manager, sole underwriter or sole placement agent for each and every future public or private offering or other capital-raising financing of equity or equity-linked securities using an underwriter or placement agent by us or any of our successors or subsidiaries, subject to certain exceptions.

Tail

We have also agreed to pay the Placement Agent a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was wall-crossed by the Placement Agent with respect to a non-public offering or had back and forth correspondence with the Placement Agent with respect to a public offering of our securities, in each case during the term of its engagement, provides us with capital in any public or private offering or other financing or capital raising transaction during the 12-month period following expiration or termination of our engagement of the Placement Agent, subject to an exception.

Other Relationships

From time to time, the Placement Agent may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which it may receive customary fees and commissions. Except as disclosed in this prospectus, we have no present arrangements with the Placement Agent for any services.

Determination of Offering Price

The combined offering price per share and accompanying Warrants and the combined offering price per pre-funded warrants and accompanying Warrants we are offering and the exercise prices and other terms of the Warrants were negotiated between us and the investors, in consultation with the Placement Agent based on the trading of our common stock prior to this offering, among other things. Other factors considered in determining the offering prices of the securities we are offering and the exercise prices and other terms of the Warrants include the history and prospects of our company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Lock-up Agreements

We and each of our executive officers, directors and holders of 10% or greater of our outstanding shares of common stock have agreed with the Placement Agent to be subject to a lock-up period of 45 days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock, subject to customary exceptions. The Placement Agent may waive the terms of these lock-up agreements in its sole discretion and without notice. In addition, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our common stock or upon a specified or contingent event in the future or enter into any agreement to issue securities at a future determined price for a period of one year following the closing date of this offering, subject to an exception. The Placement Agent may waive this prohibition in its sole discretion and without notice.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC.

Nasdaq Listing

Our common stock is currently listed on the Nasdaq Capital Market under the symbol “MBIO.” On , 2025, the reported closing price per share of our common stock was \$. We do not plan to list the Warrants or the pre-funded warrants on the Nasdaq Capital Market or any other securities exchange or trading market.

Indemnification

We have agreed to indemnify the Placement Agent against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the Placement Agent may be required to make with respect to any of these liabilities.

Regulation M

The Placement Agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The Placement Agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agent. Under these rules and regulations, the Placement Agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the Placement Agent, if any, participating in this offering and the Placement Agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the Placement Agent, and should not be relied upon by investors.

LEGAL MATTERS

The validity of the securities offered in this prospectus will be passed upon for us by Troutman Pepper Locke LLP, Charlotte, North Carolina. The Placement Agent is being represented by .

EXPERTS

The financial statements of Mustang Bio, Inc. as of December 31, 2023 and 2022, and for each of the years in the two-year period ended December 31, 2023, have been included in this prospectus and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2023 financial statements contains an explanatory paragraph that states the Company's expectation to generate operating losses and negative operating cash flows in the future, and the need for additional funding to support its planned operations raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement of which this prospectus forms a part. Each of these statements is qualified in all respects by this reference.

You may read our SEC filings, including this registration statement, over the Internet at the SEC's website at www.sec.gov. Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review on the web site of the SEC referred to above. We also maintain a website at www.mustangbio.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

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As of and for the years ended December 31, 2023 and 2022

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Mustang Bio, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Mustang Bio, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's expectation to generate operating losses and negative operating cash flows in the future, and the need for additional funding to support its planned operations raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements and supplemental information do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for the transaction with uBriGene

As discussed in Note 5 to the financial statements, during 2023, the Company entered into an Asset Purchase Agreement and related amendments with uBriGene Biosciences, Inc. (uBriGene), pursuant to which the Company has agreed to sell its leasehold interest in its cell processing facility and associated assets relating to the production of cell and gene therapies to uBriGene. The Company received proceeds of \$6.0 million, which it allocated to the individual sold assets on a relative fair value basis. The Company recognized a gain of \$1.5 million and recorded \$0.2 million of the consideration as deferred income of in its 2023 financial statement. The transaction requires governmental and lessor approval before the lease interest can be transferred to uBriGene. The Company will recognize the deferred income and will receive additional proceeds from uBriGene totaling \$5.0 million, if the Company, within two years from the closing date, (i) completes an issuance of equity securities in an amount equal to or greater than \$10.0 million and (ii) obtains consent of the landlord to the proposed lease transfer.

We identified the evaluation of the Company's accounting for the transaction with uBriGene as a critical audit matter. Specifically, challenging and complex auditor judgment and specialized skills and knowledge were required in identifying the elements of the transaction, including those that were delivered in 2023 and those that were yet to be delivered, and evaluating the application of the relevant accounting guidance.

The following are the primary procedures we performed to address this critical audit matter. We inspected the Company's accounting analysis for the transaction. We compared management's assessment of the elements of the transaction delivered and those that were yet to be delivered to supporting documentation. We involved professionals with specialized skills and knowledge, who assisted in: inspecting the underlying agreements to understand the relevant terms and conditions and identify the elements of the transaction evaluating whether the Company's accounting for the transaction is in accordance with the relevant accounting guidance.

/s/ KPMG LLP

We have served as the Company's auditor since 2021.

Boston, Massachusetts
March 11, 2024

MUSTANG BIO, INC.
BALANCE SHEETS
(in thousands, except for share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 6,234	\$ 75,656
Other receivables - related party	—	36
Other receivables	3,879	263
Prepaid expenses and other current assets	1,233	2,897
Total current assets	11,346	78,852
Property, plant and equipment, net	3,218	8,440
Fixed assets - construction in process	29	951
Restricted cash	750	1,000
Other assets	833	261
Operating lease right-of-use asset, net	1,566	2,918
Total Assets	\$ 17,742	\$ 92,422
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 14,017	\$ 13,731
Payables and accrued expenses - related party	834	766
Operating lease liabilities - short-term	520	612
Total current liabilities	15,371	15,109
Deferred income	270	270
Note payable, long-term, net	—	27,436
Operating lease liabilities - long-term	1,978	3,334
Total Liabilities	17,619	46,149
Commitments and Contingencies (Note 7)		
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 December 31, 2023 and December 31, 2022, respectively	—	—
Common stock (\$0.0001 par value), 200,000,000 shares authorized as of December 31, 2023 and December 31, 2022, respectively		
Class A common shares, 845,385 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	—	—
Common shares, 8,374,869 and 7,100,111 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	1	11
Common stock issuable, 419,089 and 187,134 shares as of December 31, 2023 and December 31, 2022, respectively	591	1,109
Additional paid-in capital	380,502	374,522
Accumulated deficit	(380,971)	(329,369)
Total Stockholders' Equity	123	46,273
Total Liabilities and Stockholders' Equity	\$ 17,742	\$ 92,422

See accompanying notes to financial statements.

MUSTANG BIO, INC.
STATEMENTS OF OPERATIONS
(in thousands, except for share and per share amounts)

	For the year ended December 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 40,513	\$ 62,475
Research and development – licenses acquired	527	1,474
Gain on the sale of property and equipment	(1,466)	—
General and administrative	9,686	12,210
Total operating expenses	49,260	76,159
Loss from operations	(49,260)	(76,159)
Other income (expense)		
Other income	917	1,304
Interest income	850	689
Interest expense	(4,109)	(3,359)
Total other income (expense)	(2,342)	(1,366)
Net Loss	\$ (51,602)	\$ (77,525)
Net loss per common share outstanding, basic and diluted	\$ (6.00)	\$ (10.09)
Weighted average number of common shares outstanding, basic and diluted	8,604,104	7,684,508

See accompanying notes to financial statements.

MUSTANG BIO, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Class A Preferred Stock		Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2021	250,000	\$ —	845,385	\$ —	6,238,866	\$ 9	\$ 4,329	\$ 359,906	\$ (251,844)	\$ 112,400
Common stock issuable - Annual Stock Dividend	—	—	—	—	—	—	1,109	—	—	1,109
Issuance of common shares - Annual Stock Dividend	—	—	—	—	169,107	—	(4,212)	4,212	—	—
Issuance of common shares, net of offering shares - At-the-Market Offering	—	—	—	—	525,206	2	—	6,498	—	6,500
Issuance of common shares - Equity fee on At-the-Market Offering	—	—	—	—	16,550	—	(117)	283	—	166
Issuance of common shares under ESPP	—	—	—	—	22,056	—	—	206	—	206
Stock-based compensation expenses	—	—	—	—	64,664	—	—	2,283	—	2,283
Issuance of common shares - Equity fee on RWG debt	—	—	—	—	63,662	—	—	750	—	750
Issuance of warrants for RWG debt	—	—	—	—	—	—	—	384	—	384
Net loss	—	—	—	—	—	—	—	—	(77,525)	(77,525)
Balances at December 31, 2022	250,000	\$ —	845,385	\$ —	7,100,111	\$ 11	\$ 1,109	\$ 374,522	\$ (329,369)	\$ 46,273
Common stock issuable - Annual Stock Dividend	—	—	—	—	—	—	—	477	—	477
Issuance of common shares - Annual Stock Dividend	—	—	—	—	187,134	—	(1,109)	1,109	—	—
Issuance of common shares, net of offering costs - At-the-Market Offering	—	—	—	—	51,880	—	—	160	—	160
Issuance of common shares, equity fee on At-the-Market Offering	—	—	—	—	—	—	—	4	—	4
Issuance of common shares, net of offering costs - Registered Direct Offering	—	—	—	—	920,000	—	—	3,955	—	3,955
Issuance of common shares, equity fee on Registered Direct Offering	—	—	—	—	—	—	110	—	—	110
Issuance of common shares under ESPP	—	—	—	—	47,511	—	—	178	—	178
Stock-based compensation expenses	—	—	—	—	69,773	—	—	568	—	568
Exercise of warrants	—	—	—	—	93	—	—	—	—	—
Reverse Split (15:1) adjustment	—	—	—	—	(1,633)	(10)	—	10	—	—
Net loss	—	—	—	—	—	—	—	—	(51,602)	(51,602)
Balances at December 31, 2023	250,000	\$ —	845,385	\$ —	8,374,869	\$ 1	\$ 591	\$ 380,502	\$ (380,971)	\$ 123

See accompanying notes to financial statements.

MUSTANG BIO, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	For the year ended December 31,	
	2023	2022
Cash Flows from Operating Activities:		
Net loss	\$ (51,602)	\$ (77,525)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common shares - Equity fee on at-the-market offering to Fortress Biotech	—	166
Common shares issuable - Equity fee on at-the-market offering to Fortress Biotech	4	—
Common shares issuable - Equity fee on Registered Direct Offering to Fortress Biotech	110	—
Common shares issuable - Annual Stock Dividend to Fortress Biotech	477	1,109
Issuance of common shares - Equity fee on note payable to Fortress Biotech	—	750
Research and development - licenses acquired	50	365
Stock-based compensation expenses	568	2,283
Depreciation expense	1,860	2,723
Amortization of debt discount	118	470
Amortization of operating lease right-of-use assets	365	308
Loss on disposal of property and equipment	—	255
Gain on sale of property and equipment	(1,466)	—
Loss on extinguishment of debt	2,796	—
Gain on lease modification	220	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,092	(1,006)
Other receivables	(3,616)	(15)
Other receivables - related party	36	14
Accounts payable and accrued expenses	125	5,257
Payable and accrued expenses - related party	67	43
Lease liabilities	(680)	(263)
Net cash used in operating activities	<u>(49,477)</u>	<u>(65,066)</u>
Cash Flows from Investing Activities:		
Purchase of research and development licenses	(50)	(365)
Proceeds from the sale of property and equipment	6,000	127
Purchase of fixed assets	(64)	(2,714)
Net cash provided by (used in) investing activities	<u>5,886</u>	<u>(2,952)</u>
Cash Flows from Financing Activities:		
Payment of debt	(30,375)	—
Proceeds from issuance of common shares - at-the-market offering	163	6,623
Offering costs for the issuance of common shares -at-the-market offering	(3)	(123)
Proceeds from issuance of common shares - Registered Direct Offering	4,398	—
Offering costs for the issuance of common shares - Registered Direct Offering	(443)	—
Proceeds from debt issuance	—	30,000
Fees paid on the issuance of debt	—	(2,650)
Proceeds from issuance of common shares under ESPP	178	206
Net cash (used in) provided by financing activities	<u>(26,081)</u>	<u>34,056</u>
Net change in cash, cash equivalents and restricted cash	(69,672)	(33,962)
Cash, cash equivalents and restricted cash, beginning of the period	76,656	110,618
Cash, cash equivalents and restricted cash, end of the period	<u>\$ 6,984</u>	<u>\$ 76,656</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,352	\$ 2,710
Supplemental disclosure of noncash activities:		
Issuance of common shares - Founders Agreement	\$ 1,109	\$ 4,212
Note payable final payment fee (incurred but not paid)	\$ —	\$ 1,050
Issuance of warrants - note payable	\$ —	\$ 384
Lease liabilities arising from obtaining right-of-use assets	\$ —	\$ 2,176

See accompanying notes to financial statements.

Notes to Financial Statements

Note 1 - Organization and Description of Business

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

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

The Company’s common stock is listed on the Nasdaq Capital Market and trades under the symbol “MBIO.”

Reverse Stock Split

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

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

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

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

Liquidity and Capital Resources

The Company has incurred substantial operating losses and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2023, the Company had an accumulated deficit of \$381.0 million.

The Company has funded its operations to date primarily through the sale of equity and via debt raises, which included its loan and financing agreement with Runway Growth Finance Corporation (the “Lender”), herein referred to as the “Term Loan.” On April 11, 2023, the Company repaid the Term Loan, see Note 8. The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, including financing the Company’s growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments.

On May 18, 2023, the Company entered into an Asset Purchase Agreement (the “Asset Purchase Agreement”) with uBriGene (Boston) Biosciences, Inc. (“uBriGene”), pursuant to which the Company agreed to sell its leasehold interest in its cell processing facility located in Worcester, MA (the “Facility”) and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility to uBriGene. The Company and uBriGene subsequently entered into Amendment No. 1, dated as of June 29, 2023, and Amendment No. 2, dated as of July 28, 2023, to the Asset Purchase Agreement (the Asset Purchase Agreement, as so amended, the “Amended Asset Purchase Agreement”). On July 28, 2023, pursuant to the terms and conditions of the Amended Asset Purchase Agreement, the Company completed the sale of all of the Company’s assets primarily relating to the manufacturing and production of cell and gene therapies to uBriGene for a base consideration of \$6.0 million. uBriGene will be obligated to pay to the Company a contingent amount of \$5.0 million less certain severance obligations and payments payable in connection with the transfer of certain contracts related to the transferred assets, if the Company, within two years of the closing date, (i) completes an issuance of equity securities in an amount equal to or greater than \$10.0 million after the closing and (ii) obtains consent of the landlord to the proposed lease transfer within two years of the closing date. As contemplated by the Asset Purchase Agreement, the Company entered into a Manufacturing Services Agreement, where the Company contracted uBriGene to manufacture its lead product candidates, including MB-106, and it committed to spend at least \$8.0 million over a period of two years after the closing of the transaction to purchase manufacturing and related services from uBriGene.

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

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

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

The Company will be required to expend significant funds in order to advance the development of its product candidates. The Company will require additional financings through equity and debt offerings, collaborations and licensing arrangements or other sources to fully develop, prepare regulatory filings, obtain regulatory approvals and commercialize its existing and any new product candidates. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations.

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

The Company's expectation to generate operating losses and negative operating cash flows in the future, and the need for additional funding to support its planned operations raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that these consolidated financial statements are issued. The Company continues to monitor its spending by reducing 2024 expenses, which may include projected savings through delaying the development timelines of certain programs, or termination of such programs and the pursuit of additional cash resources through public or private equity or debt financings. The Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these consolidated financial statements.

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

Note 2 - Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The Company has no subsidiaries.

All inter-company transactions between Fortress and Mustang are classified as due from or due to related party in the financial statements. The Company believes that the assumptions underlying the financial statements are reasonable.

Segments

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 operating and reporting segment.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2023 and 2022, consisted of cash and certificates of deposit in institutions in the United States. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are currently adequately protected against credit risk. At times, portions of the Company's cash and cash equivalents may be uninsured or in deposit accounts that exceed Federal Deposit Insurance Corporation (FDIC) limits, though the Company customarily invests a significant portion of its cash in Certificate of Deposit Account Registry Service ("CDARS") accounts to maximize FDIC insurance coverage across its holdings. As of December 31, 2023, the Company had not experienced losses on these accounts, and management believes the Company is not exposed to significant risk on such accounts.

