

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2025

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Transition Period from _____ to _____.

Commission File No. 001-38191

MUSTANG BIO, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

47-3828760
(I.R.S. Employer Identification No.)

95 Sawyer Road, Suite 110
Waltham, Massachusetts 02453

(Address including zip code of principal executive offices)

(781) 652-4500

(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter: \$3.2 million.

Class of Common Stock	Outstanding Shares as of March 17, 2026
Class A Common Stock, \$0.0001 par value	845,385
Common Stock, \$0.0001 par value	6,732,092

MUSTANG BIO, INC.
ANNUAL REPORT ON FORM 10-K
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SPECIAL CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this Annual Report on Form 10-K (this “Form 10-K”) may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended (the “Securities Act”) and the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words “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 similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the caption “Risk Factors,” set forth in Part I, Item 1A of this Form 10-K. Such forward-looking statements include, but are not limited to, statements about our:

- expected losses;
- expectations for increases or decreases in expenses;
- expectations for future capital requirements;
- expectations for generating revenue or becoming profitable on a sustained basis;
- 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 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;
- ability to secure adequate protection for our intellectual property;
- ability to attract and retain key personnel;
- ability to obtain reimbursement for our product candidates, 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; and
- stock price and the volatility of the equity markets, including as a result of economic and geopolitical conditions.

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. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements whether as a result of new information, future events or otherwise.

SUMMARY OF RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in Part I, Item 1A of this Form 10-K, and the other reports and documents that we have filed with the Securities and Exchange Commission (the “SEC”).

Risks Related to our Finances and Capital Requirements

- We have incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future.
- We may in the future need to raise additional funding, which may not be available on acceptable terms to us, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our potential product candidates.
- We have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue.
- Our short operating history makes it difficult to evaluate our business and prospects.
- Our success is contingent on raising additional capital, and our efforts to do so may fail. Even if successful, our future capital raising activities may dilute our current stockholders, restrict our operations, or cause us to relinquish proprietary rights.

Risks Pertaining to our Business Strategy, Structure and Organization

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

Risks Inherent in Drug Development and Commercialization

- Preclinical and clinical development are both highly speculative and carry 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 events, we may need to abandon or limit the development of such product candidate.
- Even if a product candidate is approved, it may be subject to various post-marketing requirements, including studies or clinical trials, and increased regulatory scrutiny.
- Our competitors may develop treatments for our product candidates’ target indications, which could limit our product candidates’ commercial opportunity and profitability, if approved.
- If our product candidates, if approved, are not broadly accepted by the healthcare community, the revenues from any such product will likely be limited.
- Any successful products’ liability claims related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of any such product candidates, if approved.

Risks Related to Reliance on Third Parties

- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.
- We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and may also do so for commercialization, if and when our product candidates are approved.
- We rely on clinical data and results obtained by third parties, which may prove inaccurate or unreliable.
- We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

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

- We operate in a heavily regulated industry, and we cannot predict the impact that any future legislation or administrative or executive action may have on our operations.
- We may be subject to anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.
- We are subject to numerous environmental, health and safety laws and regulations and could become subject to fines or penalties or incur costs that could harm our business.

Risks Pertaining to Intellectual Property and Potential Disputes with Licensors Thereof

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

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

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

General Risks and Risks Associated with Ownership of Our Common Stock

- We may become involved in securities class action litigation that could divert management's attention and harm our business.
- The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future.
- The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits, or we could lose key data which could cause us to curtail or cease operations.
- We rely on information technology, and any internet or internal computer system failures, inadequacies, interruptions or compromises of our systems or the security of confidential information could damage our reputation and harm our business.
- Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of which could have a material adverse effect on our business.
- We may not be able to manage our business effectively if we are unable to attract and retain key personnel.
- Our growth is subject to economic and geopolitical conditions.
- Our business could be adversely affected by the effects of health pandemics or epidemics, which could cause significant disruptions in our operations.
- Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties' cybersecurity.
- We have previously failed to satisfy certain continued listing rules of The Nasdaq Stock Market LLC ("Nasdaq"), and if we again are unable to meet the continued listing requirements and/or regain compliance with such rules, our Common Stock may be subject to delisting from The Nasdaq Capital Market. The delisting of our Securities from Nasdaq may decrease the market liquidity and market price of our Common Stock.

PART I

Item 1. Business

OVERVIEW

Mustang Bio, Inc. (“Mustang,” “we,” “us,” “our” or the “Company”) is a clinical-stage biopharmaceutical company focused on translating today’s medical breakthroughs into potential cures for difficult-to-treat cancers. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

Our pipeline is currently focused on novel therapies for solid tumors. For these therapies we have partnered with world class research institutions, including the City of Hope National Medical Center (“COH” or “City of Hope”), and Nationwide Children’s Hospital (“Nationwide”).

Development Pipeline

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

We are developing a 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) has also completed the treatment phase and patients continue to be assessed for long-term safety. In October 2023, we announced that the FDA accepted our IND application for the combination of MB-101 and MB-108 – which is referred to as MB-109 – for the treatment of patients with IL13R α 2+ relapsed or refractory glioblastoma (“GBM”) and high-grade astrocytoma. Pursuant to termination of the lease of our cell processing facility in Worcester, MA, we are exploring with COH and Nationwide the possibility of initiating this clinical trial as an investigator-sponsored single-institution study at COH in the second quarter of 2026.

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 letter 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. The Phase 1 clinical study under that IND would 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 would be treated with MB-101 alone without prior MB-108 administration. After successful confirmation of the safety profile of MB-101 alone, the study would 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, an HSV-1 oncolytic virus, for the treatment of malignant glioma. On July 7, 2025, we announced that the FDA granted Orphan Drug Designation to us for MB-101, IL13R α 2-targeted CAR T-cells, for the treatment of recurrent diffuse and anaplastic astrocytoma (astrocytomas) and glioblastoma. The Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials upon approval and prescription drug user fee waivers. If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in which it has Orphan Drug Designation, which is independent from intellectual property protection.

We are currently exploring with COH and Nationwide the possibility of conducting an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma with MB-109 that could potentially be initiated in the second quarter of 2026. Because cell processing for MB-101 will revert back to COH – where the product continues to be manufactured today for other investigator-sponsored clinical trials being conducted by COH in malignant brain tumors (NCT04003649, NCT04661384, NCT04510051), we believe that it is reasonable to assume that the FDA will not require the aforementioned lead-in cohort. Should this, indeed, be the case, the first patient enrolled will receive the combination of MB-101 and MB-108, which will represent a considerable savings of time and money – as well as afford the potential benefit of both therapies to every patient treated on study.

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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 December 31, 2025, we had an accumulated deficit of \$398.6 million.

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

CORPORATE INFORMATION

We were incorporated in Delaware on March 13, 2015. Our executive offices are located at 95 Sawyer Road, Suite 110, Waltham, Massachusetts 02453. Our telephone number is (781) 652-4500, and our email address is info@mustangbio.com.

Our website address is www.mustangbio.com. The information set forth on our website is not a part of this Form 10-K. We will make available free of charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this Form 10-K. The SEC maintains a website that contains annual, quarterly, and current reports, proxy and information statements, and other information that issuers (including us) file electronically with the SEC. The SEC’s website address is <https://www.sec.gov/>.

THERAPEUTIC PIPELINE

MB-109: Combination MB-101(IL13Ra2 CAR T Cell Program for Glioblastoma) and MB-108 (HSV-1 oncolytic virus C134) as a Potential Treatment for IL13Ra2+ 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 IL13Ra2-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 IL13Ra2-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 IL13Ra2-directed CAR-T cells (MB-101).

In October 2023, we received a safe-to-proceed letter 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 evaluation 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 and Nationwide the possibility of conducting an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13Ra2+ recurrent GBM and high-grade astrocytoma with MB-109 that could potentially be initiated in the second quarter of 2026.

On November 7, 2024, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-108, an HSV-1 oncolytic virus, for the treatment of malignant glioma. On July 7, 2025, we announced that the FDA granted Orphan Drug Designation to us for MB-101, IL13Ra2-targeted CAR T-cells, for the treatment of recurrent diffuse and anaplastic astrocytoma (astrocytomas) and glioblastoma. The Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials upon approval and prescription

drug user fee waivers. If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in which it has Orphan Drug designation, which is independent from intellectual property protection.

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 52% of malignant primary brain and CNS tumors and approximately 14% of all primary brain and CNS tumors. On average during the years 2017 through 2021, more than 13,000 new cases of GBM were diagnosed per year in the U.S. While GBM is a rare disease, with only 3.3 cases per 100,000 persons per year in the U.S., it is quite lethal, with a median survival of only 12-15 months. Standard of care therapy for patients less than 70 years of age consists of maximal surgical resection, radiation, chemotherapy with temozolomide, and alternating electric field therapy (“tumor treating fields”). Since the approval of temozolomide for frontline GBM treatment in 2005, tumor treating fields is the only novel therapy that has improved survival in this indication, and there is no standard of care whatsoever for recurrent GBM.

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 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 cytokine release syndrome 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 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. These 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 MB-101 studies that are currently enrolling patients and one possible combination study in the future:

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 (active, not recruiting; ClinicalTrials.gov Identifier: NCT04661384) sponsored by COH;

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3. MB-101 in treating children with recurrent or refractory IL13R α 2 positive brain tumors (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04510051) sponsored by COH;
4. 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. We refer to this combination therapy as MB-109, and we are currently exploring with COH and Nationwide the possibility of conducting a Phase 1 trial with this therapy to treat patients with these poor-prognosis malignant brain tumors. This trial would be an investigator-sponsored single-institution trial under the COH IND and could potentially be initiated in the second quarter of 2026

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 first Phase 1 trial of MB-108. This site initiated in 2019 (ClinicalTrials.gov Identifier: NCT03657576) and, after enrolling 19 patients, has completed the treatment phase, and patients continue to be assessed for long-term safety. 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. Results from this trial were used to determine the dose of MB-108 approved by the FDA for (1) combination with MB-101 in the treatment of patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma under the originally proposed Mustang IND multicenter trial and (2) administration as a single agent in a UAB-sponsored Phase 1B 2-dose trial (ClinicalTrials.gov Identifier: NCT06614855; active, not recruiting). We believe that the same doses of both therapies will be appropriate for the Phase 1 investigator-sponsored single-institution combination trial currently under discussion with COH and Nationwide.

Also listed on ClinicalTrials.gov is a Phase 1 trial at UAB (ClinicalTrials.gov Identifier: NCT06193174) designed to determine the safety and tolerability of administering a second dose of MB-108 to patients who previously received a first dose of study drug on the aforementioned first-in-human 19-patient Phase 1 trial, NCT03657576. This trial is enrolling by invitation only.

Terminated Product Candidate (CAR-T Therapy)

In September 2025, we received notice from Fred Hutchinson Cancer Center (“Fred Hutch”) of its intent to terminate the CD20 License for cause in connection with unpaid patent expenses and maintenance fees. A 90-day cure period was applicable under the CD20 License. In December 2025, we agreed to terminate the CD20 License with Fred Hutch in exchange for a mutual release of liability and forgiveness of approximately fifty percent of amounts previously owed to them. Additionally, we are eligible to receive royalties on any subsequent licensing consideration Fred Hutch may enter into during the three-year period following the termination.