Other Receivables – Related Party

Other receivables include amounts due to the Company from Fortress and is recorded at the invoiced amount.

Restricted Cash

The Company records cash held in an escrow account as a security deposit for the manufacturing facility in Worcester, Massachusetts, as restricted cash. The Company had \$0.8 million and \$1.0 million in restricted cash as of December 31, 2023 and 2022, respectively. The Facility initiated cell processing operations for personalized CAR T and gene therapies in 2018.

Property, plant and equipment, net

Property and equipment, net, which consists primarily of leasehold improvements, are carried at cost less accumulated depreciation. Depreciation for leasehold improvements is computed over the shorter of the estimated useful lives or the term of the respective leases. Depreciation for all other property and equipment assets is recorded over the useful lives of the respective assets, generally five years, using the straight-line method.

Property and equipment - Construction in Process

In connection with the Company's Mercantile Street Facility, the Company incurred costs for the design and buildout of the office space of \$29,000 recorded in fixed assets – construction in process on the Balance Sheet at December 31, 2023. The Company does not yet occupy the Mercantile Street Facility. In connection with the Company's Plantation Street Facility, the Company incurred costs for the design and construction of the facility and the purchase of equipment of \$1.0 million recorded in fixed assets - construction in process on the Balance Sheet at December 31, 2022. Upon completion of the facility's buildout and the improvements being placed into service, the costs will be recorded as leasehold improvements and amortized over the shorter of the estimated useful lives or the term of the respective leases.

Research and Development Costs

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

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

In accordance with Accounting Standards Codification ("ASC") 730-10-25-1, *Research and Development*, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired is reflected as research and development – licenses acquired in the Company's Statements of Operations.

Annual Stock Dividend

In July 2016, in connection with the Amended and Restated Articles of Incorporation, the Company issued 250,000 Class A preferred shares to Fortress. The Class A preferred shares entitle the holder to a stock dividend equal to 2.5% of the fully diluted outstanding equity of the Company (the "Annual Stock Dividend"). The Annual Stock Dividend was part of the consideration payable for formation of the Company and the identification of certain assets, including the license contributed to Mustang by Fortress (see Note 4).

In June 2018, in connection with the Amended and Restated Articles of Incorporation, the Company amended the Annual Stock Dividend due date from March 13th to January 1st.

Pursuant to the Amended and Restated Articles of Incorporation, the Company issued 353,086 shares of common stock to Fortress for the Annual Stock Dividend, representing 2.5% of the fully-diluted outstanding equity of Mustang on January 1, 2024. The value of these shares is shown in the Statement of Stockholders' Equity at December 31, 2023, as Common stock issuable – Annual Stock Dividend. The Company recorded an expense of approximately \$0.5 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2023.

Pursuant to the Amended and Restated Articles of Incorporation, the Company issued 187,134 shares of common stock to Fortress for the Annual Stock Dividend, representing 2.5% of the fully-diluted outstanding equity of Mustang on January 1, 2023. The value of these shares is shown in the Statement of Stockholders' Equity at December 31, 2022, as Common stock issuable – Annual Stock Dividend. The Company recorded an expense of approximately \$1.1 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2022.

Fair Value Measurement

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured at fair value on a recurring basis. Under the accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Leases

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

Stock-Based Compensation

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

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

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit.

Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period less unvested restricted stock. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common shares pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of warrants or outstanding Class A preferred shares, as their inclusion would be anti-dilutive. The two-class method is an earnings allocation formula that treats participating securities as having rights that would otherwise have been available to common stockholders. In addition, as our non-pre-funded warrants are participating securities, we are required to calculate diluted earnings per share under the if-converted method and utilize the most dilutive result. In periods where there is a net loss, no allocation of undistributed net loss to non-pre-funded warrants is performed as the holders of our non-pre-funded warrants are not contractually obligated to participate in our losses.

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 year ended December 31,	
	2023	2022
Warrants ⁽¹⁾	2,813,632	70,195
Options	76,112	76,112
Class A Preferred Shares	250,000	250,000
Unvested restricted stock awards	64,706	34,016
Unvested restricted stock units	95,197	165,912
Total	<u>3,299,647</u>	<u>596,235</u>

(1) Excludes 1,668,236 pre-funded warrants. The shares underlying the pre-funded warrants are included in basic net loss per share.

Comprehensive Loss

The Company has no components of other comprehensive loss, and therefore, comprehensive loss equals net loss.

Recent Accounting Pronouncements

In October 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC’s Disclosure Updated and Simplification Initiative*, which amends the disclosure or presentation requirements related to various subtopics in the FASB Accounting Standards Codification. ASU 2023-06 was issued in response to the U.S. Securities and Exchange Commission’s (the “SEC”) August 2018 final rule that updated and simplified disclosure requirements and is intended to align U.S. GAAP requirements with those of the SEC and to facilitate the application of U.S. GAAP for all entities. For entities subject to the SEC’s existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC removes that related disclosure from its rules. However, if by June 30, 2027, the SEC has not removed the related disclosure from its regulations, the amendments will be removed from the Codification and not become effective for any entity. We are currently evaluating the impact of this guidance, but we do not expect the adoption of this guidance to have a material impact on our financial statements and disclosures.

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2023-07, “*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*.” The amendments in ASU 2023-07 improve reportable segment disclosure requirements through enhanced disclosures about significant segment expenses. The amendments introduce a new requirement to disclose significant segment expenses regularly provided to the chief operating decision maker (“CODM”), extend certain annual disclosures to interim periods, clarify single reportable segment entities must apply ASC 280 in its entirety, permit more than one measure of segment profit or loss to be reported under certain conditions, and require disclosure of the title and position of the CODM. This guidance is effective for fiscal years, beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption will be permitted. The Company is currently evaluating the impact of this standard on its financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands disclosures in an entity’s income tax rate reconciliation table and disclosures regarding cash taxes paid both in the U.S. and foreign jurisdictions. The update will be effective for annual periods beginning after December 15, 2024. We are currently evaluating the impact that this guidance will have on our financial statements and disclosures.

Note 3 - License, Clinical Trial and Sponsored Research Agreements

Research and Development Expenses – All Licenses

For the years ended December 31, 2023 and 2022, the Company recorded the following expense in research and development for licenses acquired:

(\$ in thousands)	For the year ended December 31,	
	2023	2022
City of Hope National Medical Center		
IV/ICV	—	125
HER2	—	200
CSL Behring (Calimmune)	50	40
Fortress Annual Stock Dividend	477	1,109
Total	<u>\$ 527</u>	<u>\$ 1,474</u>

License Agreements

City of Hope

IV/ICV

In February 2017, the Company entered into an exclusive license agreement (the “IV/ICV License”) with COH to acquire intellectual property rights in patent applications related to the intraventricular (“IV”) and intracerebroventricular (“ICV”) methods of delivering T cells that express CARs. Pursuant to the IV/ICV License, in March 2017, the Company paid COH an upfront fee of \$0.1 million. COH is eligible to receive a milestone payment totaling approximately \$0.1 million, upon and subject to the achievement of a milestone, and an annual maintenance fee of \$25,000. Royalty payments in the low single digits are due on net sales of licensed products. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-thirties, but no such payments are due in connection with sublicenses that are granted in conjunction with the sublicense of other CAR T programs that are licensed from COH to the Company.

For the year ended December 31, 2022, the Company expensed a non-refundable milestone payment of \$0.1 million in connection with the first patent within the Patent Rights issued. There were no such expenses for the year ended December 31, 2023.

HER2 License (MB-103)

On May 31, 2017, the Company entered into an exclusive license agreement with the COH for the use of human epidermal growth factor receptor 2 (“HER2”) CAR T technology, which will initially be applied in the treatment of glioblastoma multiforme. Pursuant to this agreement, the Company paid an upfront fee of \$0.6 million and pays an annual maintenance fee of \$50,000 (which began in 2019). Additional payments are due for the achievement of ten development milestones totaling \$14.9 million, and royalty payments in the mid-single digits are due on net sales of licensed products.

For the year ended, December 31, 2022, the Company expensed a non-refundable milestone payment of \$0.2 million in connection with the first patent within the Patent Rights issued. There were no such expenses for the year ended December 31, 2023. In May 2023, the Company terminated the HER2 License and associated Clinical Research Support Agreement.

CSL Behring (Calimmune) License

On August 23, 2019, the Company entered into a non-exclusive license agreement with CSL Behring (Calimmune, Inc.) (“Calimmune License”) for the rights to the Cytegrity™ stable producer cell line for the production of viral vector for our lentiviral gene therapy program for the treatment of XSCID (MB-107 and MB-207). We previously licensed the XSCID gene therapy program from St. Jude Children’s Research Hospital, Inc. (“St. Jude”) in August 2018. Pursuant to the terms of the Calimmune License, the Company paid an upfront fee of \$0.2 million. CSL Behring is eligible to receive additional payments totaling \$1.2 million upon the achievement of three development and commercialization milestones. Royalty payments in the low-single digits are due on net sales of licensed products.

For the year ended December 31, 2023 and 2022, the Company expensed a non-refundable milestone payments of \$50,000 and \$40,000, respectively, in connection with the Calimmune license. On August 14, 2023, we notified Calimmune that we were terminating the Calimmune license, which took effect 60 days following notification.

Research and Development Expenses - Sponsored Research and Clinical Trial Agreements

For the year ended December 31, 2023 and 2022, the Company recorded the following expense in research and development for sponsored research and clinical trial agreements:

<i>(\$ in thousands)</i>	For the year ended December 31,	
	2023	2022
City of Hope National Medical Center		
CD123	\$ 23	\$ 166
IL13Rα2	1,115	1,486
CS1	188	482
HER2	—	784
PSCA	44	103
Fred Hutchinson Cancer Center - CD20	1,254	1,987
St. Jude Children’s Research Hospital - XSCID	637	508
Leiden University Medical Center - RAG1 SCID	350	505
Mayo Clinic	551	968
Total	\$ 4,162	\$ 6,989

City of Hope

CD123 (MB-102) Clinical Research Support Agreement

In February 2017, the Company entered into a Clinical Research Support Agreement for CD123 (the “CD123 CRA”). Pursuant to the terms of the CD123 CRA the Company made an upfront payment of \$19,450 and will contribute an additional \$0.1 million per patient in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately \$0.2 million over three years pertaining to the clinical development of CD123. For the years ended December 31, 2023 and 2022, the Company recorded \$23,000 and \$0.2 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement. In May 2023, the Company terminated the CD123 License and associated Clinical Research Support Agreement.

IL13R α 2 (MB-101) Clinical Research Support Agreements

In February 2017, the Company entered into a Clinical Research Support Agreement for IL13R α 2 (the “IL13R α 2 CRA”). Pursuant to the terms of the IL13R α 2 CRA the Company made an upfront payment of approximately \$9,300 and will contribute an additional \$0.1 million related to patient costs in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately \$0.2 million over three years pertaining to the clinical development of IL13R α 2. For the years ended December 31, 2023 and 2022, the Company recorded \$1.1 million and \$1.5 million, respectively, in research and development expenses under the IL13R α 2 CRA in the Statements of Operations pursuant to the terms of this agreement.

In October 2020, the Company entered into a Clinical Research Support Agreement for the IL13R α 2-directed CAR T program for adult patients with leptomeningeal glioblastoma, ependymoma or medulloblastoma (the “IL13R α 2 Leptomeningeal CRA”). Pursuant to the terms of the IL13R α 2 Leptomeningeal CRA, the Company made an upfront payment of approximately \$29,000 and will contribute an additional \$0.1 million per patient in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately \$0.2 million annually pertaining to the clinical development of the IL13R α 2-directed CAR T therapy.

In October 2020, the Company entered into a Sponsored Research Agreement (“SRA”) with COH to conduct combination studies of a potential IL13R α 2 CAR and C134 oncolytic virus therapy. Pursuant to the SRA, the Company funded research in the amount of \$0.3 million for the program. In November 2022, the SRA was amended to include additional funding of \$0.6 million.

In March 2021, the Company entered into a clinical research support agreement for an Institutional Review Board-approved, investigator-initiated protocol entitled: “Single Patient Treatment with Intraventricular Infusions of IL13R α 2-targeting and HER2-targeting CAR T cells for a Single Patient (UPN 181) with Recurrent Multifocal Malignant Glioma.” Pursuant to the terms of this agreement, the Company will contribute up to \$0.2 million in connection with the ongoing investigator-initiated study.

CS1 (MB-104) Clinical Research Support Agreement

In June 2020, the Company entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: “Phase I Study to Evaluate Cellular Immunotherapy Using Memory-Enriched T Cells Lentivirally Transduced to Express a CS1-Targeting, Hinge-Optimized, 41BB-Costimulatory Chimeric Antigen Receptor and a Truncated EGFR Following Lymphodepleting Chemotherapy in Adult Patients with CS1+ Multiple Myeloma.” The CAR T being studied under this protocol has been designated as MB-104. Under the terms of the agreement the Company will reimburse COH for costs associated with this trial not to exceed \$2.4 million. The agreement will expire upon the delivery of a final study report or earlier. For the years ended December 31, 2023 and 2022, the Company recorded \$0.2 million and \$0.5 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement. In May 2023, the Company terminated the CS1 License and associated Clinical Research Support Agreement.

HER2 (MB-103) Clinical Research Support Agreement

In September 2020, the Company entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: “Phase I Study of Cellular Immunotherapy using Memory-Enriched T Cells Lentivirally Transduced to Express a HER2-Specific, Hinge-Optimized, 41BB-Costimulatory Chimeric Receptor and a Truncated CD19 for Patients with Recurrent/Refractory Malignant Glioma.” The CAR T being studied under this protocol has been designated as MB-103. Under the terms of the agreement the Company will pay COH \$29,375 upon execution and will reimburse COH for costs associated with this trial not to exceed \$3.0 million. The agreement will expire upon the delivery of a final study report or earlier. For the year ended December 31, 2023 and 2022, the Company recorded zero and \$0.8 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement. In May 2023, the Company terminated the HER2 License and associated Clinical Research Support Agreement.

PSCA (MB-105) Clinical Research Support Agreement

In October 2020, the Company entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: "A Phase 1b study to evaluate PSCA-specific chimeric antigen receptor (CAR)-T cells for patients with metastatic castration resistant prostate cancer." The CAR T being studied under this protocol has been designated as MB-105. Under the terms of the agreement the Company will pay COH \$33,000 upon execution and will reimburse COH for costs associated with this trial not to exceed \$2.3 million. The agreement will expire upon the delivery of a final study report or earlier. For the years ended December 31, 2023 and 2022, the Company recorded \$44,000 and \$0.1 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement. In May 2023, the Company terminated the PSCA License and associated Clinical Research Support Agreement.