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 broadest intellectual property protection for our product candidates,

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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 City of Hope (“COH”). The portfolio of rights licensed from COH 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. and China, and this patent family further includes a pending application in the U.S. Any patents issuing from the IL13R α 2-targeting CAR will expire no sooner than 2035. The licensed intellectual property relating to modified CAR hinge regions includes an issued patent in China, as well as pending applications in the U.S. and China. The patents issuing from the modified CAR hinge region family will expire no sooner than 2034. The licensed intellectual property relating to methods of preparing or administering CAR T cells includes issued patents in China and the U.S., as well as pending applications in the U.S. and China. The patents relating to the administration methods will expire no sooner than 2037. The licensed intellectual property relating to methods of preparing CAR T cells in particular subpopulations of cells include issued patents in Japan and the U.S., as well as pending applications in the U.S., Australia, Canada, Europe, and China. The patents relating to these manufacturing methods will expire no sooner than 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.

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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 and COH own, as co-applicants, a pending U.S. application directed to methods of treating glioblastoma multiforme (GBM) with a combination therapy of a CAR targeting IL13R α 2 and an oncolytic virus.

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 IL13R α 2-directed CAR T program, and one relating to the Spacer technology (described below). As of March 2026, COH owns 845,385 shares of our Class A common stock, which are convertible into 1,127 shares of Common Stock. The Class A Common Stock had the right to appoint a member to our Board of Directors (the “Board”) until March 15, 2025.

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 IL13R α 2-directed CAR T program, the CD123-directed CAR T program, and the Spacer technology.

IL13R α 2 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 IL13R α 2-directed CAR T program (the “IL13R α 2 License”). Pursuant to the IL13R α 2 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.

IL13R α 2 CRA (Glioblastoma)

In February 2017, we entered into a Clinical Research Support Agreement for the IL13R α 2-directed CAR T program (the “IL13R α 2 GBM CRA”). Pursuant to the terms of the IL13R α 2 CRA, we made an upfront payment of approximately \$9,000 and expected to contribute an additional \$140,000 per patient in connection with the aforementioned Phase 1 trial of the IL13R α 2-directed CAR T therapy (also known as MB-101) to treat recurrent/refractory malignant glioma (ClinicalTrials.gov Identifier: NCT02208362). Further, we agreed to fund approximately \$66,000 annually pertaining to the clinical development of MB-101.

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IL13R α 2 CRA (Leptomeningeal Glioblastoma)

In October 2020, we 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, we made an upfront payment of approximately \$29,000 and expected to contribute an additional \$150,000 per patient in connection with the investigator-initiated study (ClinicalTrials.gov Identifier: NCT04661384). Further, we agreed to fund approximately \$200,000 annually pertaining to the clinical development of the IL13R α 2-directed CAR T therapy.

Sponsored Research Agreement - IL13R α 2 and C134 Combination

In October 2020, we 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 (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 IL13R α 2 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.

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.

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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 cellular therapy – including CAR T and CAR NK cell therapies – for the treatment of cancer is extremely active. We are aware of at least two companies currently engaged in clinical trials with cellular therapy for the treatment of glioblastoma and/or high-grade astrocytoma, including: Gilead Sciences and ImmunityBio, Inc. At the present time, academic medical centers still dominate the field of cellular therapies to treat these high-grade gliomas, with the following institutions known to be developing early clinical-stage programs that have not yet been partnered with industry: University of Pennsylvania, City of Hope (which is developing CAR-T therapies to treat glioblastoma in addition to MB-101), Massachusetts General Hospital, University of California at San Francisco, Stanford University, and University College London.

EMPLOYEES

As of December 31, 2025, we had 4 full-time employees. None of our employees is 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, business development, scientific and other strategic contributions to our Company on a regular basis.

SUPPLY AND MANUFACTURING

As an early-stage development company, we rely on City of Hope to manufacture or have manufactured the lentiviral vector (“LV”) used in the MB-101 clinical development program currently in progress at COH under its IND applications. In addition, we rely on the National Institutes of Health (the “NIH”) to produce oncolytic virus for the aforementioned UAB Phase 1 trials of Nationwide’s herpes simplex virus type 1 oncolytic virus (MB-108), and potentially as well for the Phase 1 investigator-sponsored single-institution MB-109 combination trial currently under discussion with COH and Nationwide.

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 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 expect to continue to rely on our academic partners and future contract manufacturing relationships to support cell processing for clinical trials of our CAR T products.

Furthermore, we expect to rely on contract manufacturing relationships for the MB-101 LV 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. 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 (BTDD), 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 biologics license application ("BLA") or a new drug application ("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 an NDA or 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 events 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 adverse events in animals and in humans when administered at sufficiently high doses and/or for a

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sufficiently long period of time. Unacceptable toxicity or adverse events 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 adverse events 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 not consistent with 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

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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.

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

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

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

Item 1A. Risk Factors

Investing in our common stock or any other type of equity or debt securities we may offer (together, our “Securities”) involves a high degree of risk. The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Form 10-K, including our consolidated financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us, or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. Some of the statements in the following risk factors constitute forward-looking statements. Please see the section titled “Special Cautionary Note Regarding Forward-Looking Statements.”

Risks Related to Our Finances and Capital Requirements

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability. We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

We have a limited operating history. We have focused primarily on organizing, acquiring, developing and securing our proprietary technology and identifying and obtaining preclinical data for various product candidates, with the goal of supporting regulatory approval for these product candidates. We have incurred losses since our inception in March 2015. Our net losses were \$1.9 million and \$15.8 million for the years ended December 31, 2025 and 2024, respectively, and we had an accumulated deficit of \$398.6 million as of December 31, 2025. 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;

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- manufacture or have manufactured commercial quantities of one or more of our product candidates or any future product candidate, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate, if approved.

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

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

We are currently advancing our programs in hematologic cancers, autoimmune diseases 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. We will need to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we may receive regulatory approval, including building our own commercial organizations to address certain markets. We will require substantial additional capital for the further development and, if approved, commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures.

Since our inception, we have incurred substantial operating losses and expect to continue to incur significant operating losses for the foreseeable future, and we may never become profitable. To date, we have not generated positive cash flows from operations and have funded our operations primarily with the proceeds from sales of equity securities. As of December 31, 2025, we had an accumulated deficit of \$398.6 million, and cash and cash equivalents of \$17.3 million.

We previously disclosed in our financial statements for the year ended December 31, 2024 and in our most recent quarterly report on Form 10-Q for the period ended September 30, 2025 that substantial doubt existed regarding our ability to continue as a going concern. Although we have a history of negative cash flows from operations and operating losses, during the year ended December 31, 2025 we raised approximately \$14.5 million in net proceeds from the February 2025 Equity Offering, the ATM Agreement and the July 2025 warrant exercises. In addition to these net proceeds, we have been actively negotiating settlements of aged payables and have recognized approximately \$2.1 million in savings during the year ended December 31, 2025, and we have significantly reduced our operating costs. Based on the resulting improvement in our cash position for the year ended December 31, 2025, we believe we have sufficient cash and cash equivalents to fund our operations for at least twelve months from the date of this Annual Report on Form 10-K, and therefore have concluded that substantial doubt about our ability to continue as a going concern no longer exists.

Notwithstanding this improvement, we expect to continue generating operating losses and negative operating cash flows as we develop our product candidates, and we may need to raise substantial additional financing in the future to fund our operations and to support the continued development and potential commercialization of our product candidates. We may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. Our future fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our potential products following marketing approval, if and when obtained. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Additional funding may be more difficult to obtain, or may be more expensive, as a result of recent increases in inflation and interest rates in the U.S. economy generally.

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

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

- the scope, timing, design and conduct of, and results from, preclinical studies and clinical trials for our product candidates;
- the potential for delays in our efforts to seek regulatory approval for our product candidates, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute our product candidates;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA or BLA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of our product candidates from our contract manufacturers for clinical trials and in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates;
- the success of the commercialization of one or more of our product candidates, if approved;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- macroeconomic factors such as inflationary pressures, rising interest rates, liquidity constraints, failures and instability in U.S. and international financial banking systems, supply disruptions due to political unrest, conflict and war or other factors, and pandemics.

In addition, in order to address our current or future funding constraints, we may be required to further revise our business plan and strategy, which may result in us (i) curtailing, delaying or discontinuing one or more of our research or development programs or the commercialization of any product candidates, (ii) selling certain of our assets and/or (iii) being unable to expand our operations or otherwise capitalize on our business opportunities. Such actions may become necessary whether or not we are able to raise additional capital. As a result, our business, financial condition, and results of operations could be materially affected. Furthermore, if we are unable to raise capital, the value of our stock could decline, or we could be required to wind down our operations or seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.

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

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

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

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

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

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

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

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

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

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

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

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

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, (the “Sarbanes-Oxley Act”), as well as rules subsequently implemented by the SEC, and the rules of The Nasdaq Stock Market LLC (“Nasdaq”). These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees or as executive officers.

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

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

We are a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is 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 net operating loss carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

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

Risks Related to Our Business Strategy, Structure, and Organization

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

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. We have not demonstrated our ability to perform the functions necessary for the successful acquisition, development or commercialization of the technologies we are seeking to develop. As an early-stage company, we have limited experience and have not yet demonstrated 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. 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;

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- establishing and maintaining agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- conducting sales and marketing activities including hiring, training, deploying and supporting our sales force and creating market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote our product candidates that we may establish;
- maintaining patent protection and regulatory exclusivity for our product candidates; and
- raising additional required capital on acceptable terms.

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

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

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

Our product candidates are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to develop into commercially viable therapies to treat human patients with cancer or other diseases. One of the reasons for the lack of commercial viability could be our inability to obtain regulatory approval for such technologies.

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

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

- obtaining regulatory approval from the FDA and other regulatory authorities that may have very limited experience with the commercial development of genetically modified T cell therapies for cancer;
- complying with evolving regulatory requirements specifically applicable to gene and cell therapies, including potential class-wide safety concerns and long-term patient follow-up obligations, any of which could delay, limit or prevent the development and approval of our CAR T product candidates;
- developing and deploying consistent and reliable processes for engineering a patient's T cells ex vivo and infusing the engineered T cells back into the patient;
- conditioning patients with chemotherapy in conjunction with delivering our CAR T product candidate, which may increase the risk of adverse events associated with our CAR T product candidate;
- educating medical personnel regarding the potential side effect profile of each of our CAR T product candidate;
- developing processes for the safe administration of this product candidate, including long-term follow-up for all patients who receive our product candidate;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our CAR T product candidate;

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- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for indications beyond those addressed by our current product candidate.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay the pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately and/or effectively evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Risks Inherent in Drug Development and Commercialization

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

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

- commencing a clinical trial as a result of regulatory authority action;
- identifying, recruiting and training suitable clinical investigators;
- reaching and preserving agreements on acceptable terms with prospective 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

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equipment and facilities are inadequate to support approval. Approval policies or regulations may change, and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in the clinical development of product candidates, regulatory approval is never guaranteed.

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

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

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

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

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

Any regulatory approval is limited to the indications for use and related treatment of those specific diseases and indications set forth in the approval for which a product is deemed to be safe and effective by the FDA, or other similar regulatory authorities outside the United States. In addition to the regulatory approval required for new drug products, new formulations or indications for an approved product also require regulatory approval. If we are not able to obtain regulatory approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities ("off-label uses"), our ability to promote the products is limited to those indications that are specifically approved by the FDA, or similar regulatory authorities outside the United States. Such off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in certain circumstances. Regulatory authorities in the U.S. generally do not regulate practice of medicine or the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the promotion of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to compliance or enforcement actions, including Warning

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Letters, by these authorities. In addition, our failure to follow FDA laws, regulations and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, request a recall or institute fines or penalties, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business.