Fred Hutch

CD20 Clinical Trial Agreement

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

For the years ended December 31, 2023 and 2022, the Company recorded \$1.3 million and \$2.0 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

St. Jude - XSCID (MB-117) Data Transfer Agreement

In June 2020, the Company entered into a Data Transfer Agreement with St. Jude under which we will reimburse St. Jude for costs associated with St. Jude's clinical trial for the treatment of infants with XSCID. Pursuant to the terms of this agreement the Company paid an upfront fee of \$1.1 million in July 2020, and will continue to reimburse St. Jude for costs incurred in connection with this clinical trial. For the years ended December 31, 2023 and 2022, the Company recorded \$0.6 million and \$0.5 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

LUMC - RAG1-SCID (MB-110) Sponsored Research Support Agreement

On September 8, 2021, in connection with the LUMC License, the Company entered into an SRA with LUMC under which the Company will fund research in the amount of approximately \$0.5 million annually over a period of 5 years. The research performed pursuant to this agreement will support technology the Company has licensed from LUMC for the use of a gene therapy under development for the treatment of severe immunodeficiency caused by RAG1. For the year ended December 31, 2023 and 2022, the Company recorded \$0.4 million and \$0.5 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

Mayo Clinic - Sponsored Research Support Agreement

In June 2021, the Company entered into an SRA with Mayo Clinic under which the Company will fund research in the amount of \$2.1 million over a period of two years. The research performed pursuant to this agreement will support technology the Company has licensed from Mayo Clinic for a novel technology that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy. In October 2022, the SRA was amended to include additional funding of approximately \$0.1 million. For the year ended December 31, 2023 and 2022, the Company recorded \$0.6 million and \$1.0 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

Note 4 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 13, 2015, the Company entered a Founders Agreement with Fortress, which was amended and restated on May 17, 2016, and again on July 26, 2016 (the “Mustang Founders Agreement”). The Mustang Founders Agreement provides that, in exchange for the time and capital expended in the formation of Mustang and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Fortress loaned \$2.0 million, representing the up-front fee required to acquire the Company’s license agreement with COH. The Mustang Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Fortress and the Company or a Change in Control (as defined in the Mustang Founders Agreement) occurs. Concurrently with the second amendment on July 26, 2016, to the Mustang Founders Agreement, Fortress entered into an Exchange Agreement whereby Fortress exchanged its 7.25 million Class B Common shares for 7.0 million common shares and 250,000 Class A Preferred shares. Class A Preferred Stock is identical to common stock other than as to voting rights, conversion rights and the Annual Stock Dividend right (as described below). Each share of Class A Preferred Stock is entitled to vote 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 Mustang common stock and (B) the whole shares of Mustang common stock into which the shares of outstanding Class A Common Stock and Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Each share of Class A Preferred Stock is convertible, at Fortress’ option, into one fully paid and nonassessable share of Mustang common stock, subject to certain adjustments. As holders of Class A Preferred Stock, Fortress will receive on each January 1 (each a “Annual Stock Dividend Payment Date”) until the date all outstanding Class A Preferred Stock is converted into common stock, pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock (“Annual Stock Dividends”) such that the aggregate number of shares of common stock issued pursuant to such Annual Stock Dividend is equal to two and one-half percent (2.5%) of Mustang’s fully-diluted outstanding capitalization on the date that is one (1) business day prior to any Annual Stock Dividend Payment Date. The Company records the value of all shares issued for the Annual Stock Dividend as research and development – licenses expense in its Statements of Operations.

Pursuant to the Amended and Restated Articles of Incorporation, the Company issued 353,086 shares of common stock to Fortress for the Annual Stock Dividend, representing 2.5% of the fully-diluted outstanding equity of Mustang on January 1, 2024. The value of these shares is shown in the Statement of Stockholders’ Equity at December 31, 2023, as Common stock issuable – Annual Stock Dividend. The Company recorded an expense of approximately \$0.5 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2023.

Pursuant to the Amended and Restated Articles of Incorporation, the Company issued 187,134 shares of common stock to Fortress for the Annual Stock Dividend, representing 2.5% of the fully-diluted outstanding equity of Mustang on January 1, 2023. The value of these shares is shown in the Statement of Stockholders’ Equity at December 31, 2022, as Common stock issuable – Annual Stock Dividend. The Company recorded an expense of approximately \$1.1 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2022.

As additional consideration under the Mustang Founders Agreement, Mustang will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Mustang that occurs after the effective date of the Mustang Founders Agreement and ending on the date when Fortress no longer has majority voting control in the Company’s voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of the Company’s annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, the Company will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%) (see Note 9). The Company records the value of all shares issued for the equity fee component of the Mustang Founders Agreement as Stock-based compensation expense in its Statements of Operations.

Effective as of March 13, 2015, the Company entered into a Management Services Agreement (the “MSA”) with Fortress, pursuant to which Fortress renders advisory and consulting services to the Company. The MSA has an initial term of five years and is automatically renewed for successive five-year terms unless terminated in accordance with its provisions. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of the Company’s operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the “Services”). The Company is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of its actions or inactions based upon their advice. Pursuant to the MSA and the Company’s Certificate of Incorporation, Fortress and its affiliates, including all members of the Company’s Board of Directors, will have no fiduciary or other duty to communicate or present any corporate opportunities to the Company or to refrain from engaging in business that is similar to that of the Company. In consideration for the Services, the Company will pay Fortress an annual consulting fee of \$0.5 million (the “Annual Consulting Fee”), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to \$1.0 million for each calendar year in which the Company has net assets in excess of \$100 million at the beginning of the calendar year. The Company records fifty percent of the Annual Consulting Fee in research and development expense and fifty percent in general and administrative expense in the Statement of Operations. For the years ended December 31, 2023 and 2022, the Company recorded expense of \$1.0 million and \$0.5 million, respectively, related to this agreement.

For the year ended December 31, 2023, the Company did not issue any shares of common stock and recorded the value of 66,003 shares issuable to Fortress, which equaled 2.5% of the sum of the gross proceeds of \$0.2 million from the sale of shares of common stock under Mustang’s At-the-Market Offering and \$4.4 million gross proceeds on the Registered Direct Offering. The Company recorded an expense of approximately \$0.1 million in general and administrative expenses related to these shares for the year ended December 31, 2023.

For the year ended December 31, 2022, the Company issued 13,131 shares of common stock and did not record any shares issuable to Fortress, which equaled 2.5% of the gross proceeds of \$6.6 million from the sale of shares of common stock under Mustang’s At-the-Market Offering. The Company recorded an expense of approximately \$0.2 million in general and administrative expenses related to these shares for the year ended December 31, 2022.

Payables and Accrued Expenses Related Party

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

Director Compensation

Dr. Rosenwald

Pursuant to the terms of the Director Compensation Plan, Dr. Rosenwald will receive a cash fee of \$50,000 per year paid quarterly and an annual stock award of the greater of (i) a number of shares of common stock having a fair market value on the grant date of \$50,000 or (ii) 10,000 shares of common stock, which shares shall vest and become non-forfeitable on the third anniversary of the grant date, subject to continued service on the Board on such date.

For the year ended December 31, 2023, the Company recognized \$100,000 in expense in its Statements of Operations related to the director compensation, including approximately \$50,000 in expense related to equity incentive grants. For the year ended December 31, 2022, the Company recognized \$100,000 in expense in its Statements of Operations related to the director compensation, including approximately \$0,000 in expense related to equity incentive grants. The Company issued Dr. Rosenwald 7,246 and 4,777 restricted stock awards for the years ended December 31, 2023 and 2022, respectively.

Mr. Weiss - Advisory Agreement with Caribe BioAdvisors, LLC

The Board of the Company by unanimous written consent approved and authorized the execution of an advisory agreement dated January 1, 2017 (the “Advisory Agreement”), with Caribe BioAdvisors, LLC (the “Advisor”), owned by Michael S. Weiss, the Chairman of the Board, to provide the board advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the Advisory Agreement, the Advisor will be paid an annual cash fee of \$ 60,000, paid quarterly and an annual stock award of the greater of (i) a number of shares of common stock having a fair market value on the grant date of \$50,000 or (ii) 10,000 shares of common stock, which shares shall vest and become non-forfeitable on the third anniversary of the grant date, subject to continued service on the Board on such date.

For the year ended December 31, 2023, the Company recognized \$110,000 in expense in its Statements of Operations related to the advisory agreement, including approximately \$50,000 in expense related to equity incentive grants. For the year ended December 31, 2022, the Company recognized \$10,000 in expense in its Statements of Operations related to the advisory agreement, including approximately \$50,000 in expense related to equity incentive grants. The Company issued Mr. Weiss 7,246 and 4,777 shares of restricted stock for the years ended December 31, 2023 and 2022, respectively.

Note 5 – Property, Plant and Equipment, and Fixed Assets – Construction in Process

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

In connection with the sale of such assets, the Company received base proceeds of \$6.0 million for the assets and lab supplies on-hand as of the transaction date. Based on the fair value of the consideration received and the relative fair value allocation of the consideration, the Company recorded a gain of \$1.5 million in the Statements of Operations, for the year ended December 31, 2023. The Company recorded approximately \$0.2 million of the consideration as deferred income, which will be recognized upon the transfer of the lease. The Company will record adjustments to the fair value of the potential future consideration each reporting period, prospectively.

Mustang’s property, plant and equipment consisted of the following:

<i>(\$ in thousands)</i>	Estimated Useful Life (in years)	December 31, 2023	December 31, 2022
Computer equipment	3	\$ —	\$ 145
Furniture and fixtures	5	—	370
Machinery and equipment	5	—	8,632
Leasehold improvements	9	7,694	7,694
Total property, plant and equipment		7,694	16,841
Less: accumulated depreciation		(4,476)	(8,401)
Property, plant and equipment, net		<u>\$ 3,218</u>	<u>\$ 8,440</u>

Depreciation expense for the years ended December 31, 2023 and 2022, was approximately \$1.9 million and \$2.7 million, respectively, and was recorded in research and development expense in the Statements of Operations.

Fixed assets – construction in process primarily reflects buildout costs and equipment that have not yet been placed into service. For the years ended December 31, 2023, and 2022, fixed assets – construction in process was approximately \$29,000 and \$1.0 million, respectively.

Note 6 - Accounts Payable and Accrued Expenses

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

(\$ in thousands)	December 31,	
	2023	2022
Accounts payable	\$ 6,322	\$ 6,833
Accrued research and development	4,118	2,782
Accrued compensation	2,838	3,468
Other	739	648
Total accounts payable and accrued expenses	<u>\$ 14,017</u>	<u>\$ 13,731</u>

Note 7 - Commitments and Contingencies**Leases**

On June 14, 2022, the Company entered into a sublease agreement with The Paul Revere Life Insurance Company. Pursuant to the terms of the sublease agreement, the Company agreed to lease 26,503 square feet, located at 1 Mercantile Street, Worcester, MA (the "Mercantile Street Facility"), through January 2030. The Company recorded a right of use asset and related operating lease liability of \$2.2 million on the Balance Sheet at the lease inception.

On July 18, 2023, the Company executed, with a retroactive Effective Date of June 15, 2023, a Third Amendment to Sublease (the "Third Amendment"), with the Paul Revere Life Insurance Company, pursuant to which the Company relocated from the 26,503 square feet of rentable space on the fourth floor of the Mercantile Center to 11,916 square feet of rentable space on the second floor of the Mercantile Center. As a result of the modification, the Company recorded an adjustment to its right of use asset and related operating lease liability of \$1.0 million and \$1.2 million, respectively, and \$0.2 million gain on the modification of the sublease, which is recorded in Other Income in the Statements of Operations. The Company does not yet occupy the Mercantile Street Facility.

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

The terms of the lease also require that the Company post an initial security deposit of \$0.8 million, in the form of \$0.5 million letter of credit and \$0.3 million in cash, which increased to \$1.3 million (\$1.0 million letter of credit, \$0.3 million in cash) on November 1, 2019. After the fifth lease year, the letter of credit obligation is subject to reduction. In January 2023, the letter of credit was reduced to \$0.8 million.

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

The Company leases office space and copiers under agreements classified as operating leases that expire on various dates through 2030. The Company's lease liabilities result from the lease of its facilities in Massachusetts, which expire in 2030 and 2026, for the Mercantile Street Facility and Plantation Street Facility, respectively, and its copiers, which expire in 2024. Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right of use assets as the Company is not reasonably certain to exercise the options. The Company does not act as a lessor or have any leases classified as financing leases. At December 31, 2023, the Company had operating lease liabilities of \$2.5 million and right of use assets of \$1.6 million, which were included in the Balance Sheet. At December 31, 2022, the Company had operating lease liabilities of \$3.9 million and right of use assets of \$2.9 million, which were included in the Balance Sheet.

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

	For the Year Ended	
	December 31, 2023	December 31, 2022
<i>(\$ in thousands)</i>		
Lease cost		
Operating lease cost	\$ 439	\$ 565
Variable lease cost	467	488
Total	\$ 906	\$ 1,053

	For the Year Ended	
	December 31, 2023	December 31, 2022
<i>(\$ in thousands)</i>		
Operating cash flows from operating leases	\$ 529	\$ 485
Gain on lease modification	\$ 220	\$ —
Weighted-average remaining lease term – operating leases	4.5	5.9
Weighted-average discount rate – operating leases	9.1 %	9.1 %

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

<i>(\$ in thousands)</i>	
Year ended December 31, 2024	\$ 723
Year ended December 31, 2025	774
Year ended December 31, 2026	703
Year ended December 31, 2027	269
Year ended December 31, 2028	274
Thereafter	303
Total	3,046
Less present value discount	(548)
Operating lease liabilities	\$ 2,498

Note 8 – Notes Payable

On April 11, 2023, the Company's long-term debt facility with Runway Growth Finance Corp. (the "Term Loan") was terminated upon receipt by Runway of a payoff amount of \$30.4 million from the Company comprised of principal, interest and the applicable final payment amount. The loss on extinguishment was recorded in interest expense in the Statements of Operations. For the years ended December 31, 2023 and 2022, the Company recorded the following components in interest expense:

	For the year ended December 31,	
	2023	2022
<i>(\$ in thousands)</i>		
Interest expense	\$ 1,187	\$ 2,899
Amortization of Debt Discount	118	445
Loss on Extinguishment	2,795	—
Other	9	15
Total Interest Expense	\$ 4,109	\$ 3,359

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

The Term Loan accrued interest at a variable annual rate equal to 8.75% plus the greater of (i) 0.50% and (ii) the three month LIBOR Rate for U.S. dollar deposits or the rate otherwise reasonably determined by the Lender to be the rate at which U.S. dollar deposits with a term of three months would be offered by banks in London, England to major banks in the London or other offshore interbank market (the “Applicable Rate”); provided that the Applicable Rate would not be less than 9.25%. On December 7, 2022, the Company entered into the First Amendment (the “First Amendment”) to the Loan Agreement by and between the Company and Runway. The First Amendment amended certain definitions and other provisions of the Loan Agreement to replace LIBOR-based benchmark rates applicable to loans outstanding under the Loan Agreement with SOFR-based rates, subject to adjustments as specified in the First Amendment. The Applicable Rate at December 31, 2022 was 11.69%. For the year ended December 31, 2023, the Company made interest payments of \$1.3 million, recorded in interest expense in the Statements of Operations. For the year ended December 31, 2022, the Company made interest payments of \$2.7 million, recorded in interest expense in the Statements of Operations.

<i>(\$ in thousands)</i>	December 31, 2023	December 31, 2022
Note payable	\$ —	\$ 31,050
Discount on note payable	—	(3,614)
Long-term note payable	<u>\$ —</u>	<u>\$ 27,436</u>

Amortization of the debt discount associated with the Term Loan was approximately \$0.1 million and \$0.5 million for the year ended December 31, 2023, and 2022, respectively, and was recorded in interest expense in the Statements of Operations.

In addition, the Term Loan was secured by a lien on substantially all of our assets other than certain intellectual property assets and certain other excluded collateral, and it contained a minimum liquidity covenant and other covenants that include among other items: (i) limits on indebtedness, repurchase of stock from employees, officers and directors.

Note 9 - Stockholders' Equity

Common Stock

The Company, in accordance with its certificate of incorporation, as amended in November 2020 and June 2021, which was retroactively applied, and July 2022, is authorized to issue (i) 200,000,000 common shares with a par value of \$0.0001 per share, of which 1,000,000 shares are designated as Class A Common Stock and the remainder are undesignated Common Stock, and (ii) 2,000,000 shares of Preferred Stock, 250,000 of which are designated as Class A Preferred Stock and the remainder are undesignated Preferred Stock (see below Stock Issuances to Fortress and Note 4).

In connection with the Company's formation, Fortress subscribed for 7,000,000 shares of the Class B Common Stock and 2,000,000 shares of the Company's Common Stock, pursuant to the Founders Agreement. Fortress paid the par value of \$900 in 2016. The fair value of the Company's common shares approximated par value as no licenses had been transferred at that time. In July 2016, the Class B Common Stock held by Fortress was exchanged for Class A Preferred Stock, and the Company amended and restated its Certificate of Incorporation to eliminate the Class B Common Stock and authorized a new series of Class A Preferred Stock. Dividends, if and when declared, are to be distributed pro-rata to the Class A Common Stock, Common Stock and Class A Preferred Common Stock.

The holders of Common Stock are entitled to one vote per share of Common Stock held. The holders of Class A Common Stock are entitled to the number of votes equal to the number of whole shares of Common Stock into which the shares of Class A Common Stock held by such holder are convertible and for a period of ten years from its issuance, the holders of the Class A Common Stock have the right to appoint one member of the board of directors of Mustang; to date, the holders of Class A Common Stock have not yet appointed such director.