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

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

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

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

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

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

Additionally, if one or more of our product candidates or any future product candidate receives marketing approval and we or others later identify adverse events associated with this product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of unfavorable labeling statements, including specific warnings, black box warnings, adverse reactions, precautions, and/or contraindications;
- regulatory authorities may suspend or withdraw their approval of the product, and/or require it to be removed from the market;

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- 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 either of our product candidates or any future product candidate, if approved, or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues, or any revenues, from their sale.

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

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

The FDA, or other regulatory authorities, may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA and other applicable regulatory authorities closely 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 in a way which is not consistent with the approved labeling, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetics Act ("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

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- injunctions, consent decrees, and/or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, or negatively affect those products for which we may have already received regulatory approval, if any. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to the various actions listed above, including losing any marketing approval that we may have obtained.

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

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

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

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

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

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

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;

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- 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 events; and
- the effectiveness of our sales and marketing efforts.

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

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

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. We intend to seek approval to market our product candidates in the U.S., the European Union (“EU”) and other selected foreign jurisdictions. Market acceptance and sales of our product candidates, if approved, in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government and other third-party payors are increasingly attempting to contain healthcare

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costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates, if approved. These payors may conclude that our product candidates are less safe, less effective or less cost-effective than existing or future introduced products, and third-party payors may not approve our product candidates, if approved, for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates.

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

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

If we are unable to establish sales, marketing and distribution capabilities or to enter into agreements with third parties to market and sell our product candidates, we may be unsuccessful in commercializing our product candidates, if they are approved.

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

Factors that may inhibit our efforts to commercialize our product candidates, if approved, on our own include, but are not necessarily limited to:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating our own sales and marketing organization.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or 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.

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

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

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

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

Risks Related to Reliance on Third Parties

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

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

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

The third parties with whom we have contracted to help perform our preclinical studies and/or clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we

will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, if approved.

If any of our relationships with these third-party CROs or site management organizations terminates, we may not be able to enter into arrangements with alternative CROs or site management organizations or to do so on commercially reasonable terms. Switching or adding additional CROs or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We are currently reliant on COH, Nationwide and UAB for all of our research and development efforts and the early clinical testing of our product candidates.

A substantial portion of our research and development has been and will continue to be conducted by COH, Nationwide, and UAB pursuant to a sponsored research agreement and/or clinical trial agreements between us and COH, as well as a Memorandum of Understanding between Nationwide and UAB under which UAB is conducting its MB-108 Phase 1 clinical trials. As a result, our future success is heavily dependent on the results of research and development efforts of these institutions and their personnel. We have limited control over the nature or timing of their research and limited visibility into their day-to-day activities, and as a result can provide little assurance that their efforts will be successful.

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

Due to limited resources, and in light of our reduction in work force in April 2024, we may increase our reliance on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of one or more product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including, but not necessarily limited to:

- reliance on the third party for regulatory compliance and quality assurance, while still being required by law to establish adequate oversight and control over products furnished by that third party;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers are unable to obtain raw materials due to supply chain disruptions, give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We rely on our third-party manufacturers to produce or purchase from third-party suppliers the materials and equipment necessary to produce our product candidates for our preclinical and clinical trials. Forces beyond our control could disrupt the global supply chain, including imposition of tariffs, and impact our or our third-party manufacturers' ability to obtain raw materials or other products necessary to manufacture our product candidates. There are a limited number of suppliers for raw materials and equipment that we use (or that are used on our behalf) to manufacture our product candidates, and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials and equipment necessary to produce our product candidates for our preclinical and clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials or equipment by our third-party manufacturers. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing preclinical or clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of 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.

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The facilities used by contract manufacturers to potentially manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a New Drug Application (“NDA”) or BLA to the FDA. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our contract manufacturers, but we do not control the day-to-day manufacturing operations of, and are dependent on, the contract manufacturers for compliance with current Good Manufacturing Practices (“cGMP”) regulations for manufacture of our product candidates. Third-party manufacturers may not be able to comply with the cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, restrictions on imports and exports, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

One or more of the product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers.

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

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

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

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

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

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

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

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

As part of our strategy to mitigate development risk, we seek to develop product candidates with well-studied mechanisms of action, and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. Further, such clinical data and results

may be based on products or product candidates that are significantly different from our product candidates or any future product 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 of our product candidates and commercialization, if approved. It may be necessary for us to use the patented or proprietary technology of third parties, who may or may not be interested in granting such a license, to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

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

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

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

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

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

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

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

along with funding for such research; and established a Center for Medicare and Medicaid Innovation (“CMMI”) at the CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

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

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

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

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

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

These and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any current or future product candidates. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of any current or future product candidates, if any, may be. In addition, increased Congressional scrutiny of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, ability to accept the payment of user fees, and statutory, regulatory, and policy changes.

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Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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

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

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal healthcare program;
- The False Claims Act and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from the federal government or making or using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;
- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the 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 government authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

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

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

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Intellectual Property and Potential Disputes Thereof

If we are unable to obtain and maintain sufficient patent protection for our technology and products, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

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

- patent applications may not result in any patents being issued, or the scope of issued patents may not extend to competitive product candidates and their formulations and uses developed or produced by others;

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- 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

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applications in the U.S. and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or such licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we and our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to, among other things:

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

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

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

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

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

As discussed elsewhere herein, in September 2025, we received a notice from Fred Hutch of its intent to terminate the CD20 License for cause in connection with unpaid patent expenses and maintenance fees. A 90-day cure period was applicable under the CD20 License. In December 2025, we agreed to terminate the CD20 License with Fred Hutch in exchange for a mutual release of liability and forgiveness of approximately fifty percent of amounts previously owed to them. Additionally, we are eligible to receive royalties on any subsequent licensing consideration Fred Hutch may enter into during the three-year period following the termination. If Fred Hutch or a third party successor to the program experiences future success in the development and/or commercialization of the CD20 program, it is possible that

we will have forfeited the opportunity to realize the relatively greater value from such program that would have resulted if we had continued to develop this technology ourselves.

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;

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- 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

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

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

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

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

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

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not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

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

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

Our growth is subject to economic and geopolitical conditions.

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

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

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

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

Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of which could have a material adverse effect on our business.

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

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

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

We are vulnerable to damage and/or loss of vital data from the physical impacts of climate change and other natural or man-made disasters, such as earthquakes, tornadoes, power loss, fire, health epidemics and pandemics, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our businesses could be seriously impaired. Our operations, and those of our third-party manufacturers, suppliers, clinical sites and other partners, depend on infrastructure and facilities that may be located in areas increasingly subject to extreme weather events and other physical risks and natural or man-made disasters. These events could cause damage to or disrupt the operations of our contract manufacturers, suppliers, clinical trial sites, laboratories, data centers and other critical infrastructure, which could in turn:

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

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

We have property, liability and business interruption insurance that may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial

condition and prospects. Any of the aforementioned circumstances may also impede our employees' and consultants' abilities to provide services in-person and/or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of "force majeure" clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such "force majeure" clauses, or the enforceability of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time-consuming.

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

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

- the commencement, enrollment, or results of our current and future preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- manufacturing, supply or distribution delays or shortages;
- our ability to identify and successfully acquire or in-license new product candidates on acceptable terms;
- FDA, state or international regulatory actions, including actions on regulatory applications 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. In 2024 and early 2025, we were not in compliance with certain standards for continued listing on the Nasdaq Capital Market, namely, the minimum stockholders' equity requirement (the "Equity Rule") and the minimum bid price requirement (the "Bid Price Rule").

On January 15, 2025, we effected a 1-for-50 reverse stock split. Thereafter, we were subsequently notified by the Staff of Nasdaq's Listing Qualifications department (the "Staff") that we had regained compliance with the Bid Price Rule.

On February 10, 2025, we completed a best-efforts public offering for net proceeds of approximately \$6.8 million, and we were subsequently notified by the Staff that we had regained compliance with the Equity Rule and are subject to mandatory monitoring by a Nasdaq Hearings Panel for one year.

There can be no assurance that we will be able to maintain compliance with Nasdaq's continued listing rules in the future. If we are unable to maintain compliance, we may be delisted from Nasdaq. In the event we are delisted from Nasdaq, there can be no assurance that our common stock will be eligible for trading on another stock exchange or quotation on an over-the-counter market. If we are not able to obtain a listing on another stock exchange or quotation service for our common stock, it may be extremely difficult or impossible for stockholders to sell their shares. Additionally, if we are delisted from Nasdaq, but obtain a substitute listing or quotation service for our common stock, it will likely be on a market with less liquidity and our common stock may therefore experience potentially more price volatility than it has historically experienced on Nasdaq. Stockholders may not be able to sell their shares of common stock on any such substitute market in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if our common stock is delisted from Nasdaq, the value and liquidity of our common stock would likely be adversely affected. A delisting of our common stock from Nasdaq could also adversely affect our ability to obtain financing for our operations and/or result in a loss of confidence by investors, employees and/or business partners.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have established certain processes for identifying, evaluating, and managing material risks from cybersecurity threats as a part of our overall technology management strategy. These processes are designed and reassessed on a periodic basis to help protect our technology assets and operations from internal and external security threats. We also engage with third parties, including consultants, to enhance our security processes.

We have previously engaged and currently engage third parties to assess the effectiveness of our cybersecurity and technology management strategy and continue to seek to implement new, and improve existing, processes regularly to adjust for changes in technology, internal or external threats, business strategy, and regulatory requirements. We, and our third parties, have deployed managed detection and response services to monitor our technology infrastructure and information systems for possible threats. Our technology management strategy also includes ongoing security training and education for employees regarding threats, including their role and responsibility in detecting and responding to such threats.

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We review the processes of our third-party vendors and consider their ability to adhere to relevant industry practices and maintain adequate technology risk programs. In addition, we maintain cyber and cyber-related crime insurance coverage policies as part of our overall risk management strategy, however, our policies may not be sufficient to cover against all potential future claims, if any.

In the last two fiscal years, we have not identified cybersecurity threats that have materially affected, or are reasonably likely to materially affect, our business, results of operations, or financial condition. Although we proactively attempt to prevent all threats, we are unable to eliminate all risk from cybersecurity threats or provide assurance that we have not experienced an undetected cybersecurity incident. For more information about these risks, please see Item 1A. Risk Factors “Our business and operations would suffer in the event of computer system failures, cyber-attacks, or deficiencies in our or third parties’ cybersecurity.”

Cybersecurity Governance

While our board of directors is responsible for oversight and risk management in general, our Audit Committee provides oversight of our technology management strategy to ensure that cybersecurity threats and risks are identified, evaluated, and managed. The Audit Committee receives periodic updates from our management team regarding the overall state of our technology management strategy and any relevant risks from cybersecurity threats and cybersecurity incidents.

Our management team is responsible for assessing and managing the material risks from cybersecurity threats. Our management team members have expertise in information systems, compliance and corporate governance, which we believe are disciplines that are effective in the management of the Company’s cybersecurity risk. Our management team is informed of and monitors the prevention, detection, and mitigation of cybersecurity threats and incidents.

Item 2. Properties

Our corporate and executive office is located at 95 Sawyer Road, Waltham, MA 02453.

Item 3. Legal Proceedings

We are not involved in any legal proceedings that we believe could have a material adverse effect on our financial position or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of our executive officers, threatened against or affecting our company or our officers or directors in their capacities as such.

Item 4. Mine Safety Disclosures

Not applicable

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market information

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

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Form 10-K.