At-the-Market Offering of Common Stock

In July 2018, the Company entered into an At-the-Market Issuance Sales Agreement (the “Mustang ATM”) with B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.), Cantor Fitzgerald & Co., National Securities Corporation, (now B. Riley FBR, Inc.), and Oppenheimer & Co. Inc. (each an “Agent” and collectively, the “Agents”), relating to the sale of shares of common stock pursuant to the 2020 S-3. Under the Mustang ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. On December 31, 2020, the Mustang ATM was amended to add H.C. Wainwright & Co., LLC as an Agent. On April 14, 2023, the Mustang ATM was amended to add the limitations imposed by General Instruction I.B.6 to Form S-3 and remove Oppenheimer & Co., Inc. as an Agent.

During the year ended December 31, 2023, the Company issued approximately 52,000 shares of common stock at an average price of \$1.15 per share for gross proceeds of \$163,000 under the ATM Agreement. In connection with these sales, the Company paid aggregate fees of approximately \$3,000 for net proceeds of approximately \$160,000.

During the year ended December 31, 2022, the Company issued approximately 0.5 million shares of common stock at an average price of \$2.61 per share for gross proceeds of \$6.6 million under the ATM Agreement. In connection with these sales, the Company paid aggregate fees of approximately \$0.1 million for net proceeds of approximately \$6.5 million.

Pursuant to the Founders Agreement, the Company did not issue any shares of its common stock to Fortress for the year ended December 31, 2023, and recorded the value of 1,297 shares issuable to Fortress in connection with the Mustang ATM. Pursuant to the Founders Agreement, Mustang issued 13,131 shares of common stock to Fortress at a weighted average price of \$13.56 per share for the year ended December 31, 2022, in connection with the Mustang ATM.

Registered Direct Offering

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

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

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

Pursuant to the Founders Agreement, the Company did not issue any shares of its common stock to Fortress and recorded the value of 64,706 shares issuable to Fortress in connection with the Registered Direct Offering as of December 31, 2023.

Registration Statements

On December 12, 2023, we filed registration statement No. 333-275997 on Form S-1, which registered the offer and sale of common stock on behalf of the Selling Stockholders, of up to 2,743,530 shares of our common stock, issuable upon the exercise of certain warrants held by the Selling Stockholders.

On October 23, 2020, the Company filed a shelf registration statement No. 333-249657 on Form S-3 (the “2020 S-3”), which was declared effective on December 4, 2020. Under the 2020 S-3, the Company may sell up to a total of \$100.0 million of its securities. The 2020 S-3 expired on October 23, 2023.

On April 23, 2021, the Company filed a shelf registration statement No. 333-255476 on Form S-3 (the “2021 S-3”), which was declared effective on May 24, 2021. Under the 2021 S-3, the Company may sell up to a total of \$200.0 million of its securities. As of December 31, 2023, approximately \$195.6 million of the 2021 S-3 remains available for sale of securities.

Stock Issuances to Fortress

Under the terms of the Second Amended and Restated Founders Agreement, which became effective July 22, 2016, Fortress will receive a grant of shares of our common stock equal to two and one-half percent (2.5%) of the gross amount of any equity or debt financing. Additionally, pursuant to the Amended and Restated Articles of Incorporation, Fortress receives an Annual Stock Dividend on January 1st, representing 2.5% of the fully-diluted outstanding equity of Mustang.

For the year ended December 31, 2023, the Company recorded the value of 353,086 shares of common stock to Fortress for the Annual Stock Dividend, as Common stock issuable – Annual Stock Dividend in the Statement of Stockholders’ Equity. The Company recorded an expense of approximately \$ 0.5 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2023.

For the year ended December 31, 2022, the Company recorded the value of 187,134 shares of common stock to Fortress for the Annual Stock Dividend, as Common stock issuable – Annual Stock Dividend in the Statement of Stockholders’ Equity. The Company recorded an expense of approximately \$ 1.1 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2022.

For the year ended December 31, 2023, the Company did not issue any shares of common stock and recorded the value of 297 shares issuable to Fortress, which equaled 2.5% of the gross proceeds of \$0.2 million from the sale of shares of common stock under Mustang’s At-the-Market Offering. In connection with the Registered Direct Offering, the Company recorded 64,706 shares issuable to Fortress, which equaled 2.5% of the gross proceeds of \$4.4 million.

For the year ended December 31, 2022, the Company issued 13,131 shares of common stock to Fortress at a weighted average price of \$13.56 per share, the value of which equaled 2.5% of the gross proceeds of \$6.6 million from the sale of shares of common stock under the Mustang ATM.

Equity Incentive Plan

The Company has in effect the 2016 Incentive Plan (the “Incentive Plan”). The Incentive Plan was adopted in 2016 by our stockholders and the compensation committee of the Company’s board of directors and is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan initially authorized grants to issue up to 133,333 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

In June 2018, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 333,333 shares. In June 2021, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 533,333 shares. In June 2022, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 733,333 shares

As of December 31, 2023, 282,334 shares are available for issuance of stock-based awards under the Incentive Plan.

Stock Options

The following table summarizes stock option activities for the years ended December 31, 2023 and 2022:

	<u>Stock Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>
Outstanding at December 31, 2021	76,112	\$ 85.95	5.31
Outstanding at December 31, 2022	76,112	\$ 85.95	4.31
Outstanding at December 31, 2023	<u>76,112</u>	<u>\$ 85.95</u>	<u>3.31</u>
Options vested and exercisable at December 31, 2023	<u>47,570</u>	<u>\$ 85.95</u>	<u>3.31</u>

As of December 31, 2023, the Company had no unrecognized stock-based compensation expense related to options. The Company accounts for forfeited awards as they occur as permitted.

Restricted Stock Awards

Certain employees and directors have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted stock award activities for the years ended December 31, 2023 and 2022:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Nonvested at December 31, 2021	18,732	\$ 60.75
Granted	23,888	10.50
Vested	<u>(8,604)</u>	<u>73.35</u>
Nonvested at December 31, 2022	34,016	\$ 22.20
Granted	36,230	6.90
Vested	<u>(5,540)</u>	<u>46.20</u>
Nonvested at December 31, 2023	<u>64,706</u>	<u>\$ 11.59</u>

As of December 31, 2023, the Company had unrecognized stock-based compensation expense related to restricted stock of \$0.4 million, which is expected to be recognized over a weighted average period of approximately 2.1 years.

Restricted Stock Units

The following table summarizes restricted stock units' activities for the year ended December 31, 2023 and 2022:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2021	155,704	\$ 49.05
Granted	98,976	11.40
Forfeited	(34,333)	37.95
Vested	(54,435)	44.70
Nonvested at December 31, 2022	165,912	\$ 27.60
Granted	29,732	5.13
Forfeited	(51,366)	27.22
Vested	(49,081)	31.53
Nonvested at December 31, 2023	95,197	\$ 18.78

As of December 31, 2023, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately \$0.5 million, which is expected to be recognized over a weighted average period of approximately 2.1 years.

The following table summarizes stock-based compensation expense for the years ended December 31, 2023 and 2022 (in thousands).

	For the year ended December 31,	
	2023	2022
General and administrative	\$ 436	\$ 700
Research and development	132	1,583
Total stock-based compensation expense	\$ 568	\$ 2,283

Stock Warrants

In connection with the Company's Registered Direct Offering on October 26, 2023, the Company issued pre-funded warrants to purchase up to 1,668,236 shares of common stock, and in a concurrent private placement, the Company issued unregistered warrants to purchase up to 2,588,236 shares of common stock. In connection with these offerings, H.C. Wainwright received Placement Agent Warrants to purchase up to 155,294 shares of common stock.

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

A summary of warrant activities for years ended December 31, 2023 and 2022, is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2021	220,577	\$ 120.30	0.73
Expired	(200,251)	127.49	—
Granted	49,869	12.03	9.18
Outstanding as of December 31, 2022	70,195	\$ 22.80	8.29
Exercised	(93)	—	—
Granted	4,411,766	1.00	5.29
Outstanding as of December 31, 2023	<u>4,481,868</u>	<u>\$ 1.34</u>	<u>5.34</u>

Upon the exercise of warrants, the Company will issue new shares of Common Stock.

Employee Stock Purchase Plan

In connection with our Employee Stock Purchase Plan (“ESPP”), eligible employees of Mustang and Fortress 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 December 31, 2023, 86,578 shares have been purchased and 380,089 shares are available for future sale under the Company’s ESPP.

Note 10 – Income Taxes

The Company has accumulated net losses since inception and has not recorded an income tax provision or benefit during the years ended December 31, 2023 and 2022.

A reconciliation of the statutory U.S. federal rate to the Company’s effective tax rate is as follows:

	For the year ended December 31,	
	2023	2022
Statutory federal income tax rate	21 %	21 %
State taxes, net of federal tax benefit	16 %	16 %
Non-deductible items	— %	(1)%
Tax credits	4 %	5 %
Other	(3)%	1 %
Change in valuation allowance	(38)%	(42)%
Income taxes provision (benefit)	<u>—</u>	<u>—</u>

The components of the net deferred tax asset as of December 31, 2023 and 2022 are the following:

<i>(\$ in thousands)</i>	For the year ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryovers	\$ 84,651	\$ 75,011
Stock compensation and other	1,946	2,399
Change in fair value of warrant liabilities	59	59
Amortization of license	11,856	13,375
Lease liability	929	1,466
Accruals and reserves	1,841	1,434
Startup costs	5	6
Tax credits	18,189	15,649
174 Capitalization	28,800	19,787
Total deferred tax assets	148,276	129,186
Less: valuation allowance	(147,694)	(128,101)
Net deferred tax assets	<u>\$ 582</u>	<u>\$ 1,085</u>
Deferred tax liabilities:		
Right of use asset	(582)	(1,085)
Total deferred tax assets, net	<u>\$ —</u>	<u>\$ —</u>

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax assets as of December 31, 2023 and 2022. A valuation allowance of approximately \$147.7 million and \$128.1 million, respectively, was recorded for the years ended December 31, 2023 and 2022.

As of December 31, 2023, the Company had federal and state net operating loss carryforwards of approximately \$244.1 million and \$514.9 million, respectively. Approximately \$220.4 million and \$0.4 million of the federal and state net operating loss carryforwards, respectively, can be carried forward indefinitely. As of December 31, 2023, the Company had federal and state income tax credits of approximately \$14.1 million and \$5.2 million, respectively, which will begin to expire in 2034. Under the provisions of Section 382 of the Internal Revenue Code, a corporation that undergoes an “ownership change”, as defined therein, is subject to limitations on its use of pre-change NOLs and income tax credits carryforwards to offset future tax liabilities. Certain tax attributes may be subject to an annual limitation as a result of the Company’s January 2017 capital raise, as it appears to constitute an ownership change under Section 382. Additionally, under Section 382, annual use of the Company’s net operating loss carryforwards to offset taxable income may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such limitations have been triggered as of December 31, 2023. The Company has no income tax effect due to the recognition of a full valuation allowance on all of its deferred tax assets as it believes that it is more likely than not that the deferred tax assets will not be realized regardless of whether an “ownership change” has occurred.

There are no significant items determined to be unrecognized tax benefits taken or expected to be taken in a tax return, in accordance with ASC 740 “Income Taxes” (“ASC 740”), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements, that have been recorded on the Company’s financial statements for the periods ended December 31, 2023 and 2022. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

Additionally, ASC 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for the periods ended December 31, 2023 and 2022.

The Company is subject to U.S. federal and various state taxes. As of December 31, 2023, the earliest federal tax year open for the assessment of income taxes under the applicable statutes of limitations is its 2020 tax year.

Beginning with the 2022 tax year, the Company is required to capitalize research and development expenses for tax purposes as defined under Internal Revenue Code Section 174. For expenses that are incurred for research and development in the U.S., the amounts will be amortized over 5 years, and for expenses that are incurred for research and development outside the U.S., the amounts will be amortized over 15 years. As a result of Section 174 capitalization, the Company recognized a deferred tax asset of \$28.8 million.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer’s social security payments, net operating loss utilization and carryback periods and modifications to the net interest deduction limitations. The CARES Act did not have a material impact on the Company’s income tax provision for 2023 and 2022. The Company will continue to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

On December 27, 2020, the Consolidated Appropriations Act, 2021 (“Consolidated Appropriations Act”) was signed into law. The Consolidated Appropriations Act is intended to enhance and expand certain provisions of the CARES Act, allows for the deductions of expenses related to the Payroll Protection Program funds received by companies, and provides an update to meals and entertainment expensing for 2021. The Consolidated Appropriations Act did not have a material impact to the Company’s income tax provision for 2023 and 2022.

Note 11 – Subsequent Events

In connection with the sale of the Company’s leasehold interest in its cell processing facility located in Worcester, Massachusetts and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility (the “Transaction”) to uBriGene (Boston) Biosciences, Inc., a Delaware corporation (“uBriGene”) and an indirect, wholly owned subsidiary of UBriGene (Jiangsu) Biosciences Co., Ltd., a Chinese contract development and manufacturing organization, the Company and uBriGene previously submitted a voluntary notice with the U.S. Committee on Foreign Investment in the United States (“CFIUS”) on August 10, 2023 to obtain clearance for the Transaction, although obtaining such clearance was not a condition to closing the Transaction.

Following an initial 45-day review period and subsequent 45-day investigation period, on November 13, 2023, CFIUS requested that the Company and uBriGene withdraw and re-file our joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon CFIUS’s request, the Company and uBriGene submitted a request to withdraw and re-file our joint voluntary notice to CFIUS, and on November 13, 2023, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period on November 14, 2023. CFIUS’s 45-day review ended on December 28, 2023. Since CFIUS had not concluded its review by December 28, 2023, the proceeding transitioned to a subsequent 45-day investigation period, which ended on February 12, 2024.

Following the 45-day review period and subsequent 45-day investigation period described above, on February 12, 2024, the Company and uBriGene requested permission to withdraw and re-file their joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon the Company’s and uBriGene’s request to withdraw and re-file their joint voluntary notice to CFIUS, on February 12, 2024, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period on February 13, 2024. The new 45-day review period will conclude no later than March 28, 2024. If CFIUS does not conclude its review by March 28, 2024, the proceeding will transition to a second 45-day phase as CFIUS further investigates the Transaction.