Holders of Record

As of March 17, 2026, there were approximately fifty-seven holders of record of our common stock and one holder of record for our Class A common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders

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who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our Board 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 deems relevant.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved

Item 7. Management’s Discussion and Analysis of the Results of Operations

Statements in the following discussion and throughout this Form 10-K that are not historical in nature are “forward-looking statements.” You can identify forward-looking statements by the use of words such as “expect,” “anticipate,” “estimate,” “may,” “will,” “should,” “intend,” “believe,” and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A “Risk Factors.” We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. Please see “Special Cautionary Note Regarding Forward-Looking Statements” at the beginning of this Form 10-K.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes thereto and other financial information appearing elsewhere in this Form 10-K. We undertake no obligation to update any forward-looking statements in the discussion of our financial condition and results of operations to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a clinical-stage biopharmaceutical company focused on translating today’s medical breakthroughs into potential cures for difficult-to-treat cancers. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

Our pipeline is currently focused on novel therapies for solid tumors. For these therapies we have partnered with world class research institutions, including the City of Hope National Medical Center (“COH” or “City of Hope”), and Nationwide Children’s Hospital (“Nationwide”).

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

Development Pipeline

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

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In partnership with COH, we are developing CAR T therapy for solid tumors 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) has also completed the treatment phase and patients continue to be assessed for long-term safety. In October 2023, we announced that the FDA accepted our IND application for the combination of MB-101 and MB-108 – which is referred to as MB-109 – for the treatment of patients with IL13R α 2+ relapsed or refractory glioblastoma (“GBM”) and high-grade astrocytoma. Pursuant to termination of the lease for our cell processing center in Worcester, MA, we are exploring with COH and Nationwide the possibility of initiating this clinical trial as an investigator-sponsored single-institution study at COH in the second quarter of 2026.

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 letter 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. The Phase 1 clinical study under that IND would 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. As originally written and approved by the FDA, the study involved first a lead-in cohort, wherein patients would be treated with MB-101 alone without prior MB-108 administration. This lead-in cohort was required by the FDA due to the change in cell processing site from COH to Mustang Bio, which would have involved methodological changes as well as the obvious change in equipment and personnel. After successful confirmation of the safety profile of MB-101 alone, the study would 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, an HSV-1 oncolytic virus, for the treatment of malignant glioma. On July 7, 2025, we announced that the FDA granted Orphan Drug Designation to Mustang for MB-101, IL13R α 2-targeted CAR T-cells, for the treatment of recurrent diffuse and anaplastic astrocytoma (astrocytomas) and glioblastoma. The Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials upon approval and prescription drug user fee waivers. If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in which it has Orphan Drug designation, which is independent from intellectual property protection.

We are currently exploring with COH and Nationwide the possibility of conducting an investigator-sponsored single-institution trial under the COH IND to treat patients with IL13R α 2+ recurrent GBM and high-grade astrocytoma with MB-109 that could potentially be initiated in the second quarter of 2026. Because cell processing for MB-101 will revert back to COH – where the product continues to be manufactured today for other investigator-sponsored clinical trials being conducted by COH in malignant brain tumors (NCT04003649, NCT04661384, NCT04510051), we believe that it is reasonable to assume that the FDA will not require the aforementioned lead-in cohort. Should this, indeed, be the case, the first patient enrolled will receive the combination of MB-101 and MB-108, which will represent a considerable savings of time and money – as well as afford the potential benefit of both therapies to every patient treated on study.

Terminated Product Candidate (CAR-T Therapy)

In September 2025, we received notice from Fred Hutch of its intent to terminate the CD20 License for cause in connection with unpaid patent expenses and maintenance fees. A 90-day cure period was applicable under the CD20 License. In December 2025, we agreed to terminate the CD20 License with Fred Hutch in exchange for a mutual release of liability and forgiveness of approximately fifty percent of amounts previously owed to them. Additionally, we are eligible to receive royalties on any subsequent licensing consideration Fred Hutch may enter into during the three-year period following the termination.

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 Events

Reverse Stock Split

On January 15, 2025, we filed 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, to effect a 1-for-50 reverse stock split of our issued and outstanding common

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stock, without any change to par value. The Amendment became effective upon such filing. No fractional shares were issued in connection with the reverse stock split as all fractional shares were rounded down to the next whole share. The reverse stock split was intended to bring the Company into compliance with the continued listing requirements of The Nasdaq Stock Market LLC (“Nasdaq”).

All share and per share amounts of our common stock listed in this Form 10-K have been adjusted to give effect to the reverse stock split.

Termination of lease and sale of equipment

On February 10, 2025, we entered into a Bill of Sale and Surrender Agreement (the “Sale/Surrender Agreement”), effective as of January 31, 2025 (the “Effective Date”), with AbbVie Bioresearch Center Inc., a Delaware corporation (“AbbVie”). We were the tenant in the leased premises located at 377 Plantation Street, Worcester, Massachusetts (the “Premises”) under a Lease Agreement, dated as of October 27, 2017 (the “Lease”) with WCS - 377 Plantation Street, Inc., a Massachusetts nonprofit corporation (the “Landlord”). In connection with the entrance into the Sale/Surrender Agreement, we also entered into an Escrow Agreement, dated February 10, 2025 (the “Escrow Agreement”), with Bowditch & Dewey, LLP, as escrow agent (the “Escrow Agent”), pursuant to which the Escrow Agent would disburse the Purchase Price (defined herein) pursuant to the terms of the Escrow Agreement.

Pursuant to the terms of the Sale/Surrender Agreement, AbbVie agreed to purchase from us, and we agreed to sell and convey to AbbVie, certain furniture, fixtures and equipment (“FF&E”), which we classified as held for sale as of December 31, 2024, located in the Premises and other items as set forth in the Sale/Surrender Agreement for a purchase price of \$1.0 million (the “Purchase Price”). AbbVie also agreed to lease the Premises from the Landlord following the termination of the Lease pursuant to a First Amendment to Lease Agreement (the “Amendment”), dated as of February 7, 2025.

The closing of the transactions described above occurred on February 21, 2025 (the “Closing”), with AbbVie’s issuance of an Acceptance Notice (as defined in the Sale/Surrender Agreement) to us stating that a Sufficient Percentage (as defined in the Sale/Surrender Agreement) of the FF&E items listed in the Sale/Surrender Agreement are present in the Premises and functional for their intended purpose without the need for repair or replacement. On February 25, 2025, as a result of the issuance of the Acceptance Notice, pursuant to the terms of the Escrow Agreement, the Escrow Agent released the Purchase Price to us. On February 27, 2025, we announced the relocation of our corporate headquarters to 95 Sawyer Road, Waltham, Massachusetts 02453.

Financing Activities

February 2025 Equity Offering (the “February 2025 Equity Offering”)

On February 5, 2025, we commenced a best efforts public offering of an aggregate of (i) 495,000 shares (the “Shares”) of its common stock, par value \$0.0001 per share, (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to an aggregate of 2,162,807 shares of common stock (the “Pre-Funded Warrant Shares”), (iii) Series C-1 warrants (the “Series C-1 Warrants”) to purchase up to an aggregate of 2,657,807 shares of common stock (the “Series C-1 Warrant Shares”), and (iv) Series C-2 warrants (the “Series C-2 Warrants,” and together with the Series C-1 Warrants, the “Warrants”) to purchase up to an aggregate of 2,657,807 shares of common stock (the “Series C-2 Warrant Shares,” and together with the Series C-1 Warrant Shares, the “Warrant Shares”). Each Share or Pre-Funded Warrant was sold together with one Series C-1 Warrant to purchase one share of common stock and one Series C-2 Warrant to purchase one share of common stock. The combined public offering price for each Share and accompanying Warrants was \$3.01, and the combined public offering price for each Pre-Funded Warrant and accompanying Warrants was \$3.0099.

The Pre-Funded Warrants have an exercise price of \$0.0001 per share, are exercisable immediately upon issuance and will expire when exercised in full. Each Warrant has an exercise price of \$3.01 per share and will be exercisable beginning on the effective date of stockholder approval of the issuance of the Warrant Shares (the “Warrant Stockholder Approval”). The Series C-1 warrants will expire five years from the Warrant Stockholder Approval and the Series C-2 warrants will expire twenty-four months from the Warrant Stockholder Approval.

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

July 2025 Warrant Exercises

In July 2025, certain investors from the February 2025 Equity Offering exercised outstanding Pre-Funded and Series C-2 warrants resulting in us issuing approximately 2.9 million shares of our common stock and our receipt of proceeds of approximately \$7.1 million.

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 year ended December 31, 2025, we issued approximately 54,000 shares of common stock at an average price of \$11.55 for gross proceeds of \$0.6 million under the ATM Agreement. In connection with these sales, we paid aggregate fees of approximately \$27,000.

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 Annual Report on Form 10-K, 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.

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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 have no alternative future use. Accordingly, the total purchase price for the licenses acquired during the period was reflected as research and development expenses on the Statements of Operations for the years ended December 31, 2025, and 2024.

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.

Recent Accounting Pronouncements

See Note 2 to the financial statements included in this Form 10-K.

Smaller Reporting Company Status

We are a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. As a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K, have reduced disclosure obligations regarding executive compensation, and smaller reporting companies are permitted to delay adoption of certain recent accounting pronouncements discussed in Note 2 to our financial statements located in “Part IV, Item 15., Exhibits and Financial Statement Schedules” in this Form 10-K.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

(\$ in thousands)	For the year ended December 31,		Change	
	2025	2024	\$	%
Operating expenses:				
Research and development	\$ (1,516)	\$ 8,418	\$ (9,934)	(118)%
Asset impairment	—	3,692	(3,692)	100 %
General and administrative	3,948	4,135	(187)	(5)%
Total operating expenses	2,432	16,245	(13,813)	(85)%
Loss from operations	(2,432)	(16,245)	13,813	(85)%
Other income				
Other income	—	314	(314)	(100)%
Interest income, net	511	179	332	185 %
Total other income	511	493	18	4 %
Net Loss	\$ (1,921)	\$ (15,752)	\$ 13,831	(88)%

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 \$9.9 million from \$8.4 million for the year ended December 31, 2024, to (\$1.5) million for the year ended December 31, 2025. The decrease in research and development expense for the year ended December 31, 2025, was primarily attributable to the following:

- \$3.2 million decrease in costs incurred related to the non-repeat of the termination of the transaction with uBriGene and the June 2024 Repurchase of Assets;
- \$1.0 million decrease in clinical trial related costs;
- \$2.3 million decrease in outside service expenses, including assay development costs;
- \$2.0 million decrease in sponsored research and license related expenses;
- \$0.5 million decrease in consulting expenses;
- \$0.6 million decrease in depreciation expense;
- \$0.4 million gain recognized on the termination of the Plantation Street Facility lease;
- \$0.3 million decrease in expense related to the Annual Stock Dividend to Fortress
- \$1.0 million decrease in other expenses; offset by
- \$1.4 million increase in personnel related costs related to the non-repeat of stock compensation expense credits and reversal of accrued bonus from the April 2024 reduction in the workforce.

Additionally, we have been actively negotiating settlements of aged payables, and recognized savings of approximately \$2.1 million, which resulted in a credit for research and development expenses during the year ended December 31, 2025. This credit is not indicative of our research and development expenses going forward.

Asset Impairment

For the year ended December 31, 2024, we incurred impairment charges of \$3.7 million, of which approximately \$2.7 million was attributable to our assessment of the recoverability of the asset group consisting of leasehold improvements and associated right-of-use asset, and approximately \$1.0 million was attributable to property, plant and equipment held for sale at December 31, 2024, and subsequently sold in 2025. No impairment was recorded in the year ended December 31, 2025.

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 \$0.2 million from \$4.1 million for the year ended December 31, 2024, to \$3.9 million for the year ended December 31, 2025. The decrease in general and administrative expense for the year ended December 31, 2025, was primarily attributable to the following:

- \$0.5 million decrease in consulting expenses;
- \$0.1 million decrease in legal and patent protection expenses; offset by
- \$0.4 million increase in state taxes, primarily due to non-repeat credits for overpayments recorded in the prior year.

Total Other Income

Other income for the year ended December 31, 2025, was \$0.5 million relating to interest income. Other income for the year ended December 31, 2024, was \$0.5 million relating to the non-repeat gain on the termination of the Mercantile Center lease in June 2024 and \$0.2 million of interest income.

Liquidity and Capital Resources

Since our inception, we have incurred substantial operating losses and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. To date, we have funded our operations primarily with the proceeds from sales of equity securities. As of December 31, 2025, we had an accumulated deficit of \$398.6 million and cash and cash equivalents of \$17.3 million.

We have previously disclosed in our financial statements for the year ended December 31, 2024, and our most recent quarterly report on Form 10-Q for the period ended September 30, 2025, that substantial doubt existed regarding our ability to continue as a going concern. Although we have a history of negative cash flows from operations and operating losses, we have raised approximately \$14.5 million in net proceeds from the February 2025 Equity Offering, the ATM Agreement and the July 2025 warrant exercises, as described in “Financing Activities” above, during the year ended December 31, 2025. In addition to these net proceeds, we have been actively negotiating settlements of aged payables and have recognized approximately \$2.1 million in savings during the year ended December 31, 2025, and we have significantly reduced our operating costs.

We expect to continue generating operating losses and negative operating cash flows as we develop our products through to potential approval, however, based on the improvement in our cash position for the year ended December 31, 2025, we believe we have sufficient cash and cash equivalents to fund our operations for at least twelve months from the date of this annual report on Form 10-K. Therefore, we have concluded that substantial doubt no longer exists.

As of the date of this Form 10-K, our public float was less than \$75 million. As a result, we are subject to the limitations of General Instruction I.B.6 to Form S-3 until such time as our public float exceeds \$75 million, which means we only have the capacity to sell an amount of securities up to one-third of our public float under shelf registration statements in any twelve-month period. If our public float decreases, the number of securities we may sell under our Form S-3 shelf registration statements will also decrease. We will remain constrained by the limitations of General Instruction I.B.6 to Form S-3 until such time as our public float exceeds \$75 million, at which time the number of securities we may sell under a Form S-3 registration statement will no longer be limited by limitations of General Instruction I.B.6 to Form S-3.

Sources of Liquidity

Registration Statements

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 December 31, 2025, approximately \$34.2 million of the 2024 S-3 remained available for sales of securities.

As of the filing of this Form 10-K, 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.

Equity Offerings

During the year ended December 31, 2025, we completed the February 2025 Equity Offering and the July 2025 Warrant Exercises (together, the “Capital Raises”), as described above in “Management’s Discussion and Analysis of the Results of Operations – Financing Activities.” Net proceeds from the Capital Raises were approximately \$14.3 million. We intend to use the net proceeds from the Capital Raises for working capital and general corporate purposes.

In connection with the February 2025 Equity Offering and July 2025 Warrant Exercises, pursuant to the Founders Agreement, we issued 125,779 shares of common stock to Fortress.

[Table of Contents](#)*At-the-Market Offering*

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 year ended December 31, 2025, the Company issued approximately 54,000 shares of common stock at an average price of \$11.55 per share for gross proceeds of \$0.6 million under the ATM Agreement. In connection with these sales, the Company paid aggregate fees of approximately \$27,000 for net proceeds of approximately \$0.6 million.

During the year ended December 31, 2024, the Company issued approximately 140,000 shares of common stock at an average price of \$18.78 per share for gross proceeds of \$2.6 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 \$2.5 million.

Pursuant to the Founders Agreement, the Company issued 1,361 shares of common stock to Fortress at a weighted average price of \$11.55 per share for the year ended December 31, 2025. For the year ended December 31, 2024, the Company issued 3,509 shares of common stock to Fortress at a weighted average price of \$18.78 per share.

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.”

Cash Flows

The following table summarizes our cash flows during the years ended December 31, 2025 and 2024:

<i>(\$ in thousands)</i>	For the year ended December 31,	
	2025	2024
Statement of cash flows data:		
Total cash (used in) provided by:		
Operating activities	\$ (5,264)	\$ (11,410)
Investing activities	1,165	—
Financing activities	14,526	11,265
Net change in cash and cash equivalents	<u>\$ 10,427</u>	<u>\$ (145)</u>

Operating Activities

Net cash used in operating activities for the year ended December 31, 2025, was primarily due to approximately \$1.9 million in net loss, \$1.7 million change in operating assets and liabilities, \$2.1 million non-cash savings from the settlement of payables, \$0.4 million gain on the termination of the Plantation Street Facility lease, partially offset by \$0.4 million equity fee to Fortress, \$0.3 million common shares issuable in connection with Annual Stock Dividend to Fortress and \$0.1 million non-cash stock based compensation.

Net cash used in operating activities for the year ended December 31, 2024, was primarily due to approximately \$15.8 million in net loss, \$2.4 million non-cash savings from the settlement of payables, \$0.5 million of non-cash stock based compensation, and \$0.3 million gain on the termination of lease, partially offset by \$3.7 million of asset impairment, \$1.8 million change in operating assets and liabilities, \$0.7 million of depreciation expense, \$0.6 million of common shares issuable in connection with the Annual Stock Dividend to Fortress, \$0.3 million equity fee to Fortress related to Mustang ATM and Equity Offerings, \$0.2 million of amortization of operating lease right-of-use assets, and \$0.3 million in research and development – licenses acquired.

Investing Activities

Net cash provided by investing activities was \$1.2 million for the year ended December 31, 2025, which primarily reflects the proceeds from the sale of equipment to AbbVie.

No cash was used in or provided by investing activities for the year ended December 31, 2024.

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Financing Activities

Net cash provided by financing activities was \$14.5 million during the year ended December 31, 2025, primarily reflecting the proceeds from the February 2025 Equity Offering, the ATM Agreement and the July 2025 warrant exercises.

Net cash provided by financing activities was \$11.3 million during the year ended December 31, 2024, primarily reflecting the proceeds from the May 2024 Offering, June 2024 Offering and the ATM Agreement.

Contractual Obligations

We enter into contracts in the normal course of business with licensors, CROs, contract manufacturing organizations (“CMOs”) and other third parties for the procurement of various products and services, including without limitation biopharmaceutical development, biologic assay development, commercialization, clinical and preclinical development, clinical trials management, pharmacovigilance and manufacturing and supply. These contracts typically do not contain minimum purchase commitments (although they may) and are generally terminable by us upon written notice. Payments due upon termination or 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risks

None.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item is set forth in the financial statements and notes thereto beginning at page F-1 of this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) are designed only to provide reasonable assurance that they will meet their objectives. Under the supervision and with the participation of our management, including our principal executive and financial officer, we conducted an evaluation of the effectiveness, as of December 31, 2025, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive and financial officer concluded that, as of such date, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

Management’s Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive and financial officer, and effected by our Board, management and other personnel, to provide

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reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles in the United States (“GAAP”), and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making the assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in *Internal Control - Integrated Framework (2013)*.

Based on our assessment, our management has concluded that, as of December 31, 2025, our internal controls over financial reporting were effective based upon those criteria.

Changes in Internal Controls over Financial Reporting.

There were no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

During the three months ended December 31, 2025, none of our directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevents Inspections.

None.

PART III**Item 10. Directors, Executive Officers and Corporate Governance**

The following table sets forth information regarding our executive officers and directors, including their ages as of the date of this Form 10-K.

Name	Age	Position(s)
Executive Officers		
Manuel Litchman, M.D.	72	President, Chief Executive Officer, Interim Chief Financial Officer and Director
Non-Employee Directors		
Michael S. Weiss	60	Chairman of the Board of Directors and Executive Chairman
Adam J. Chill	58	Director
Neil Herskowitz	69	Director
David Jin	35	Director
Lindsay A. Rosenwald, M.D.	70	Director
Michael J. Zelefsky, M.D.	65	Director

Information about our 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 since April 2017 and as Interim Chief Financial Officer since November 2024. Dr. Litchman has also served on the board of Cascade Prodrug, LLC, a private biotechnology company, since August 2025. 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.

Information about our Non-Employee Directors***Michael S. Weiss – Chairman of the Board of Directors and Executive Chairman***

Mr. Weiss has served as Chairman of our Board 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. Since December 2011, Mr. Weiss has served in multiple capacities at TG Therapeutics, Inc., and is currently its Chairman, President and Chief Executive Officer. 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. From 2002 to 2009, Mr. Weiss was the Chairman and Chief Executive Officer of Keryx Biopharmaceuticals, Inc. Additionally, Mr. Weiss co-founded and served as Co-Portfolio Manager and Managing Partner of Opus Point Partners, LLC from 2009 to 2019. 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.

Effective January 1, 2017, our Board 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 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 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 our affiliate, 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 since October 2024. Mr. Jin has served as the Chief Financial Officer of Fortress since August 2022 and Head of Corporate Development since May 2020. He also serves as Chief Operating Officer, Interim Chief Financial Officer and Corporate Secretary of Avenue Therapeutics, Inc. (a Fortress partner company) and as a member of the board of directors of Crystalys Therapeutics. 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. Previously, he was on the investment team in the Private Equity & Real Assets group at Barings, Director of Corporate Development at Sorrento Therapeutics, Vice President of Healthcare Investment Banking at FBR & Co., and was in the management consulting group at IMS Health (now IQVIA). He holds a B.S. 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.

Lindsay A. Rosenwald, M.D. – Director

Dr. Rosenwald has served as a member of our Board 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. 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.

Michael J. Zelefsky, M.D. – Director

Dr. Zelefsky has served as a member of our Board 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

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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.

Family Relationships

There is no family relationship between and among any of our executive officers or directors.

Board Structure and Leadership

Our Bylaws provide that our Board 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.

The Board does not have a formal policy regarding the separation of the roles of Chief Executive Officer and Chairman of the Board, as the Board 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. The Board 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.

During 2025, our Board held six meetings. During 2025, each director attended at least 75% of the meetings of the Board and the meetings of those committees on which each director served, in each case during the period that such person was a director. The permanent committees established by our Board are the Audit Committee and the Compensation Committee, descriptions of which are set forth in more detail below. Our directors are expected to attend each Annual Meeting of Stockholders.

Director Independence

We adhere to the corporate governance standards adopted by Nasdaq. Nasdaq rules require our Board to make an affirmative determination as to the independence of each director. Consistent with these rules, our Board completed its annual review of director independence and considered relationships and transactions during 2025 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 determined that Adam Chill, Neil Herskowitz, and Michael Zelefsky, M.D., are independent under the criteria established by Nasdaq and our Board.

Fortress Biotech, Inc. ("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 the Nasdaq corporate governance rules. As a controlled company, we are not required to have a majority of "independent directors" on our Board as defined under the 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.

Board Committees

The permanent committees established by our Board are the Audit Committee and the Compensation Committee, descriptions of which are set forth in more detail below.