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

	September 30, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 3,525	\$ 6,234
Other receivables	237	3,879
Prepaid expenses and other current assets	84	1,233
Property, plant and equipment, held for sale	2,209	—
Total current assets	6,055	11,346
Property, plant and equipment, net	421	3,247
Restricted cash	375	750
Other assets	250	833
Operating lease right-of-use asset, net	92	1,566
Total Assets	\$ 7,193	\$ 17,742
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 12,061	\$ 14,017
Payables and accrued expenses – related party	2,535	834
Operating lease liabilities – short-term	442	520
Total current liabilities	15,038	15,371
Deferred income	270	270
Operating lease liabilities – long-term	541	1,978
Total Liabilities	15,849	17,619
Commitments and Contingencies (Note 12)		
Stockholders' Equity		
Preferred stock (\$0.0001 par value), 2,000,000 shares authorized, 250,000 shares of Class A preferred stock issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Common stock (\$0.0001 par value), 200,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively		
Class A common shares, 845,385 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Common shares, 36,827,671, and 8,374,869 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	3	1
Common stock issuable, zero and 419,089 shares as of September 30, 2024 and December 31, 2023, respectively	—	591
Additional paid-in capital	387,112	380,502
Accumulated deficit	(395,771)	(380,971)
Total Stockholders' Equity	(8,656)	123
Total Liabilities and Stockholders' Equity	\$ 7,193	\$ 17,742

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 57	\$ 9,527	\$ 8,221	\$ 34,363
Asset impairment	—	—	2,649	—
Gain on the sale of property and equipment	—	(1,351)	—	(1,351)
General and administrative	1,400	2,131	4,358	7,507
Total operating expenses	<u>1,457</u>	<u>10,307</u>	<u>15,228</u>	<u>40,519</u>
Loss from operations	<u>(1,457)</u>	<u>(10,307)</u>	<u>(15,228)</u>	<u>(40,519)</u>
Other income (expense)				
Other income	—	138	314	918
Interest income	48	115	118	727
Interest expense	(1)	(4)	(4)	(4,112)
Total other income (expense)	<u>47</u>	<u>249</u>	<u>428</u>	<u>(2,467)</u>
Net Loss	<u>\$ (1,410)</u>	<u>\$ (10,058)</u>	<u>\$ (14,800)</u>	<u>\$ (42,986)</u>
Net loss per common share outstanding, basic and diluted	<u>\$ (0.04)</u>	<u>\$ (1.23)</u>	<u>\$ (0.62)</u>	<u>\$ (5.29)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>36,840,427</u>	<u>8,171,582</u>	<u>23,786,939</u>	<u>8,131,191</u>

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

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

	For the Three Months Ended September 30, 2024									
	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, 2024	250,000	\$ —	845,385	\$ —	34,098,059	\$ 3	\$ —	\$ 386,028	\$ (394,361)	\$ (8,330)
Issuance of common shares – Founders Agreement	—	—	—	—	66,549	—	—	29	—	29
Issuance of common shares, net of offering costs – At-the-Market Offering	—	—	—	—	2,661,943	—	—	1,118	—	1,118
Offering costs – Equity Offerings	—	—	—	—	—	—	—	(105)	—	(105)
Stock-based compensation expenses	—	—	—	—	1,120	—	—	42	—	42
Exercise of warrants	—	—	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(1,410)	(1,410)
Balances at September 30, 2024	<u>250,000</u>	<u>\$ —</u>	<u>845,385</u>	<u>\$ —</u>	<u>36,827,671</u>	<u>\$ 3</u>	<u>\$ —</u>	<u>\$ 387,112</u>	<u>\$ (395,771)</u>	<u>\$ (8,656)</u>

	For the Nine Months Ended September 30, 2024									
	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, 2023	250,000	\$ —	845,385	\$ —	8,374,869	\$ 1	\$ 591	\$ 380,502	\$ (380,971)	\$ 123
Issuance of common shares – Founders Agreement	—	—	—	—	994,826	—	(477)	669	—	192
Issuance of common shares, equity fee on At-the-Market Offering	—	—	—	—	66,003	—	(114)	114	—	—
Issuance of common shares, net of offering costs – Equity Offerings	—	—	—	—	4,185,000	—	—	5,160	—	5,160
Issuance of common shares, net of offering costs – At-the-Market Offering	—	—	—	—	2,661,943	—	—	1,118	—	1,118
Issuance of common shares under ESPP	—	—	—	—	47,463	—	—	48	—	48
Stock-based compensation expenses	—	—	—	—	6,693	—	—	(500)	—	(500)
Exercise of warrants	—	—	—	—	20,490,874	2	—	1	—	3
Net loss	—	—	—	—	—	—	—	—	(14,800)	(14,800)
Balances at September 30, 2024	<u>250,000</u>	<u>\$ —</u>	<u>845,385</u>	<u>\$ —</u>	<u>36,827,671</u>	<u>\$ 3</u>	<u>\$ —</u>	<u>\$ 387,112</u>	<u>\$ (395,771)</u>	<u>\$ (8,656)</u>

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

	For the Three Months Ended September 30, 2023									
	Class A Preferred Stock		Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at June 30, 2023	250,000	\$ —	845,385	\$ —	7,320,444	\$ 1	\$ —	\$ 376,009	\$ (362,297)	\$ 13,713
Issuance of common shares, net of offering shares -At-the-Market Offering	—	—	—	—	51,880	—	—	160	—	160
Issuance of common shares – Equity fee on At-the-Market Offering	—	—	—	—	—	—	4	—	—	4
Issuance of common shares under ESPP	—	—	—	—	34,869	—	—	90	—	90
Stock-based compensation expenses	—	—	—	—	43,822	—	—	100	—	100
Net loss	—	—	—	—	—	—	—	—	(10,058)	(10,058)
Balances at September 30, 2023	250,000	\$ —	845,385	\$ —	7,451,015	\$ 1	\$ 4	\$ 376,359	\$ (372,355)	\$ 4,009

	For the Nine Months Ended September 30, 2023									
	Class A Preferred Stock		Class A Common Shares		Common Shares		Common Stock Issuable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	250,000	\$ —	845,385	\$ —	7,100,111	\$ 11	\$ 1,109	\$ 374,522	\$ (329,369)	\$ 46,273
Issuance of common shares – Founders Agreement	—	—	—	—	187,134	—	(1,109)	1,109	—	—
Issuance of common shares, net of offering shares -At-the-Market Offering	—	—	—	—	51,880	—	—	160	—	160
Issuance of common shares – Equity fee on At-the-Market Offering	—	—	—	—	—	—	4	—	—	4
Issuance of common shares under ESPP	—	—	—	—	47,511	—	—	178	—	178
Stock-based compensation expenses	—	—	—	—	65,919	—	—	380	—	380
Exercise of warrants	—	—	—	—	93	—	—	—	—	—
Reverse Split (15:1) adjustment	—	—	—	—	—	(10)	—	10	—	—
Fractional share adjustment	—	—	—	—	(1,633)	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(42,986)	(42,986)
Balances at September 30, 2023	250,000	\$ —	845,385	\$ —	7,451,015	\$ 1	\$ 4	\$ 376,359	\$ (372,355)	\$ 4,009

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

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

	For the nine months ended September 30,	
	2024	2023
Cash Flows from Operating Activities:		
Net loss	\$ (14,800)	\$ (42,986)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common shares – Equity fee on Equity Offerings to Fortress Biotech	192	—
Common shares issuable – Equity fee on at-the-market offering to Fortress Biotech	—	4
Research and development – licenses acquired	—	50
Stock-based compensation expenses	(500)	380
Depreciation expense	620	1,576
Amortization of debt discount	—	118
Amortization of operating lease right-of-use assets	128	286
Loss on disposal of property and equipment	29	—
Asset impairment	2,649	—
Gain on sale of property and equipment	—	(1,351)
Loss on extinguishment of debt	—	2,796
Gain on lease modification	(314)	(220)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	702	(1,688)
Other receivables	659	—
Other receivables – related party	—	36
Accounts payable and accrued expenses	(150)	(1,299)
Payable and accrued expenses – related party	1,701	239
Lease liabilities	(329)	(163)
Net cash used in operating activities	<u>(9,413)</u>	<u>(42,223)</u>
Cash Flows from Investing Activities:		
Purchase of research and development licenses	—	(50)
Proceeds from the sale of property and equipment	—	6,000
Purchase of fixed assets	—	(34)
Net cash from investing activities	<u>—</u>	<u>5,916</u>
Cash Flows from Financing Activities:		
Payment of debt	—	(30,375)
Proceeds from issuance of common shares – Equity Offerings	5,944	163
Offering costs for the issuance of common shares – Equity Offerings	(784)	(3)
Proceeds from issuance of common shares – At-the-Market Offering	1,163	—
Offering costs for the issuance of common shares – At-the-Market Offering	(45)	—
Proceeds from exercise of warrants	3	—
Proceeds from issuance of common shares under ESPP	48	178
Net cash provided by financing activities	<u>6,329</u>	<u>(30,037)</u>
Net change in cash, cash equivalents and restricted cash	(3,084)	(66,344)
Cash, cash equivalents and restricted cash, beginning of the period	6,984	76,656
Cash, cash equivalents and restricted cash, end of the period	<u>\$ 3,900</u>	<u>\$ 10,312</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ —	\$ 1,340
Supplemental disclosure of noncash activities:		
Issuance of common shares – Founders Agreement and Equity fee to Fortress	\$ 591	\$ 1,109
Supplemental disclosure of noncash activities related to the uBriGene Repurchase Transaction (see Note 5):		
Fair value of assets received	\$ 2,209	\$ —
Fair value of supplies received expensed to research and development	\$ 2,509	\$ —
Accounts receivable written off	\$ (6,967)	\$ —
Accounts payable written off	\$ 3,644	\$ —
Deferred purchase consideration	\$ (1,295)	\$ —

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 in cell therapy into potential treatments. 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. As of September 30, 2024, the Company had an accumulated deficit of \$395.8 million.

The Company has funded its operations to date primarily through the sale of equity. The Company expects to continue to use the proceeds from its previous financing transactions and asset sale primarily for working capital and general corporate purposes.

The Company will require substantial additional financings through equity and debt offerings, collaborations and licensing arrangements or other sources to fully develop, prepare regulatory filings, obtain regulatory approvals and commercialize its existing product candidates. The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations.

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

The Company’s expectation to generate operating losses and negative operating cash flows in the future, and the need for additional funding to support its planned operations raise substantial doubt regarding the Company’s ability to continue as a going concern for a period of one year after the date that these unaudited financial statements are issued. The Company made strategic decisions, including a significant reduction in the workforce by approximately 81%, and the termination of certain license agreements with St. Jude and Leiden University Medical Centre in April 2024, and with Mayo Clinic in June 2024, to preserve capital and prioritize the allocation of resources. The Company continues to pursue raising additional cash resources through public or private equity or debt financings. The Company has concluded that substantial doubt exists about the Company’s ability to continue as a going concern for a period of at least 12 months from the date of issuance of these unaudited financial statements.

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

Note 2 – Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X 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. They do not include all of the information and footnotes required by GAAP for complete financial statements. Therefore, these financial statements should be read in conjunction with the Company’s audited financial statements and notes thereto for the year ended December 31, 2023, which were included in the Company’s Annual Report on Form 10-K and filed with the Securities and Exchange Commission (“SEC”) on March 11, 2024 (the “2023 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.

Cash, Cash Equivalents and Restricted Cash

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

The following table provides a reconciliation of cash, cash equivalents, and restricted cash from the Unaudited Balance Sheets to the Unaudited Statements of Cash Flows for the nine months ended September 30, 2024, and 2023:

(\$ in thousands)	September 30,	
	2024	2023
Cash and cash equivalents	\$ 3,525	\$ 9,562
Restricted cash	375	750
Total cash, cash equivalents and restricted cash	<u>\$ 3,900</u>	<u>\$ 10,312</u>

Assets Held for Sale

Assets held for sale represent assets that have met the criteria of “held for sale” accounting, as specified by Accounting Standards Codification (“ASC”) 360, “Long-lived Assets.” As of September 30, 2024, there were \$2.2 million of lab and cell processing equipment, furniture and fixtures and computer equipment that are recorded as assets held for sale. The effect of suspending depreciation on the assets held for sale is immaterial to the results of operations. The assets held for sale were part of the repurchase of assets from uBriGene (see Note 5).

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including tangible assets and other intangible assets with definitive lives, for impairment whenever events or changes in circumstances indicate that the asset’s carrying amount may not be recoverable. The Company conducts its long-lived asset impairment analyses in accordance with ASC 360-10, “Impairment or Disposal of Long-Lived Assets. ASC 360-10-15 requires the Company to group assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities and evaluate the asset group against the sum of the undiscounted future cash flows. If the undiscounted cash flows do not indicate the carrying amount of the asset group is recoverable, an impairment charge is measured as the amount by which the carrying amount of the asset group exceeds its fair value based on discounted cash flow analysis or appraisals.

Significant Accounting Policies

There have been no material changes to the Company’s significant accounting policies previously disclosed in the 2023 Form 10-K.

Recently Issued Accounting Standards

As of September 30, 2024, there were no new accounting pronouncements or updates to recently issued accounting pronouncements disclosed in the 2023 Form 10-K that affect the Company’s present or future results of operations, overall financial condition, liquidity, or disclosures upon adoption.

Note 3 - Clinical Trial and Sponsored Research Agreements

Research and Development Expenses – Clinical Trial and Sponsored Research Agreements

For the three and nine months ended September 30, 2024 and 2023, the Company recorded the following expenses in research and development for sponsored research and clinical trial agreements in the Unaudited Statements of Operations pursuant to the terms of these agreements:

(\$ in thousands)	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
City of Hope National Medical Center				
CD123	\$ —	\$ 23	\$ —	\$ 23
IL13Rα2	66	180	457	817
CS1 ⁽¹⁾	—	—	—	188
PSCA ⁽¹⁾	—	—	—	44
Fred Hutchinson Cancer Center - CD20	—	142	312	1,239
St. Jude Children’s Research Hospital - XSCID ⁽²⁾	—	(106)	(434)	528
Leiden University Medical Center - RAG1 SCID	—	125	241	349
Mayo Clinic ⁽³⁾	—	—	(275)	551
Total	\$ 66	\$ 364	\$ 301	\$ 3,739

⁽¹⁾ Licenses and associated sponsored research agreements were terminated in May 2023.

⁽²⁾ License and associated Data Transfer Agreement were terminated in April 2024.

⁽³⁾ License and associated sponsored research agreement were terminated in June 2024.

Ongoing Clinical Trial and Sponsored Research Agreements

IL13Rα2 (MB-101) Clinical Research Support Agreements with City of Hope

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

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

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

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

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

Terminated Clinical Trial and Sponsored Research Agreements

In May 2023, the Company determined to discontinue development of certain programs, including CS1 (MB-104) and PSCA (MB-105), and terminated the associated CRA and license with COH. In April 2024, the Company terminated its license agreement and the associated Data Transfer Agreement with St. Jude, in exchange for a mutual release of liability and forgiveness by St. Jude of all amounts previously owed by the Company, which totaled approximately \$0.6 million. Additionally, in April 2024, the Company delivered a termination notice to LUMC, pursuant to which it terminated the license agreement underpinning the MB-110 product candidate; the Company is currently in discussions with LUMC regarding the terms that will govern such termination. In June 2024, the Company terminated its license agreement and associated SRA with the Mayo Clinic, in exchange for a mutual release of liability and forgiveness by Mayo Clinic of all amounts previously owed by the Company, which totaled approximately \$0.3 million. The forgiven amounts, totaling approximately \$0.9 million, were recognized as a reduction of research and development expense in the Unaudited Statements of Operations.

Note 4 - 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, 2024 and 2023, expenses related to the MSA are recorded 50% in research and development expenses and 50% in general and administrative expenses in the Unaudited Statements of Operations. For the three months ended September 30, 2024 and 2023, the Company recorded expense of \$0.1 million and \$0.1 million, respectively, related to the MSA. For the nine months ended September 30, 2024 and 2023, the Company recorded expense of \$0.4 million and \$0.4 million, respectively.

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 nine months ended September 30, 2024, the Company issued 641,740 shares to Fortress in connection with the equity financings. For the three months ended September 30, 2024 and 2023, the Company recorded expense of approximately \$29,000 and \$4,000, respectively, in general and administrative expenses related to these shares. For the nine months ended September 30, 2024 and 2023, the Company recorded expense of approximately \$0.2 million and \$4,000, respectively, 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 353,086 shares of common stock to Fortress as the Annual Stock Dividend (as such term is defined in the Certificate of Incorporation), representing 2.5% of the fully-diluted outstanding equity of Mustang on January 2, 2024. This was recorded in the Statement of Stockholders’ Equity at December 31, 2023, as Common stock issuable – Founders Agreement. The Company recorded an expense of approximately \$0.5 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2023.

Payables and Accrued Expenses Related Party

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

Note 5 – Assets Purchase Agreements

Agreements with uBriGene

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

On July 28, 2023, pursuant to the Prior Asset Purchase Agreement, the Company completed the sale of all of its assets that primarily relate to the manufacturing and production of cell and gene therapies at the Facility (such operations, the “Transferred Operations” and such assets, the “Transferred Assets”) to uBriGene for upfront consideration of \$6 million cash (the “Base Amount”). The Transferred Assets included all of the Company’s assets, except for the Company’s lease and related leasehold improvements of the Facility and contracts that are primarily used in the Transferred Operations. The Company recorded a gain of \$1.4 million in connection with the sale of the Transferred Assets, and recorded approximately \$0.3 million of the base consideration as deferred income, that was to be recognized upon the transfer of the lease.

In connection with the Prior Asset Purchase Agreement, the Company and uBriGene submitted a voluntary joint notice to the U.S. Committee on Foreign Investment in the United States (“CFIUS”). Following CFIUS’s review and subsequent investigation of the transactions related to the Prior Asset Purchase Agreement, on May 13, 2024, the Company, together with uBriGene and CFIUS, executed a National Security Agreement (the “NSA”), pursuant to which the Company and uBriGene agreed to abandon the transactions related to the Prior Asset Purchase Agreement and the agreements entered into in connection therewith. The NSA obligated uBriGene and the Company to terminate agreements between the two parties, including the Manufacturing Services Agreement, Quality Services Agreement, and Subcontracting CDMO Agreement. In addition, uBriGene must sell, or otherwise dispose of, the equipment assets purchased within 180 days after the execution of the NSA.