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 Audit Committee held four meetings during the fiscal year ended December 31, 2025. 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.

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The SEC and Nasdaq have established rules and regulations regarding the composition of audit committees and the qualifications of audit committee members. Our Board 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 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 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 and our Audit Committee. Please see Mr. Chill’s biography in Item 10. Directors, Executive Officers, and Corporate Governance.

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 Compensation Committee held one meeting during the fiscal year ended December 31, 2025. 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 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 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.

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, 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. A stockholder who wishes to recommend a candidate for nomination to our Board must submit such recommendation to our Corporate Secretary, at our offices located at 95 Sawyer Road, Suite 110, Waltham, MA 02453. 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.

On April 7, 2017, we entered into an Executive Employment Agreement with Dr. Litchman, pursuant to which, among other things, we agreed to use our best efforts to cause Dr. Litchman to be nominated and reelected to the Board. 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.

We believe that our Board 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 by reviewing their biographical information and qualifications. If the directors determine that a candidate is qualified to serve on our Board, such candidate is interviewed by at least one of the directors and our Chief Executive Officer. Other members of the Board 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

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recommend to the Board 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 the Board. 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: 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; 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 and the evolving needs of our business. We believe that each of the current members of our Board has the requisite business, biopharmaceutical, financial or managerial experience to serve as a member of the Board, as described above in their biographies under the heading "Information about our Executive Officers" and "Information about our Non-Employee Directors." We also believe that each of the current members of our Board 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 and its committees.

Code of Business Conduct and Ethics

We have 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. We have posted a copy of the Code on our website, located at www.mustangbio.com.

Insider Trading Policy; Policy Prohibiting Hedging and Speculative Trading

We have adopted an Insider Trading Policy that governs the purchase, sale, and other dispositions of our securities on the basis of material non-public information by directors, officers, employees, consultants and contractors. We believe these policies and procedures are reasonably designed to promote compliance with insider trading laws, rules and regulations, and applicable Nasdaq listing standards. A copy of our Insider Trading Policy is filed as an exhibit to this Form 10-K.

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

Delinquent Section 16(a) Reports

Section 16 of the Exchange Act requires our directors, certain officers, and beneficial owners of more than ten percent of our common stock to file reports with the SEC indicating their holdings of and transactions in our equity securities, and to provide copies of such reports to us. Based solely on a review of our records, publicly available information, and written representations by the persons required to file such reports, we believe that during the fiscal year ended December 31, 2025, there were no delinquent Section 16(a) filings.

Item 11. Executive Compensation

Named Executive Officers

As determined in accordance with SEC rules, our named executive officers ("NEOs"), which includes all executive officers serving during 2025, are the individuals set forth below:

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

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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, 2025, and 2024.

Summary Compensation Table

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards⁽¹⁾ (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation⁽²⁾ (\$)	All Other Compensation (\$)	Total (\$)
Manuel Litchman, M.D. <i>President, Chief Executive Officer, and Interim Chief Financial Officer</i>	2025	\$ 485,500	\$ —	\$ —	\$ —	\$ —	\$ 12,763 ⁽³⁾	\$ 498,263
	2024	485,500	—	—	—	—	12,542 ⁽³⁾	498,042

(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 incorporated by reference to Note 8 to the financial statements included in this Form 10-K. No Stock Awards were granted in 2025 and 2024.

(2) In 2025 and 2024, the Compensation Committee decided to not pay annual cash incentive bonuses. See the “Annual Cash Incentive Bonus” section below for additional details.

(3) All other compensation for Dr. Litchman is comprised of Company matching 401(k) contributions.

Narrative to Summary Compensation Table

Employment Agreements

Dr. Litchman

In April 2017, we entered into an employment agreement with Dr. Litchman, our President, Chief Executive Officer and Interim Chief Financial 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 increased Dr. Litchman’s annual base salary to \$485,500 effective as of April 1, 2023. There were no increases to Dr. Litchman’s annual base salary in 2025 and 2024. 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 or the Compensation Committee. Dr. Litchman’s target annual bonus is equal to fifty percent (50%) of his annual salary, and the Board or the Compensation Committee will determine the actual payout amount each year. 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, if such reduction would result in a better after-tax result for Dr. Litchman.

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Annual Cash Incentive Bonus

In 2025, 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 included 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. In 2025, the Compensation Committee decided not to pay the 2025 annual cash incentive bonus to preserve our cash resources.

Equity Awards

The Company maintains the Mustang Bio, Inc. 2016 Incentive Plan (the "2016 Plan"), pursuant to which it may, from time to time, grant equity awards to its service providers, including its executive officers and directors. However, no equity awards were granted in 2025.

Outstanding Equity Awards at Fiscal Year-Ended December 31, 2025

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.	868 ⁽²⁾	520 ⁽²⁾	\$ 4,297.50	4/24/2027	71 ⁽³⁾	\$ 70

- (1) Market value is based on \$0.981 per share, the closing price of our common stock on the Nasdaq Capital Market on December 31, 2025, the last trading day of the fiscal year.
- (2) The unvested portion 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 a second Company product candidate; (B) 25% of such shares will vest upon our achievement of a fully-diluted market capitalization of \$500,000,000; and (C) 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 the Company product candidates referenced in subsection (A) of this paragraph is bypassed, the corresponding percentage of the Performance Option grant that would have otherwise vested pursuant to subsection (A) 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) These restricted stock units vest as follows: (i) 46 shares will vest on April 24, 2026; and (ii) 25 shares will vest on April 24, 2027, subject in each case to Dr. Litchman's continuous service to the Company through that date.

Clawback Policy

Pursuant to Nasdaq listing requirements, we have adopted a policy providing for the recovery of erroneously awarded incentive-based compensation received by our executive officers or the executive officers of one of our subsidiaries during an applicable recovery period (the "Clawback Policy") in compliance with Section 10D of the Exchange Act. Under the Clawback Policy, in the event that financial results upon which a cash or equity-based incentive award was based becomes the subject of a financial restatement that is required because of material non-compliance with financial reporting requirements, the Compensation Committee will conduct a review of awards covered by the Clawback Policy and recoup any erroneously awarded incentive-based compensation to ensure that the ultimate award reflects the financial results as restated. The Clawback Policy covers any cash or equity-based incentive compensation award that was paid, earned or granted to covered executive officers during the last completed three fiscal years immediately preceding the date on which we are required to prepare the accounting restatement.

Stock Option Grant Policy

We did not grant stock options or similar instruments to our NEOs during 2025. We have no set policy or practice regarding the timing of stock option awards or similar instruments in relation to the disclosure of material nonpublic information. In general, the timing of stock option awards is dictated by the event or circumstance giving rise to the award and the schedules of the directors responsible for approving the award. If, in the future, a stock option grant is made at a time that material nonpublic information exists, the directors approving the award would be responsible for considering the anticipated effect of that information on our stock price and would take such effect into account when sizing and pricing the award.

Director Compensation

Directors who are also employees are not compensated separately for serving on the Board or any of its committees. For 2025, our only employee director was Dr. Litchman, and he is therefore not included in the Director Compensation Table below.

Each of our non-employee directors is eligible to receive cash and equity compensation for his or her services. The Compensation Committee periodically conducts reviews of peer company director compensation practices, including before considering changes to our director compensation program and amounts.

Director Compensation Program

In January 2016, the Board 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 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 on such date.

However, in 2025 the Board decided not to grant director equity awards due to timing of the annual shareholders meeting.

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

Director Compensation Table

The following table sets forth the cash and other compensation we paid to the non-employee members of our Board for all services in all capacities during 2025.

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

- (1) Represents the cash retainer for serving on our Board and committees of the Board.
- (2) No stock awards were granted in 2025. As of December 31, 2025, each of Mr. Herskowitz, Dr. Rosenwald, Mr. Weiss, Mr. Chill and Dr. Zelefsky had 157 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 and Executive Chairman in addition to any and all annual equity incentive grants paid to members of the Board.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2025.

Plan Category	Equity Compensation Plan Information		Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights ⁽¹⁾ (b)	
Equity compensation plans approved by security holders	1,617	\$ 4,297.50	2,506,958
Equity compensation plans not approved by security holders	—	—	—
Total	1,617	\$ 4,297.50	2,506,958

(1) The calculation of the weighted-average exercise price of outstanding options, warrants and rights in this column does not include outstanding restricted stock units, as they do not have an exercise price.

Our equity compensation plans consist of the 2016 Plan, and the Mustang Bio, Inc. 2019 Employee Stock Purchase Plan, which were each approved by our stockholders. We do not have any equity compensation plans or arrangements that have not been approved by our stockholders.

Security Ownership of Our Directors, Executive Officers, and 5% Beneficial Owners

The following table shows information, as of March 17, 2026, concerning the beneficial ownership of our common stock by:

- each person we know to be the beneficial owner of more than 5% of our common stock;
- each of our current directors;
- each of our NEOs shown in our Summary Compensation Table; and
- all current directors and executive officers as a group.

As of March 17, 2026, there were 6,732,092 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 March 16, 2026. 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		Total Shares Beneficially Owned	%	
		Units ⁽²⁾				of total CS
Michael S. Weiss ⁽³⁾	991	—		991	*	%
Manuel Litchman, M.D	1,563	939		2,502	*	%
Lindsay A. Rosenwald, M.D ⁽³⁾	1,008	—		1,008	*	%
Neil Herskowitz	145	—		145	*	%
Adam J. Chill	375	—		375	*	%
Michael J. Zelefsky, M.D	379	—		379	*	%
David Jin	286	—		286	*	%
All current executive officers and directors as a group (7 persons)	4,747	939		5,686	*	%
5% or Greater Stockholders:						
Fortress Biotech, Inc ⁽⁴⁾	536,577	—		536,577	8.0	%

* 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., 95 Sawyer Road, Suite 110, Waltham, MA 02453, 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 March 17, 2026 and unvested restricted stock units.
- (3) Includes 666 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 666 warrants issued to each of Mr. Weiss and Dr. Rosenwald, and excludes 250,000 of Class A Preferred Stock, which are convertible into 333 shares of Common Stock.

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The following table shows information, as of March 17, 2026, concerning the beneficial ownership of our Class A Common Stock:

Name and Address of Beneficial Owner ⁽¹⁾	Class A Common Stock Beneficially Owned	
	Number of Shares and Nature of Beneficial Ownership ⁽²⁾	Percentage of Total Class A Common Stock
City of Hope	845,385	100%

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

(2) Converts into 1,127 shares of common stock.

The following table shows information, as of March 17, 2026, concerning the beneficial ownership of our Class A Preferred Stock:

Name and Address of Beneficial Owner ⁽¹⁾	Class A Preferred Stock Beneficially Owned	
	Number of Shares and Nature of Beneficial Ownership ⁽²⁾	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 Island, FL 33154.

(2) Converts into 333 shares of common stock.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Except as set forth below, since January 1, 2024, 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.

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 9,333 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

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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 by Fortress and Fortress shall not be liable for any of its actions or inactions based upon their advice. Pursuant to the MSA and our Certificate of Incorporation, Fortress and its affiliates, including all members of our Board, 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, 2025 and 2024, we recorded expense of \$0.5 million and \$0.5 million, respectively, related to this agreement.

For the year ended December 31, 2025, the Company issued 127,140 shares of common stock to Fortress, which equaled 2.5% of the sum of the gross proceeds of \$0.6 million from the sale of shares of common stock under Mustang's At-the-Market Offering, \$8.0 million gross proceeds from the February 2025 Public Offering, and \$7.1 million from the July 2025 Series C-2 warrant exercises. The Company recorded an expense of approximately \$0.4 million in general and administrative expenses related to these shares for the year ended December 31, 2025.