June 2024 Repurchase of Assets

On June 27, 2024 (the “Effective Date”), the Company entered into an Asset Purchase Agreement (the “Repurchase Agreement”) with uBriGene, pursuant to which the Company agreed, subject to the terms and conditions set forth therein, to repurchase the Transferred Assets, primarily lab equipment and supplies, (collectively, the “Repurchased Assets”). Pursuant to the terms of the Repurchase Agreement, the Company and uBriGene also terminated existing manufacturing and services agreements.

As consideration for the Repurchase Agreement, the Company agreed to pay to uBriGene a total purchase price (the “Purchase Price”) of \$1.4 million, consisting of (i) an upfront payment of \$0.1 million due within five (5) business days of the Effective Date and a (ii) subsequent amount of \$1.3 million due on the date that is twelve (12) months after the closing date (the “Deferred Amount”). In the event that as of the original (or any extended) date on which the Deferred Amount is payable, the Company has, as of the date of the public reporting of its then-most recent quarterly audited or unaudited financial statements, net assets below \$20 million, then the Company may, upon written notice to uBriGene, elect to delay its payment obligation of the Deferred Amount by an additional six (6) months, with no limit on the number of such extensions available to the Company. Notwithstanding the foregoing, if the Company has not paid the Deferred Amount in full as of the date that is twelve (12) months after closing of the Repurchase Agreement, any amounts that remain outstanding will accrue interest at a rate of 5% per annum beginning on the date that is twelve (12) months after closing and until the Deferred Amount is paid in full. Additionally, in connection with the termination of the agreements described above under the Repurchase Agreement, the Company agreed to forgive a net receivable from uBriGene of approximately \$3.3 million, comprised of outstanding receivables of \$6.9 million and payables of \$3.6 million, resulting in total purchase consideration in the Repurchase Transactions of approximately \$4.7 million. The upfront payment of \$0.1 million was paid in July 2024, and as of September 30, 2024, the \$1.3 million Deferred Amount was recorded in Accrued Other Expenses (see Note 7).

The Company allocated the total purchase consideration of \$4.7 million to the Repurchased Assets on a relative fair value basis. The Company used a third-party to perform a valuation of the repurchased equipment, which resulted in a fair value less costs to sell of approximately \$2.2 million. The remaining purchase consideration of \$2.5 million was allocated to the supplies repurchased. The supplies repurchased with no alternative future use were recognized as research and development expense in an amount of \$2.2 million. Repurchased supplies with an alternative future use of \$0.3 million were also recognized in research and development expense, as the Company does not have plans to resume operations in the facility, and it intends to dispose of the supplies in a single transaction with the equipment. The Company concluded that the disposal group, which includes the repurchased equipment assets and associated supplies, with an aggregate value of approximately \$2.2 million met the criteria to be classified as held for sale at the date of acquisition. As of September 30, 2024, the disposal group continues to be held for sale.

Note 6 – Property, Plant and Equipment, and Asset Impairment

At September 30, 2024, and December 31, 2023, property, plant and equipment consisted of the following:

<i>(\$ in thousands)</i>	Estimated Useful Life (in years)	September 30, 2024	December 31, 2023
Leasehold improvements	9	7,694	7,694
Construction in process	N/A	—	29
Total property, plant and equipment		7,694	7,723
Less: impairment loss		(2,176)	—
Less: accumulated depreciation		(5,097)	(4,476)
Property, plant and equipment, net		<u>\$ 421</u>	<u>\$ 3,247</u>

Depreciation expense for the three months ended September 30, 2024 and 2023, was approximately \$0.1 million and \$0.3 million, respectively, and was recorded in research and development expense in the Unaudited Statements of Operations. Depreciation expense for the nine months ended September 30, 2024 and 2023, was approximately \$0.6 million and \$1.6 million, respectively, and was recorded in research and development expense in the Unaudited Statements of Operations.

Impairment of Long-Lived Assets

During the second quarter of fiscal year 2024, the Company concluded it had a triggering event requiring assessment of impairment for certain leasehold improvements and the related right-of-use asset. The Company assessed the carrying value of the asset group consisting of the leasehold improvements and right-of-use asset in accordance with ASC 360, given the significant changes to the Company's operations, operating cash and the repurchase of equipment. The assessment of the recoverability of the asset group concluded that there was impairment on the carrying value of the asset group of approximately \$2.6 million, which was allocated on a pro rata basis using the relative carrying amounts of the assets. Approximately \$2.2 million of the impairment loss was allocated to the leasehold improvements, with the remaining \$0.4 million allocated to the right-of-use asset.

Note 7 - Accounts Payable and Accrued Expenses

At September 30, 2024, and December 31, 2023, accounts payable and accrued expenses consisted of the following:

<i>(\$ in thousands)</i>	September 30, 2024	December 31, 2023
Accounts payable	\$ 8,759	\$ 6,322
Accrued research and development	561	4,118
Accrued compensation	984	2,838
Other ⁽¹⁾	1,757	739
Total accounts payable and accrued expenses	<u>\$ 12,061</u>	<u>\$ 14,017</u>

⁽¹⁾ Other includes approximately \$1.3 million of accrued consideration for the uBriGene Asset Purchase Agreement, see Note 5.

Note 8 – Notes Payable

On April 11, 2023, the Company's long-term debt facility (the "Term Loan") with Runway Growth Finance Corp. ("Runway"), originally entered into on March 4, 2023, was terminated upon receipt by Runway of a payoff amount of \$30.4 million from the Company comprised of principal, interest and the applicable final payment amount. The loss on extinguishment was recorded in interest expense in the Unaudited Statements of Operations. For the nine months ended September 30, 2024, and 2023, the Company recorded the following components in interest expense:

(\$ in thousands)	For the nine months ended September 30,	
	2024	2023
Interest expense	\$ —	\$ 1,187
Amortization of Debt Discount	—	118
Loss on Extinguishment	—	2,796
Other	4	11
Total Interest Expense	\$ 4	\$ 4,112

Note 9 - Stockholders' Equity*Registration Statements*

On April 23, 2021, the Company filed a shelf registration statement on Form S-3 (File No. 333-255476) (the "2021 S-3"), which was declared effective on May 24, 2021. Under the 2021 S-3, the Company was able to sell up to a total of \$200.0 million of its securities. The 2021 S-3 expired on May 24, 2024. The Company sold approximately \$4.4 million of securities under the 2021 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, 2024, approximately \$36.3 million of the 2024 S-3 remains available for sales of securities.

As of the filing of 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 limit the number of securities it can sell under its registration statements on Form S-3.

May 2024 Equity Offering

On April 29, 2024, the Company commenced a best efforts equity offering with an institutional investor (the "Investor") (the "May 2024 Offering") of an aggregate of (i) 1,160,000 shares of common stock, (ii) pre-funded warrants (the "May 2024 Pre-Funded Warrants") to purchase up to an aggregate of 15,717,638 shares of common stock (the "May 2024 Pre-Funded Warrant Shares"), (iii) Series A-1 warrants (the "Series A-1 Warrants") to purchase up to an aggregate of 16,877,638 shares of common stock (the "Series A-1 Warrant Shares"), (iv) Series A-2 warrants (the "Series A-2 Warrants") to purchase up to an aggregate of 16,877,638 shares of common stock (the "Series A-2 Warrant Shares"), and (v) Series A-3 warrants (the "Series A-3 Warrants," and together with the Series A-1 Warrants and Series A-2 Warrants, the "Warrants") to purchase up to an aggregate of 16,877,638 shares of common stock (the "Series A-3 Warrant Shares"). Each share of common stock or May 2024 Pre-Funded Warrant was sold together with one Series A-1 Warrant to purchase one share of common stock, one Series A-2 Warrant to purchase one share of common stock, and one Series A-3 Warrant to purchase one share of common stock. The public offering price for each share of common stock and accompanying Warrants was \$0.237, and the public offering price for each May 2024 Pre-Funded Warrant and accompanying Warrants was \$0.2369. The May 2024 Pre-Funded Warrants have an exercise price of \$0.0001 per share, were exercisable immediately and will expire when exercised in full. Each Warrant has an exercise price of \$0.237 per share, will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Warrants (the "Warrant Stockholder Approval"). The Series A-1 Warrant will expire on the five-year anniversary of the Warrant Stockholder Approval. The Series A-2 Warrant will expire on the twenty-four-month anniversary of the Warrant Stockholder Approval. The Series A-3 Warrant will expire on the nine-month anniversary of the Warrant Stockholder Approval. The Warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions.

The net proceeds of the May 2024 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 us, but excluding the net proceeds, if any, from the exercise of the Warrants, was approximately \$ 3.2 million. The May 2024 Offering closed on May 2, 2024.

In connection with the May 2024 Offering, the Company also entered into a warrant amendment agreement (the “Warrant Amendment Agreement”) with the Investor. Under the Warrant Amendment Agreement, the Company agreed to amend certain existing warrants to purchase up to 2,588,236 shares of common stock that were previously issued in October 2023 to the Investor, with an exercise price of \$1.58 per share (the “Existing Warrants”), in consideration for their purchase of the securities in the May 2024 Offering, as follows: (i) lower the exercise price of the Existing Warrants to \$0.237 per share, (ii) provide that the Existing Warrants, as amended, will not be exercisable until the receipt of Warrant Stockholder Approval for the exercisability of the Warrants in the May 2024 Offering, and (iii) extend the original expiration date of the Existing Warrants by five years following the receipt of such Warrant Stockholder Approval. The Warrant Amendment Agreement became effective on May 2, 2024.

June 2024 Registered Direct Offering and Concurrent Private Placement of Warrants (the “June 2024 Offering”)

On June 19, 2024, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with an institutional investor (the “June 2024 Investor”), pursuant to which the Company agreed to issue and sell, in a registered direct offering priced at-the-market under the rules of Nasdaq (the “Registered Direct Offering”), (i) 3,025,000 shares of common stock, at a price per Share of \$0.41 and (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 3,105,000 shares of our common stock, at a price per Pre-Funded Warrant equal to \$0.4099, the price per share of common stock, less \$0.0001.

The Pre-Funded Warrants were sold in lieu of shares of common stock to the June 2024 Investor. The Pre-Funded Warrants have an exercise price of \$0.0001 per share, became exercisable upon issuance and remain exercisable until exercised in full.

The Registered Direct Offering closed on June 21, 2024. The Company intends to use the net proceeds of approximately \$2.1 million from the Registered Direct Offering for general corporate purposes and working capital requirements.

In a concurrent private placement, pursuant to the terms of the Purchase Agreement, the Company also agreed to issue and sell to the June 2024 Investor unregistered warrants (the “Private Placement Warrants”) to purchase up to 6,130,000 shares of common stock, at an offering price of \$0.41 per Private Placement Warrant to purchase one share of common stock (the “Private Placement”) and, together with the Registered Direct Offering, the “Offerings”) (which offering price was included in the purchase price per share of common stock or Pre-Funded Warrant). The Private Placement Warrants have an exercise price of \$0.41 per share (subject to customary adjustments as set forth in the Private Placement Warrants), were exercisable upon issuance and will expire five years from the date of issuance. The Private Placement Warrants contain customary anti-dilution adjustments to the exercise price, including for share splits, share dividends, rights offering and pro rata distributions. The resale of the shares of common stock issuable upon the exercise of the Private Placement Warrants was subsequently registered in July 2024 on a Form S-1 (File No. 333-280927).

H.C. Wainwright & Co., LLC (“Wainwright”) acted as the exclusive placement agent in connection with the Offerings under an Engagement Letter, dated as of June 18, 2024, between us and Wainwright (the “Engagement Letter”). Pursuant to the Engagement Letter, the Company issued to Wainwright (or its designees) warrants to purchase up to 367,800 shares of common stock (the “Wainwright Warrants” and, together with the Private Placement Warrants, the “2024 Warrants”). The Wainwright Warrants have substantially the same terms as the Private Placement Warrants, except that the Wainwright Warrants will expire five years from the commencement of the sales of the Offerings and have an exercise price of \$0.5125 per share (subject to customary adjustment as set forth in the Wainwright Warrants), representing 125% of the purchase price per share of common stock in the Registered Direct Offering.

At-the-Market Offering

In July 2018, the Company entered into an At-the-Market Issuance Sales Agreement (the “Mustang ATM”) with B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.), Cantor Fitzgerald & Co., National Securities Corporation (now B. Riley FBR, Inc.), and Oppenheimer & Co. Inc. (each an “Agent” and collectively, the “Agents”), relating to the sale of shares of common stock pursuant to a registration statement on Form S-3 (File No. 333-249657). Under the Mustang ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. On December 31, 2020, the Mustang ATM was amended to add Wainwright as an Agent. On April 14, 2023, the Mustang ATM was amended to add the limitations imposed by General Instruction I.B.6 to Form S-3 and remove Oppenheimer & Co., Inc. as an Agent. On May 31, 2024, the Company delivered notice to the Agents to terminate the Mustang ATM, which was effective June 5, 2024.

On May 31, 2024, the Company entered into an At-the-Market Offering Agreement (the “Offering 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 Offering 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 Offering Agreement. The Company and the Manager may each terminate the Sales Agreement at any time upon specified prior written notice.

During the nine months ended September 30, 2024, the Company issued approximately 2.7 million shares of common stock at an average price of \$0.44 for gross proceeds of \$1.2 million under the Offering Agreement. In connection with these sales, the Company paid aggregate fees of approximately \$45,000. During the nine months ended September 30, 2023, the Company issued approximately 52,000 shares of common stock at an average price of \$3.15 for gross proceeds of \$0.2 million under the Mustang ATM. In connection with these sales, the Company paid aggregate fees of approximately \$3,000.

Equity Incentive Plan

The Company has in effect the 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 and is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan initially authorized grants to issue up to 133,333 shares of authorized but unissued common stock, expires 10 years from adoption, and limits the term of each option to no more than 10 years from the date of grant. In June 2018, the Company’s stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 333,333 shares. In June 2021, the Company’s stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 533,333 shares. In June 2022, the Company’s stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 733,333 shares.

As of September 30, 2024, 397,723 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, 2024:

	<u>Stock Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (in years)</u>
Outstanding at December 31, 2023	76,112	\$ 85.95	3.31
Outstanding at September 30, 2024	76,112	\$ 85.95	2.56
Options vested and exercisable at September 30, 2024	<u>47,570</u>	<u>\$ 85.95</u>	<u>2.56</u>

As of September 30, 2024, 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, 2024:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Nonvested at December 31, 2023	64,706	\$ 11.59
Vested	(4,595)	54.45
Nonvested at September 30, 2024	<u>60,111</u>	<u>\$ 8.32</u>

As of September 30, 2024, the Company had unrecognized stock-based compensation expense related to restricted stock of \$0.2 million, which is expected to be recognized over the remaining weighted average vesting period of approximately 1.3 years.

Restricted Stock Units

Certain employees and consultants have been awarded restricted stock units with time-based vesting. The following table summarizes restricted stock units' activities for the nine months ended September 30, 2024:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2023	95,197	\$ 18.78
Forfeited	(64,892)	18.19
Vested	(18,926)	23.26
Nonvested at September 30, 2024	<u>11,379</u>	<u>\$ 14.69</u>

As of September 30, 2024, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately \$8,000, which is expected to be recognized over the remaining weighted average vesting period of approximately 1.8 years.

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
General and administrative	\$ 52	\$ 119	\$ 150	\$ 381
Research and development	(10)	(19)	(650)	(1)
Total stock-based compensation expense	<u>\$ 42</u>	<u>\$ 100</u>	<u>\$ (500)</u>	<u>\$ 380</u>

On April 12, 2024, the Company reduced its workforce by approximately 81 percent, which resulted in the forfeiture of a significant number of outstanding 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. The Employee Stock Purchase Plan ("ESPP") is compensatory and results in stock-based compensation expense. The ESPP was initially authorized in 2019 to sell up to 26,667 shares of authorized but unissued common stock. In June 2021, the Company's stockholders approved an amendment to the ESPP to increase the number of authorized shares issuable by 40,000 shares. In addition, in June 2023, the Company's stockholders approved an amendment to the ESPP to increase the number of authorized shares issuable thereunder by 400,000 for a total of 466,667 shares.

As of September 30, 2024, 128,352 shares have been purchased and 338,315 shares are available for future sale under the Company's ESPP.