For the year ended December 31, 2024, the Company issued 23,450 shares of common stock to Fortress, which equaled 2.5% of the sum of the gross proceeds of \$2.6 million from the sale of shares of common stock under Mustang's At-the-Market Offering, \$4.0 million gross proceeds from the May 2024 Public Offering, \$2.5 million from the June 2024 PIPE, and \$4.0 million from the October 2024 warrant exercise. The Company recorded an expense of approximately \$0.3 million in general and administrative expenses related to these shares for the year ended December 31, 2024.

Payables and Accrued Expenses Related Party

In the normal course of business, Fortress pays certain expenses on behalf of the Company. Such expenses are recorded as payables and accrued expenses - related party.

Director Compensation

Dr. Rosenwald and David 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. However, no restricted stock awards were granted in 2025 or 2024. 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, 2025, we recognized \$50,000 and \$50,000 for Dr. Rosenwald and Mr. Jin, respectively, in expense related to the director compensation. For the year ended December 31, 2024, we recognized \$50,000 and \$12,500 for Dr. Rosenwald and Mr. Jin, respectively, in expense in our Statements of Operations related to the director compensation. No restricted stock awards were granted in 2025 and 2024.

Mr. Weiss - Advisory Agreement with Caribe BioAdvisors, LLC

The Board 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, 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, 2025, we recognized \$60,000 in expense related to the Advisory Agreement. For the year ended December 31, 2024, we recognized \$60,000 in expense in our Statements of Operations related to the Advisory Agreement. No restricted stock awards were granted in 2025 and 2024.

Item 14. Principal Accounting Fees and Services

Audit Fees, Audit-Related Fees, Non-Audit Fees, Tax Fees and Other Fees

Audit Fees

For the year ended December 31, 2025, KPMG LLP billed us an aggregate of approximately \$413,000 in fees and professional services rendered in connection with the audit of our annual financial statements included in our Annual Reports on Form 10-K for the 2025 fiscal year, the review of our financial statements included in our Quarterly Reports on Form 10-Q during that fiscal year, and overages incurred for final billings for the 2024 audit.

For the year ended December 31, 2024, KPMG LLP billed us an aggregate of approximately \$412,000 in fees and professional services rendered in connection with the audit of our annual financial statements included in our Annual Reports on Form 10-K for the 2024 fiscal year and the review of our financial statements included in our Quarterly Reports on Form 10-Q during that fiscal year.

Audit-Related Fees

For the year ended December 31, 2025, and 2024, KPMG LLP billed us an aggregate of approximately \$293,000 and \$255,000, respectively, in fees for audit-related services rendered in connection with securities offerings and registration statements, in addition to the fees described above under the heading “Audit Fees.”

Tax Fees

During the fiscal years ended December 31, 2025 and 2024 we were not billed by KPMG LLP for fees for professional services rendered for tax compliance, tax advice, and tax planning services.

All Other Fees

During the fiscal years ended December 31, 2025 and 2024, we were not billed by KPMG LLP for any fees for services, other than those described above, rendered to us for each of those fiscal years.

Pre-Approval of Services

Our Audit Committee has established a policy setting forth the procedures under which services provided by our independent registered public accounting firm will be pre-approved by our Audit Committee. The potential services that might be provided by our independent registered public accounting firm fall into two categories:

- Services that are permitted, including the audit of our annual financial statements, the review of our quarterly financial statements, related attestations, benefit plan audits and similar audit reports, financial and other due diligence on acquisitions, and federal, state, and non-US tax services; and
- Services that may be permitted, subject to individual pre-approval, including compliance and internal-control reviews, indirect tax services such as transfer pricing and customs and duties, and forensic auditing.

Services that our independent registered public accounting firm may not legally provide include such services as bookkeeping, certain human resources services, internal audit outsourcing, and investment or investment banking advice.

All proposed engagements of our independent registered public accounting firm, whether for audit services or permissible non-audit services, are pre-approved by our Audit Committee. We jointly prepare a schedule with our independent registered public accounting firm that outlines services which we reasonably expect we will need from our independent registered public accounting firm and categorize them according to the classifications described above. Each service identified is reviewed and approved or rejected by our Audit Committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements.

The following financial statements are filed as part of this Form 10-K:

Report of Independent Registered Public Accounting Firm (KPMG LLP, New York, NY; PCAOB ID: 185)	F-2
Financial Statements:	
Balance Sheets as of December 31, 2025 and 2024	F-4
Statements of Operations for the Years Ended December 31, 2025 and 2024	F-5
Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2025 and 2024	F-6
Statements of Cash Flows for the Years Ended December 31, 2025 and 2024	F-7
Notes to Financial Statements	F-8 - F-26

(b) Exhibits.

Exhibit No.	Description
1.1	At the Market Offering Agreement, dated May 31, 2024, between the Company, Band 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 June 6, 2024).
2.1	Bill of Sale and Surrender Agreement, dated January 31, 2025, by and between Mustang Bio, Inc. and AbbVie Bioresearch Center Inc. (incorporated by reference to the Exhibit 2.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on February 27, 2025).

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Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Mustang Bio, Inc. (formerly Mustang Therapeutics, Inc.), dated July 26, 2016 (incorporated by reference to the Exhibit 3.1 of the Registrant's Form 10-12G (File No. 000-55668) filed with the SEC on July 28, 2016).
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated June 14, 2018 (incorporated by reference to the Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-38191) filed with the SEC on June 14, 2018).
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated September 30, 2019 (incorporated by reference to the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on September 30, 2019).
3.4	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated December 4, 2020 (incorporated by reference to the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on December 4, 2020).
3.5	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated June 17, 2021 (incorporated by reference to the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 22, 2021).
3.6	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated July 5, 2022 (incorporated by reference to the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on July 5, 2022).
3.7	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated April 3, 2023 (incorporated by reference to the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on April 3, 2023).
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Mustang Bio, Inc., dated January 15, 2025 (incorporated by reference to the Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on January 17, 2025).
3.9	Amended and Restated Bylaws of Mustang Bio, Inc. (incorporated by reference to the Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on April 3, 2023).
4.1	Form of warrant agreement (incorporated by reference to the Exhibit 4.2 of the Registrant's Form 10-12G (File No. 000-55668) filed with the SEC on July 28, 2016).
4.2	Description of Securities of Mustang Bio, Inc. (incorporated by reference to Exhibit 4.2 of the Registrant's Form 10-K (File No. 001-38191) filed with the SEC on March 28, 2025).
4.3	Common Stock Warrant issued by Mustang Bio, Inc. to NSC Biotech Venture Fund I, LLC, dated July 5, 2016 (incorporated by reference to the Exhibit 10.5 of the Registrant's Form 10-12G (File No. 000-55668) filed with the SEC on July 28, 2016).
4.4	Warrant to Purchase Common Stock issued to Runway Growth Finance Corp., dated March 4, 2022 (incorporated by reference to the Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on March 8, 2022).
4.5	Form of Pre-funded Warrant (incorporated by reference to the Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on October 30, 2023).
4.6	Form of Warrant (incorporated by reference to the Exhibit 4.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on October 30, 2023).

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Exhibit No.	Description
4.7	Form of Wainwright Warrant (incorporated by reference to the Exhibit 4.3 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on October 30, 2023).
4.8	Form of May 2024 Pre-Funded Warrant (incorporated by reference to the Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on May 2, 2024).
4.9	Form of May 2024 Series A-1, A-2, and A-3 Warrant (incorporated by reference to the Exhibit 4.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on May 2, 2024).
4.10	Form of May 2024 Placement Agent Warrant (incorporated by reference to the Exhibit 4.3 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on May 2, 2024).
4.11	Form of June 2024 Pre-Funded Warrant (incorporated by reference to the Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 24, 2024).
4.12	Form of June 2024 Warrant (incorporated by reference to the Exhibit 4.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 24, 2024).
4.13	Form of June 2024 Wainwright Warrant (incorporated by reference to the Exhibit 4.3 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 24, 2024).
4.14	Form of Series B-1 Warrant (incorporated by reference to the Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on October 25, 2024).
4.15	Form of October 2024 Wainwright Warrant (incorporated by reference to the Exhibit 4.3 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on October 25, 2024).
4.16	Form of Pre-Funded Warrant (incorporated by reference to the Exhibit 4.1 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on February 11, 2025).
4.17	Form of Series C-1 and C-2 Warrant (incorporated by reference to the Exhibit 4.2 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on February 11, 2025).
4.18	Form of Placement Agent Warrant (incorporated by reference to the Exhibit 4.3 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on February 11, 2025).
10.1	Second Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Mustang Bio, Inc., dated July 26, 2016 (incorporated by reference to the Exhibit 10.1 of the Registrant's Form 10-12G (File No. 000-55668) filed with the SEC on July 28, 2016).
10.2	Management Services Agreement between Fortress Biotech, Inc. and Mustang Bio, Inc., dated March 13, 2015 (incorporated by reference to the Exhibit 10.2 of the Registrant's Form 10-12G (File No. 000-55668) filed with the SEC on July 28, 2016).
10.3	Sponsored Research Agreement by and between Mustang Bio, Inc. and City of Hope, dated March 17, 2015 (incorporated by reference to the Exhibit 10.7 of the Registrant's Form 10-12G (File No. 000-55668) filed with the SEC on July 28, 2016).
10.4	Mustang Bio, Inc. Non-Employee Directors Compensation Plan (incorporated by reference to the Exhibit 10.9 of the Registrant's Form 10-12G (File No. 000-55668) filed with the SEC on July 28, 2016). †
10.5	Board Advisory Services Agreement by and between Mustang Bio, Inc. and Caribe BioAdvisors, LLC, dated January 1, 2017 (incorporated by reference to the Exhibit 10.11 of the Registrant's Annual Report on Form 10-K (File No. 000-55668) filed with the SEC on March 31, 2017). †

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Exhibit No.	Description
10.6	Exclusive License Agreement (IV/ICV) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017 (incorporated by reference to the Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q (File No. 000-55668) filed with the SEC on August 14, 2017). #
10.7	Amended and Restated Exclusive License Agreement (IL13Ra2) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017 (incorporated by reference to the Exhibit 10.15 of the Registrant's Annual Report on Form 10-K (File No. 000-55668) filed with the SEC on March 31, 2017). #
10.8	Amended and Restated Exclusive License Agreement (Spacer) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017 (incorporated by reference to the Exhibit 10.16 of the Registrant's Annual Report on Form 10-K (File No. 000-55668) filed with the SEC on March 31, 2017). #
10.9	Employment Agreement between Manuel Litchman and Mustang Bio, Inc., effective as of April 24, 2017 (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 000-55668) filed with the SEC on April 24, 2017). †
10.10	Mustang Bio, Inc. 2016 Incentive Plan, dated May 17, 2016 (incorporated by reference to Exhibit 10.8 to the Registrant's Form 10-12G filed on July 28, 2016). †
10.11	Amendment to Mustang Bio, Inc. 2016 Incentive Plan, filed with the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders on June 14, 2018, filed on April 30, 2018. †
10.12	Second Amendment to the Mustang Bio, Inc. 2016 Equity Incentive Plan, dated June 17, 2021 (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 22, 2021). †
10.13	Third Amendment to Mustang Bio, Inc. 2016 Equity Incentive Plan, dated June 21, 2022 (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 24, 2022). †
10.14	Fourth Amendment to the Mustang Bio, Inc. 2016 Equity Incentive Plan, dated December 22, 2025 (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on December 23, 2025). †
10.15	Form of Option Agreement (incorporated by reference to Exhibit 10.28 of the Registrant's Annual Report on Form 10-K (File No. 001-38191) filed with the SEC on March 11, 2024). †
10.16	Form of Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.29 of the Registrant's Annual Report on Form 10-K (File No. 001-38191) filed with the SEC on March 11, 2024). †
10.17	Form of Director Stock Award Agreement (incorporated by reference to Exhibit 10.30 of the Registrant's Annual Report on Form 10-K (File No. 001-38191) filed with the SEC on March 11, 2024). †
10.18	Mustang Bio, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to the Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-38191) filed with the SEC on August 9, 2019). †
10.19	Amendment to the Mustang Bio, Inc. 2019 Employee Stock Purchase Plan, dated June 17, 2021 (incorporated by reference to the Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 22, 2021). †
10.20	Amendment No. 2 to the Mustang Bio, Inc. 2019 Employee Stock Purchase Plan, dated June 21, 2023 (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 21, 2023). †