Warrants

A summary of warrant activities for the nine months ended September 30, 2024, is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2023	4,481,868	\$ 1.34	5.34
Exercised	(20,490,874)	—	—
Granted	76,966,010	0.19	2.50
Outstanding as of September 30, 2024	<u>60,957,004</u>	<u>\$ 0.29</u>	<u>2.73</u>

Upon the exercise of warrants, the Company will issue new shares of common stock. In connection with the Company's Registered Direct Offering on October 26, 2023, the Company issued pre-funded warrants to purchase up to 1,668,236 shares of common stock, and in a concurrent private placement, the Company issued unregistered warrants to purchase up to 2,588,236 shares of common stock, and the resale of the underlying shares of common stock were subsequently registered in April 2024 on Form S-1 (File No. 333-275997). In connection with these offerings, H.C. Wainwright received Placement Agent Warrants to purchase up to 155,294 shares of common stock. In connection with the Public Offering the Company completed in May 2024, the 2,588,236 unregistered warrants were repriced from the original exercise price of \$1.58 per share to \$0.237 per share.

In connection with the May 2024 Offering, the Company issued pre-funded warrants to purchase up to 15,717,638 shares of common stock and issued three series of warrants to purchase up to 50,632,914 shares of common stock. In connection with these offerings, Wainwright received Placement Agent Warrants to purchase up to 1,012,658 shares of common stock.

In connection with the Registered Direct Offering, the Company issued pre-funded warrants to purchase up to 3,105,000 shares of common stock, and in the concurrent Private Placement, the Company issued unregistered warrants to purchase up to 6,130,000 shares of common stock. The resale of the underlying shares of common stock were subsequently registered in July 2024 on Form S-1 (File No. 333-280927). In connection with these offerings, Wainwright received Placement Agent Warrants to purchase up to 367,800 shares of common stock.

During the nine months ended September 30, 2024, all of the 1,668,236 pre-funded warrants issued in the October Registered Direct Offering were exercised at an exercise price of \$0.001 per share, and all of the 18,822,638 pre-funded warrants issued in the May 2024 Offering and the June Registered Direct Offering were exercised at an exercise price of \$0.0001 per share.

Note 10 – Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period less unvested restricted stock. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common shares pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of warrants or outstanding Class A preferred shares, as their inclusion would be anti-dilutive. The two-class method is an earnings allocation formula that treats participating securities as having rights that would otherwise have been available to common stockholders. In addition, as our non-pre-funded warrants are participating securities, we are required to calculate diluted earnings per share under the if-converted method and utilize the most dilutive result. In periods where there is a net loss, no allocation of undistributed net loss to non-pre-funded warrants is performed as the holders of our non-pre-funded warrants are not contractually obligated to participate in our losses.

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,	
	2024	2023
Warrants	60,957,004	70,102
Options	76,112	76,112
Class A Preferred Shares	250,000	250,000
Unvested restricted stock awards	60,111	64,706
Unvested restricted stock units	11,379	106,100
Total	61,354,606	567,020

Note 11 – Income Taxes

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

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

Note 12 – Commitments and Contingencies**Indemnification**

In accordance with its Certificate of Incorporation, 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

The Company leases office space under an agreement classified as operating leases that expires in October 2026. On June 28, 2024, the Company terminated the lease of its Mercantile Center Facility for a termination fee of \$40,000. The Company's lease liabilities result from the lease of its Plantation Street Facility, which expires in 2026. Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company's leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right of use assets as the Company is not reasonably certain to exercise the options. The Company does not act as a lessor or have any leases classified as financing leases.

During the second quarter of fiscal year 2024, the Company identified triggering events that required an impairment of the asset group consisting of the right-of-use asset and associated leasehold improvements. The assessment concluded that impairment existed, and the impairment loss was allocated to the leasehold improvements and right-of-use assets based on the relative carrying amounts of the assets (see Note 6). As of September 30, 2024, the Company had operating lease liabilities of \$1.0 million and right of use assets of \$0.1 million, which were included in the Unaudited Balance Sheet. At December 31, 2023, the Company had operating lease liabilities of \$2.5 million and right of use assets of \$1.6 million, which were included in the Unaudited Balance Sheet.

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

	For the Nine Months Ended	
	September 30, 2024	September 30, 2023
<i>(\$ in thousands)</i>		
Lease cost		
Operating lease cost	\$ 113	\$ 592
Variable lease cost	149	544
Total	<u>\$ 262</u>	<u>\$ 1,136</u>

	For the Nine Months Ended	
	September 30, 2024	September 30, 2023
<i>(\$ in thousands)</i>		
Operating cash flows from operating leases	\$ 406	\$ 395
Gain on lease modification	\$ 314	\$ 220
Weighted-average remaining lease term – operating leases	2.0	4.7
Weighted-average discount rate – operating leases	9.0 %	9.1 %

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

<i>(\$ in thousands)</i>	Future Lease Liability
Three months ended December 31, 2024	\$ 127
Year ended December 31, 2025	516
Year ended December 31, 2026	439
Total	1,082
Less present value discount	(99)
Operating lease liabilities	\$ 983

Note 13 – Subsequent Events

On October 24, 2024, the Company entered into an inducement offer letter agreement (the “Inducement Letter”) with an institutional investor that held certain outstanding Series A-3 warrants (the “Existing Warrants”) to purchase up to an aggregate of 16,877,638 shares of the Company’s common stock, originally issued to such investor on May 2, 2024 (the “Existing Warrants”). The Existing Warrants had an exercise price of \$0.237 per share.

Pursuant to the Inducement Letter, the investor agreed to exercise in full, for cash, the Existing Warrants in consideration for the Company’s agreement to issue in a private placement (x) new Series B-1 Common Stock purchase warrants (the “New Series B-1 Warrants”) to purchase up to 16,877,638 shares of Common Stock (the “New Series B-1 Warrant Shares”) and (y) new Series B-2 Common Stock Purchase Warrants (the “New Series B-2 Warrants”) and, together with the New Series B-1 Warrants, the “New Warrants”) to purchase up to 16,877,638 shares of Common Stock (the “New Series B-2 Warrant Shares” and, together with the New Series B-1 Warrant Shares, the “New Warrant Shares”). Each Warrant has an exercise price of \$0.27 per share and will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the Warrants (the “Warrant Stockholder Approval”). The New Series B-1 Warrant will expire on the five-year anniversary of the Warrant Stockholder Approval. The New Series B-2 Warrant will expire on the twelve (12) month anniversary of the Warrant Stockholder Approval.

The closing of the transaction contemplated pursuant to the Inducement Letter occurred on October 25, 2024 (the “Closing Date”). The Company received aggregate gross proceeds of approximately \$4.0 million from the exercise of the Existing Warrants by the investor, before deducting placement agent fees and other expenses payable by the Company. The Company intends to use the proceeds for working capital and general corporate purposes.

The Company engaged Wainwright to act as its exclusive placement agent in connection with the transaction summarized above and paid Wainwright a cash fee equal to 7.0% of the aggregate gross proceeds from the exercise of the Existing Warrants. In addition, the Company (i) reimbursed Wainwright for \$50,000 of the fees and expenses of Wainwright’s legal counsel and other of its out-of-pocket expenses, (ii) reimbursed Wainwright for its non-accountable expenses in the amount of \$25,000, and (iii) paid a management fee equal to 1.0% of the gross proceeds raised. The Company also issued to Wainwright or its designees (“PA Warrant Holders”) placement agent warrants (the “Placement Agent Warrants”) to purchase up to 1,012,658 shares of Common Stock (the “Placement Agent Warrant Shares”). The Placement Agent Warrants have the same terms as the New Series B-1 Warrants, except that the Placement Agent Warrants have an exercise price equal to \$0.2963 per share.

The issuance or resale of the shares of common stock underlying the Existing Warrants has been registered pursuant to an existing registration statement on Form S-1 (File No. 333-278006), declared effective by the Securities and Exchange Commission (the “SEC”) on April 29, 2024.

The Company has agreed to file a registration statement providing for the resale of the New Warrant Shares (the “Resale Registration Statement”) within 30 calendar days of the date of the Inducement Letter, and to use best efforts to cause the Resale Registration Statement to be declared effective by the SEC within 60 calendar days following the date of the Inducement Letter and to keep the Resale Registration Statement effective at all times until the investor no longer owns any New Warrants or New Warrant Shares.



	Up to	Shares of Common Stock
	Pre-funded Warrants to Purchase up to	Shares of Common Stock
	Series C-1 Warrants to Purchase up to	Shares of Common Stock
	Series C-2 Warrants to Purchase up to	Shares of Common Stock
	Series C-3 Warrants to Purchase up to	Shares of Common Stock
	Placement Agent Warrants to Purchase up to	Shares of Common Stock
Up to	Shares of Common Stock Issuable Upon Exercise of the Series C-1 Warrants, Series C-2 Warrants, Series C-3 Warrants, Pre-funded Warrants and Placement Agent Warrants	

PROSPECTUS

, 2025

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than Placement Agent fees, all of which will be paid by us. All amounts are estimated except the SEC registration fee and the Financial Industry Regulatory Authority, Inc. (“FINRA”) filing fee.

Item	Amount
SEC registration fee	\$ 4,991
FINRA filing fee	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous expenses	*
Total	\$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

Under the General Corporation Law of the State of Delaware (the “DGCL”), a corporation may include provisions in its certificate of incorporation that will relieve its directors of monetary liability for breaches of their fiduciary duty to the corporation, except under certain circumstances, including a breach of the director’s duty of loyalty, acts or omissions of the director not in good faith or which involve intentional misconduct or a knowing violation of law, the approval of an improper payment of a dividend or an improper purchase by the corporation of stock or any transaction from which the director derived an improper personal benefit. Our amended and restated Certificate of Incorporation, as amended, eliminates the personal liability of directors to us or our stockholders for monetary damages for breach of fiduciary duty as a director with certain limited exceptions set forth in the DGCL.

Section 145 of the DGCL grants to corporations the power to indemnify each officer and director against liabilities and expenses incurred by reason of the fact that he or she is or was an officer or director of the corporation if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation, as amended, and amended and restated bylaws, as amended, provide for indemnification of each of our officers and directors to the fullest extent permitted by the DGCL. Section 145 of the DGCL also empowers corporations to purchase and maintain insurance on behalf of any person who is or was an officer or director of the corporation against liability asserted against or incurred by him in any such capacity, whether or not the corporation would have the power to indemnify such officer or director against such liability under the provisions of Section 145 of the DGCL.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information as to all unregistered securities we have sold since January 1, 2021 through the date of the prospectus that is a part of this registration statement:

October 2023 Private Placement

On October 26, 2023, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with an institutional accredited investor, for a private placement offering of warrants to purchase 2,588,236 shares of common stock. Pursuant to the Purchase Agreement, we agreed to issue and sell the warrants at an offering price of \$0.125 per warrant to purchase one share of common stock. The warrants have an exercise price of \$1.58 per share (subject to adjustment as set forth in the warrants), were exercisable immediately upon issuance and will expire five and one-half (5.5) years thereafter. The warrants contain standard anti-dilution adjustments to the exercise price including for share splits, share dividend, rights offerings and pro rata distributions. This private placement closed on October 30, 2023, concurrently with an offering to the same institutional accredited investor that was registered under the Securities Act. The gross proceeds to us from the private placement, before deducting placement agent fees and other estimated offering expenses payable by the Company, were approximately \$0.32 million. H.C. Wainwright & Co., LLC (“Wainwright”) acted as the exclusive placement agent in connection with the private placement under an engagement, between the Company and Wainwright. Pursuant to the Engagement Letter, Wainwright was paid a cash fee equal to 7.0% of the gross proceeds received by us in the Offerings, a management fee equal to 1.0% of the gross proceeds of the Offering, \$75,000 for non-accountable expenses and a clearing fee of \$15,950. In addition, under the terms of the Engagement Letter, we issued to Wainwright (or its designees) warrants to purchase up to 155,294 shares of Common Stock (the “Wainwright Warrants”). The Wainwright Warrants have substantially the same terms as the Warrants, except that the Wainwright Warrants will expire five (5) years from the commencement of the sales of the Offerings and have an exercise price of \$2.125 per share (subject to customary adjustment as set forth in the Wainwright Warrants). The 2023 Warrants were offered and sold in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act. The investor also represented that it qualified as an “accredited investor” within the meaning of Rule 501 of Regulation D.

June 2024 Private Placement

On June 19, 2024, we entered into a purchase agreement (the “June 2024 Purchase Agreement”) with an institutional accredited investor, for the issuance and sale of warrants (the “June 2024 Warrants”) to purchase up to 6,130,000 shares of our common stock. Pursuant to the June 2024 Purchase Agreement, we agreed to issue and sell the June 2024 Warrants at an offering price of \$0.41 per warrant to purchase one share of common stock. The June 2024 Warrants have an exercise price of \$0.41 per share (subject to adjustment as set forth in the June 2024 Warrants), were exercisable immediately upon issuance and will expire five and one-half (5.5) years from the date on which the June 2024 Warrants become exercisable. The June 2024 Warrants contain standard anti-dilution adjustments to the exercise price including for share splits, share dividend, rights offerings and pro rata distributions. This offering closed on June 21, 2024, concurrently with a registered direct offering with the same institutional accredited investor that was registered under the Securities Act. The gross proceeds to us from the private placement, before deducting placement agent fees and other estimated offering expenses payable by us, were approximately \$2.51 million. Wainwright acted as the placement agent in connection with the private placement pursuant to an engagement agreement, between us and Wainwright. Wainwright was paid a cash fee equal to 7.0% of the gross proceeds received us in the offerings, a management fee equal to 1.0% of the gross proceeds of the offerings, \$75,000 for non-accountable expenses and a clearing fee of \$15,950. In addition, under the terms of the engagement letter with Wainwright, we issued to Wainwright (or its designees) warrants to purchase up to 367,800 shares of our common stock. The warrants issued to Wainwright have substantially the same terms as the June 2024 Warrants, except that the Wainwright warrants will expire five (5) years from the commencement of the sales of the offerings and have an exercise price of \$0.5125 per share (subject to customary adjustment as set forth in the Wainwright warrants). The June 2024 Warrants were offered and sold in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act. The investor also represented that it qualified as an “accredited investor” within the meaning of Rule 501 of Regulation D.

October 2024 Private Placement

On October 24, 2024, we entered into an inducement offer letter agreement (the “Inducement Letter”) with an institutional accredited investor which held certain outstanding (i) Series A-1 Warrants to purchase up to an aggregate of 16,877,638 shares of common stock, (ii) Series A-2 Warrants to purchase up to an aggregate of 16,877,638 shares of common stock, and (iii) Series A-3 Warrants to purchase up to an aggregate of 16,877,638 shares of common stock, originally issued to the Investor on May 2, 2024 (collectively, the “May 2024 Warrants”). The May 2024 Warrants had an exercise price of \$0.237 per share. Pursuant to the Inducement Letter, the Investor agreed to exercise in full, for cash, the Series A-3 Warrants (the “Existing Warrants”) at the exercise price of \$0.237 per share in consideration for our agreement to issue in a private placement (x) new Series B-1 Warrants to purchase 16,877,638 shares of common stock and (y) new Series B-2 Warrants to purchase 16,877,638 shares of common stock (collectively, the “New Warrants”). In addition, we issued to Wainwright or its designees placement agent warrants to purchase 1,012,658 shares of common stock. The placement agent warrants have the same terms as the Series B-1 Warrants, except that the placement agent warrants have an exercise price equal to \$0.2963 per share. The transactions contemplated by the Inducement Letter closed on October 25, 2024. We received aggregate gross proceeds of approximately \$4 million from the exercise of the Existing Warrants by the investor, before deducting placement agent fees and other expenses payable by us. The New Warrants were offered and sold in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act. The investor also represented that it qualified as an “accredited investor” within the meaning of Rule 501 of Regulation D.

Item 16. Exhibits and financial statement schedules.**(a) Exhibits.**

The exhibits listed below are filed as part of this registration statement.

The exhibits to the Registration Statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

<u>Exhibit No.</u>	<u>Description</u>	<u>Form</u>	<u>File Number</u>	<u>Date</u>	<u>Exhibit No.</u>	<u>Filed Herewith</u>
1.1	At Market Issuance Sales Agreement, dated July 27, 2018, between the Company, B. Riley FBR, Inc., Cantor Fitzgerald & Co., National Securities Corporation, and Oppenheimer & Co. Inc.	8-K	001-38191	July 27, 2018	1.1	
1.2	Amendment No. 1 to At Market Issuance Sales Agreement, dated July 20, 2020, between the Company, B. Riley FBR, Inc., Cantor Fitzgerald & Co., National Securities Corporation and Oppenheimer & Co. Inc.	8-K	001-38191	July 24, 2020	1.2	
1.3	Amendment No. 2 to At Market Issuance Sales Agreement, dated December 31, 2020, between the Company, B. Riley Securities, Inc., Cantor Fitzgerald & Co., National Securities Corporation, Oppenheimer & Co. Inc. and H.C. Wainwright & Co., LLC. (incorporated by reference to the Exhibit 1.1 of the Registrant’s Current Report on Form 8-K (file No. 001-38191) filed with the SEC on December 31, 2020).	8-K	001-38191	December 31, 2020	1.1	

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1.4	Amendment No. 3 to At Market Issuance Sales Agreement, dated April 14, 2023, between the Registrant B. Riley Securities, Inc., Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC	8-K	001-38191	April 20, 2023	1.1
1.5	At the Market Offering Agreement, dated May 31, 2024, by and between the Company and H.C. Wainwright & Co., LLC	8-K	001-38191	June 6, 2024	1.1
2.1#	Asset Purchase Agreement, dated May 18, 2023, between the Company and uBriGene (Boston) Biosciences, Inc.	8-K	001-38191	May 22, 2023	1.1
2.2	First Amendment to Asset Purchase Agreement, dated June 29, 2023, between the Company and uBriGene (Boston) Biosciences, Inc.	8-K	001-38191	June 30, 2023	2.2
2.3	Second Amendment to Asset Purchase Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc.	8-K	001-38191	July 31, 2023	2.3
3.1	Amended and Restated Certificate of Incorporation of Mustang Bio, Inc. (formerly Mustang Therapeutics, Inc.), dated July 26, 2016	10-12G	000-5568	July 28, 2016	3.1
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated June 14, 2018	10-Q	001-38191	August 13, 2018	3.1
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated September 30, 2019	8-K	001-38191	September 30, 2019	3.1
3.4	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated December 4, 2020	8-K	001-38191	December 4, 2020	3.1
3.5	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated June 17, 2021	8-K	001-38191	June 22, 2021	3.1
3.6	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated July 5, 2022	8-K	001-38191	July 7, 2022	3.1
3.7	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated April 3, 2023	8-K	001-38191	April 3, 2023	3.1
3.8	Amended and Restated Bylaws of Mustang Bio, Inc.	8-K	001-38191	April 3, 2023	3.2
4.1	Specimen certificates evidencing shares of common stock, Class A common stock and Class A preferred stock	10-12G	000-5568	July 28, 2016	4.1
4.2	Form of Warrant Agreement	10-12G	000-5568	July 28, 2016	4.2

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4.3	Common Stock Warrant issued by Mustang Bio, Inc. to NSC Biotech Venture Fund I, LLC, dated July 5, 2016	10-12G	000-5568	July 28, 2016	10.5
4.4	Warrant to Purchase Common Stock issued to Runway Growth Finance Corp., dated March 4, 2022	8-K	001-3891	March 8, 2022	4.1
4.5	Form of October Pre-funded Warrant	8-K	001-38191	October 30, 2023	4.1
4.6	Form of October Warrant	8-K	001-38191	October 30, 2023	4.2
4.7	Form of October Wainwright Warrant	8-K	001-38191	October 30, 2023	4.3
4.8	Form of May 2024 Pre-Funded Warrant	8-K	001-38191	May 2, 2024	4.1
4.9	Form of May 2024 Series A-1, A-2, and A-3 Warrant	8-K	001-38191	May 2, 2024	4.2
4.10	Form of May 2024 Placement Agent Warrant	8-K	001-38191	May 2, 2024	4.3
4.11	Form of June 2024 Pre-funded Warrant	8-K	001-38191	June 24, 2024	4.1
4.12	Form of June 2024 Warrant	8-K	001-38191	June 24, 2024	4.2
4.13	Form of June 2024 Wainwright Warrant	8-K	001-38191	June 24, 2024	4.3
4.14	Form of Series B-1 Warrant	8-K	001-38191	October 25, 2024	4.1
4.15	Form of Series B-2 Warrant	8-K	001-38191	October 25, 2024	4.2
4.16	Form of October 2024 Wainwright Warrant	8-K	001-38191	October 25, 2024	4.3
4.17#	Form of Series C-1, C-2, and C-3 Warrant				
4.18#	Form of Pre-Funded Warrant				
4.19#	Form of Placement Agent Warrant				
5.1#	Opinion of Troutman Pepper Locke LLP				
10.1	Second Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Mustang Bio, Inc., dated July 26, 2016	10-12G	000-5568	July 28, 2016	10.1
10.2	Management Services Agreement between Fortress Biotech, Inc. and Mustang Bio, Inc., dated March 13, 2015	10-12G	000-5568	July 28, 2016	10.2
10.3	Future Advance Promissory Note to Fortress Biotech, Inc., dated May 5, 2016	10-12G	000-5568	July 28, 2016	10.3
10.4	Promissory Note to NSC Biotech Venture Fund I, LLC, dated July 5, 2016	10-12G	000-5568	July 28, 2016	10.4
10.5#	License Agreement by and between Mustang Bio, Inc. and City of Hope, dated March 17, 2015	10-12G	000-5568	July 28, 2016	10.6
10.6	Sponsored Research Agreement by and between Mustang Bio, Inc. and City of Hope, dated March 17, 2015	10-12G	000-5568	July 28, 2016	10.7
10.7	Agreement by and between Mustang Bio, Inc. and Chord Advisors, LLC, dated April 8, 2016	10-12G	000-5568	July 28, 2016	10.10
10.8	Board Advisory Services Agreement by and between Mustang Bio, Inc. and Caribe BioAdvisors, LLC	10-K	000-5568	March 31, 2017	10.11

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10.9#	Exclusive License Agreement by and between Mustang Bio, Inc. and The Regents of the University of California, dated March 17, 2017	10-Q	000-5568	August 14, 2017	10.4
10.10#	Exclusive License Agreement (IV/ICV) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017	10-Q	000-55668	August 14, 2017	10.5
10.11#	Amended and Restated Exclusive License Agreement (CD123) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017	10-K	001-3891	March 31, 2017	10.14
10.12#	Amended and Restated Exclusive License Agreement (IL13Ra2) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017	10-K	000-5568	March 31, 2017	10.15
10.13#	Amended and Restated Exclusive License Agreement (Spacer) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017	10-K	000-5568	March 31, 2017	10.16
10.14†	Employment Agreement between Manuel Litchman and Mustang Bio, Inc., effective as of April 24, 2017	8-K	000-5568	April 24, 2017	10.1
10.15#	License Agreement (CSI) by and between Mustang Bio, Inc. and City of Hope, dated May 31, 2017	10-Q/A	001-38191	November 14, 2017	10.1
10.16#	License Agreement (PSCA) by and between Mustang Bio, Inc. and City of Hope, dated May 31, 2017	10-Q/A	001-38191	November 14, 2017	10.2
10.17#	License Agreement (HER2) by and between Mustang Bio, Inc. and City of Hope, dated May 31, 2017	10-Q/A	001-38191	November 14, 2017	10.3
10.18	Lease Agreement by and between Mustang Bio, Inc. and WCS - 377 Plantation Street, Inc., dated October 27, 2017	10-Q	001-3891	November 14, 2017	10.1
10.19	Sublease Agreement by and between Mustang Bio, Inc., and The Paul Reverse Life Insurance Company, dated June 14, 2022	10-K	001-3891	March 30, 2023	10.22
10.20	First Amendment to Sublease Agreement by and between Mustang Bio, Inc. and The Paul Revere Life Insurance Company, dated October 25, 2022	10-K	001-3891	March 30, 2023	10.23
10.21	Second Amendment to Sublease, dated April 27, 2023, between the Company and The Paul Revere Life Insurance Company	8-K	001-38191	July 20, 2023	10.2
10.22	Third Amendment to Sublease, dated June 15, 2023, between the Company and The Paul Revere Life Insurance Company	8-K	001-38191	July 20, 2023	10.3
10.23†	Mustang Bio, Inc. 2016 Incentive Plan†	10-12G	000-5568	July 28, 2016	10.8

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10.24 [†]	Mustang Bio, Inc. Non-Employee Directors Compensation Plan †	10-12G	000-5568	July 28, 2016	10.9
10.25 [†]	Amendment to Mustang Bio, Inc. 2016 Incentive Plan	DEF 14A	001-3891	April 30, 2018	N/A
10.26 [†]	Second Amendment to the Mustang Bio, Inc. 2016 Equity Incentive Plan, dated June 17, 2021 †	8-K	001-3891	June 22, 2021	10.1
10.27 [†]	Third Amendment to Mustang Bio, Inc. 2016 Equity Incentive Plan, dated June 21, 2022 †	8-K	001-3891	June 24, 2022	10.1
10.28 [†]	Form of Option Agreement under the Mustang Bio, Inc. 2016 Incentive Plan	10-K	001-3891	March 11, 2024	10.28
10.29 [†]	Form of Restricted Stock Unit Agreement under the Mustang Bio, Inc. 2016 Incentive Plan	10-K	001-3891	March 11, 2024	10.29
10.30 [†]	Form of Director Stock Award Agreement under the Mustang Bio, Inc. Non-Employee Directors Compensation Plan	10-K	001-3891	March 11, 2024	10.30
10.31 [†]	Mustang Bio, Inc. 2019 Employee Stock Purchase Plan †	10-Q	001-3891	August 9, 2019	10.1
10.32 [†]	Amendment to the Mustang Bio, Inc. 2019 Employee Stock Purchase Plan, dated June 17, 2021 †	8-K	001-3891	June 22, 2021	10.2
10.33 [†]	Amendment No. 2 to the Mustang Bio, Inc. 2019 Employee Stock Purchase Plan, dated June 21, 2023 †	8-K	001-3891	June 21, 2023	10.1
10.34	Loan and Security Agreement by and between Mustang Bio, Inc., the Borrower, the Lenders, and Runway Growth Finance Corp. (as agent), dated March 4, 2022	8-K	001-38191	March 8, 2022	99.1
10.35	First Amendment to Loan and Security Agreement by and between Mustang Bio, Inc., the Borrower, the Lenders and Runway Growth Finance Corp. (as agent), dated December 7, 2022	8-K	001-38191	December 13, 2022	10.1
10.36	Consulting Agreement by and between Mustang Bio, Inc. and Danforth Advisors, LLC dated March 17, 2022	8-K	001-38191	April 22, 2022	99.1
10.37	Manufacturing Services Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc.	8-K	001-38191	July 31, 2023	10.1
10.38	Sub-Contracting Manufacturing Services Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc.	8-K	001-38191	July 31, 2023	10.2
10.39	Form of Securities Purchase Agreement, dated October 26, 2023, by and between the Company and the purchaser party thereto	8-K	001-38191	October 30, 2023	10.1

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10.40	Form of Securities Purchase Agreement, dated April 29, 2024, by and between the Company and the purchaser party thereto	8-K	001-38191	May 2, 2024	10.1	
10.41	Warrant Agreement Amendment, dated April 29, 2024, by and between the Company and the holder thereto	8-K	001-38191	May 2, 2024	10.2	
10.42	Form of Securities Purchase Agreement, dated June 19, 2024, by and between the Company and the purchaser party thereto	8-K	001-38191	June 24, 2024	10.1	
10.43#	Asset Purchase Agreement, dated June 27, 2024, by and between the Company and uBriGrene (Boston) Biosciences, Inc.	8-K	001-38191	July 3, 2024	10.1	
10.44	Form of Investor Inducement Agreement	8-K	001-38191	October 25, 2024	10.1	
10.45†	Form of Indemnification Agreement	8-K	001-38191	October 25, 2024	10.2	
10.46#	Form of Securities Purchase Agreement					
23.1	Consent of Independent Registered Public Accounting Firm, KPMG LLP					X
23.2#	Consent of Troutman Pepper Locke LLP (included in Exhibit 5.1)					
24.1	Power of Attorney					X
107	Filing Fee Table					X

Portions of this Exhibit have been omitted pursuant to Item 601(b)(1)(iv) of Regulation S-K.

† Management contract or compensatory plan.

To be filed by amendment

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (7) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

- (8) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to any charter provision, by law or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Worcester, Commonwealth of Massachusetts, on January 15, 2025.

Mustang Bio, Inc.

By: /s/ Manuel Litchman, M.D.

Manuel Litchman, M.D.
Chief Executive Officer, Interim Chief Financial
Officer and President

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Manuel Litchman, M.D. and Peter Carney, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Manuel Litchman, M.D.</u> Manuel Litchman, M.D.	President, Chief Executive Officer, Interim Chief Financial Officer and Director (Principal Executive Officer, and Principal Financial and Accounting Officer)	January 15, 2025
<u>/s/ Michael S. Weiss</u> Michael S. Weiss	Chairman of the Board of Directors and Executive Chairman	January 15, 2025
<u>/s/ Adam Chill</u> Adam Chill	Director	January 15, 2025
<u>/s/ Neil Herskowitz</u> Neil Herskowitz	Director	January 15, 2025
<u>/s/ David Jin</u> David Jin	Director	January 15, 2025
<u>/s/ Lindsay A. Rosenwald, M.D.</u> Lindsay A. Rosenwald, M.D.	Director	January 15, 2025
<u>/s/ Michael Zelefsky, M.D.</u> Michael Zelefsky, M.D.	Director	January 15, 2025



KPMG LLP
Two Financial Center
60 South Street
Boston, MA 02111

Consent of Independent Registered Public Accounting Firm

We consent to the use of our report dated March 11, 2024, with respect to the financial statements of Mustang Bio, Inc., included herein, and to the reference to our firm under the heading “Experts” in the prospectus.

KPMG LLP

Boston, Massachusetts
January 15, 2025

KPMG LLP, a Delaware limited liability partnership and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee.

Calculation of Filing Fee Tables

Form S-1
(Form Type)

Mustang Bio, Inc.

(Exact Name of Each Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price ⁽¹⁾	Fee Rate	Amount of Registration Fee
Equity	Common Stock, par value \$0.0001 per share ("Common Stock") ⁽²⁾	457(o)			\$ 8,000,000	0.00015310	\$ 1,224.80
Other	Pre-funded Warrants to purchase Common Stock ⁽³⁾	Other			—		(3)
Equity	Common Stock underlying the Pre-Funded Warrant ⁽³⁾	457(o)			—		(3)
Other	Series C-1 Warrants to purchase Common Stock	Other			—		(4)
Equity	Common Stock underlying the Series C-1 Warrants to purchase Common Stock	457(o)			\$ 8,000,000	0.00015310	\$ 1,224.80
Other	Series C-2 Warrants to purchase Common Stock	Other			—		(4)
Equity	Common Stock underlying the Series C-2 Warrants to purchase Common Stock	457(o)			\$ 8,000,000	0.00015310	\$ 1,224.80
Other	Series C-3 Warrants to purchase Common Stock	Other			—		(4)
Equity	Common Stock underlying the Series C-3 Warrants to purchase Common Stock	457(o)			\$ 8,000,000	0.00015310	\$ 1,224.80
Other	Placement Agent Warrants to purchase Common Stock	Other			—		(4)(5)
Equity	Common Stock underlying the Placement Agent Warrants to purchase Common Stock	457(o)			\$ 600,000	0.00015310	\$ 91.86
Total Offering Amounts					\$ 32,600,000	0.00015310	\$ 4,991.06
Total Fees Previously Paid							—
Total Fee Offsets							—
Net Fee Due							\$ 4,991.06

(1) Estimated solely for the purpose of calculating the amount of the registration fee in pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Pursuant to Rule 416 under the Securities Act, this registration statement shall also cover any additional shares of the registrant's securities that become issuable by reason of any share splits, share dividends or similar transactions.

- (3) The proposed maximum aggregate offering price of the Common Stock will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants issued in the offering, and the proposed maximum aggregate offering price of the pre-funded warrants to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Common Stock issued in the offering. Accordingly, the proposed maximum aggregate offering price of the Common Stock and pre-funded warrants (including the Common Stock issuable upon exercise of the pre-funded warrants), if any, is \$8,000,000.
 - (4) No separate registration fee is payable pursuant to Rule 457(g) under the Securities Act.
 - (5) Represents warrants issuable to the placement agent, or its designees, to purchase a number of shares of Common Stock equal to 6.0% of the aggregate number of shares of Common Stock and pre-funded warrants being offered in this offering, at an exercise price equal to 125% of the combined public offering price per share of Common Stock and accompanying warrants.
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