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Exhibit No.	Description
10.21	Amendment No. 3 to the Mustang Bio, Inc. 2019 Employee Stock Purchase Plan, dated December 22, 2025 (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on December 23, 2025), †
10.22	Form of Securities Purchase Agreement, dated October 26, 2023, by and between the Company and the purchaser party thereto (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on October 30, 2023).
10.23	Form of Securities Purchase Agreement, dated April 29, 2024, by and between the Company and the purchaser party thereto (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on May 2, 2024).
10.24	Warrant Agreement Amendment, dated April 29, 2024, by and between the Company and the holder thereto (incorporated by reference to the Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on May 2, 2024).
10.25	Form of Securities Purchase Agreement, dated June 19, 2024, by and between the Company and the purchaser party thereto (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on June 24, 2024).
10.26	Form of Securities Purchase Agreement, dated February 5, 2025 (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on February 11, 2025).
10.27	Asset Purchase Agreement, dated June 27, 2024, by and between the Company and uBriGene (Boston) Biosciences, Inc. (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 July 3, 2024).
10.28	Form of Investor Inducement Agreement (incorporated by reference to the Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on October 25, 2024).
10.29	Form of Indemnification Agreement (incorporated by reference to the Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-38191) filed with the SEC on October 25, 2024).
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 of the Registrant's Form 10-K (File No. 001-38191) filed with the SEC on March 28, 2025).
23.1	Consent of Independent Registered Public Accounting Firm, KPMG, LLP, Boston, Massachusetts. **
31.1	Certification of Principal Executive and Financial Officer, pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. **
32.1	Certification of Principal Executive and Financial Officer, pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. ***
97	Compensation Clawback Policy (incorporated by reference to Exhibit 97 of the Registrant's Annual Report on Form 10-K (File No. 001-38191) filed with the SEC on March 11, 2024).
101	The following financial information from Mustang Bio, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2025, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statement of Stockholders' Equity, (iv) the Statements of Cash Flows, and (v) Notes to the Financial Statements (filed herewith).
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in exhibit 101)

Confidential treatment has been requested with respect to omitted portions of this exhibit.

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† Indicates management contract or compensatory plan or arrangement.

** Filed herewith.

*** Furnished herewith.

Item 16. Form 10-K Summary.

None.

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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, 2025 and 2024, 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, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

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

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

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

Boston, Massachusetts
March 19, 2026

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

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 17,266	\$ 6,839
Other receivables	217	402
Prepaid expenses and other current assets	110	200
Property, plant and equipment, held for sale	—	1,165
Total current assets	<u>17,593</u>	<u>8,606</u>
Property, plant and equipment, net	—	371
Other assets	—	250
Operating lease right-of-use asset, net	—	81
Total Assets	<u>\$ 17,593</u>	<u>\$ 9,308</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,411	\$ 9,486
Payables and accrued expenses - related party	2,503	2,667
Operating lease liabilities - short-term	—	456
Total current liabilities	<u>7,914</u>	<u>12,609</u>
Deferred income	150	150
Operating lease liabilities - long-term	—	422
Total Liabilities	<u>8,064</u>	<u>13,181</u>
Commitments and Contingencies (Note 7)		
Stockholders' Equity (Deficit)		
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, 2025 and December 31, 2024, respectively	—	—
Common stock (\$0.0001 par value), 200,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively		
Class A common shares, 845,385 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	—	—
Common shares, 6,453,701, and 985,972 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	1	5
Common stock issuable, 278,385 and 69,046 shares as of December 31, 2025 and December 31, 2024, respectively	273	611
Additional paid-in capital	407,899	392,234
Accumulated deficit	(398,644)	(396,723)
Total Stockholders' Equity (Deficit)	<u>9,529</u>	<u>(3,873)</u>
Total Liabilities and Stockholders' Equity (Deficit)	<u>\$ 17,593</u>	<u>\$ 9,308</u>

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,	
	2025	2024
Operating expenses:		
Research and development	\$ (1,516)	\$ 8,418
Asset impairment	—	3,692
General and administrative	3,948	4,135
Total operating expenses	<u>2,432</u>	<u>16,245</u>
Loss from operations	<u>(2,432)</u>	<u>(16,245)</u>
Other income		
Other income	—	314
Interest income, net	511	179
Total other income	<u>511</u>	<u>493</u>
Net Loss	<u>\$ (1,921)</u>	<u>\$ (15,752)</u>
Net loss per Class A common and common shares outstanding, basic and diluted	<u>\$ (0.39)</u>	<u>\$ (38.57)</u>
Weighted average number of Class A common and common shares outstanding, basic and diluted	<u>4,908,164</u>	<u>609,696</u>

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, 2023	250,000	\$ —	845,385	\$ —	166,974	\$ 1	\$ 591	\$ 380,502	\$ (380,971)	\$ 123
Common stock issuable - Annual Stock Dividend to Fortress	—	—	—	—	—	—	611	—	—	611
Issuance of common shares - Annual Stock Dividend to Fortress	—	—	—	—	18,564	—	(477)	477	—	—
Issuance of common shares, equity fee on At-the-Market Offering	—	—	—	—	13,266	—	(114)	443	—	329
Issuance of common shares, net of offering costs - Equity Offerings	—	—	—	—	83,700	—	—	5,160	—	5,160
Issuance of common shares, net of offering costs - At-the-Market Offering	—	—	—	—	140,402	1	—	2,534	—	2,535
Issuance of common shares under ESPP	—	—	—	—	938	—	—	48	—	48
Stock-based compensation expenses	—	—	—	—	119	—	—	(450)	—	(450)
Abyeance Shares released ⁽¹⁾	—	—	—	—	69,672	—	—	—	—	—
Exercise of warrants ⁽¹⁾	—	—	—	—	491,816	3	—	3,520	—	3,523
Reverse Split (1-for-50) adjustment	—	—	—	—	521	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(15,752)	(15,752)
Balances at December 31, 2024	250,000	\$ —	845,385	\$ —	985,972	\$ 5	\$ 611	\$ 392,234	\$ (396,723)	\$ (3,873)
Common stock issuable - Annual Stock Dividend to Fortress	—	—	—	—	—	—	273	—	—	273
Issuance of common shares - Annual Stock Dividend to Fortress	—	—	—	—	69,046	—	(611)	611	—	—
Issuance of common shares, equity fee on At-the-Market and equity offerings	—	—	—	—	127,140	—	—	395	—	395
Issuance of common shares, net of offering costs - Equity Offerings	—	—	—	—	495,000	—	—	6,782	—	6,782
Issuance of common shares, net of offering costs - At-the-Market Offering	—	—	—	—	54,440	—	—	599	—	599
Issuance of common shares under ESPP	—	—	—	—	200	—	—	—	—	—
Stock-based compensation expenses	—	—	—	—	68	—	—	129	—	129
Abyeance Shares released ⁽¹⁾	—	—	—	—	185,880	—	—	—	—	—
Exercise of warrants	—	—	—	—	4,536,162	1	—	7,144	—	7,145
Reverse Split (1-for-50) adjustment	—	—	—	—	(207)	(5)	—	5	—	—
Net loss	—	—	—	—	—	—	—	—	(1,921)	(1,921)
Balances at December 31, 2025	250,000	\$ —	845,385	\$ —	6,453,701	\$ 1	\$ 273	\$ 407,899	\$ (398,644)	\$ 9,529

(1) In connection with the induced warrant exercise in October 2024, a certain warrant holder was induced to exercise for cash 337,552 shares of common stock related to the Series A-3 warrants at the exercise price of \$11.85 per share. Of the 337,552 shares on the exercise date, 255,552 were held in abeyance and not considered outstanding. The balance of the shares held in abeyance will be held in abeyance until notice from the shareholder that the balance, or portion thereof, may be issued in compliance with a beneficial ownership limitation provision in the warrants. As of December 31, 2025, all shares held in abeyance have been issued.

See accompanying notes to financial statements.

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

	For the year ended December 31,	
	2025	2024
Cash Flows from Operating Activities:		
Net loss	\$ (1,921)	\$ (15,752)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common shares - equity fee on equity offerings to Fortress Biotech	395	329
Common shares issuable - Annual Stock Dividend to Fortress Biotech	273	611
Research and development - licenses acquired	—	250
Stock-based compensation expenses	129	(450)
Depreciation expense	34	671
Amortization of operating lease right-of-use assets	7	152
Settlement of payables	(2,104)	(2,383)
Loss on disposal of property and equipment	—	29
Asset impairment	—	3,692
Gain on lease termination	(394)	(314)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	90	586
Other receivables	435	494
Accounts payable and accrued expenses	(1,971)	(591)
Payable and accrued expenses - related party	(164)	1,833
Deferred income	—	(120)
Lease liabilities	(73)	(447)
Net cash used in operating activities	<u>(5,264)</u>	<u>(11,410)</u>
Cash Flows from Investing Activities:		
Proceeds from the sale of property and equipment	1,165	—
Net cash from investing activities	<u>1,165</u>	<u>—</u>
Cash Flows from Financing Activities:		
Proceeds from issuance of common shares, net of offering costs - equity offering	6,782	5,159
Proceeds from issuance of common shares, net of offering costs - At-the-Market offering	599	2,535
Proceeds from warrant exercises	7,145	3,523
Proceeds from issuance of common shares under ESPP	—	48
Net cash provided by financing activities	<u>14,526</u>	<u>11,265</u>
Net change in cash and cash equivalents	10,427	(145)
Cash and cash equivalents, beginning of the period	6,839	6,984
Cash and cash equivalents, end of the period	\$ <u>17,266</u>	\$ <u>6,839</u>
Supplemental disclosure of noncash activities:		
Issuance of common shares - Founders Agreement and equity fee to Fortress	\$ 611	\$ 591
Supplemental disclosure of noncash activities related to the uBriGene Repurchase Transaction (see Note 4):		
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)

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 into potential cures for difficult-to-treat cancers and autoimmune 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 January 15, 2025, the Company filed an amendment (the “Reverse Split Amendment”) to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the 1-for-50 reverse stock split of the Company’s shares of common stock (“Reverse Stock Split”). As a result of the Reverse Stock Split, every 50 shares of common stock outstanding immediately prior to effectiveness of the Reverse Stock Split were combined and converted into one share of common stock without any change in the par value per share. The Reverse Stock Split became effective on January 15, 2025, and the common stock was quoted on the Nasdaq Stock Market on a post-split basis at the open of business on January 16, 2025. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would have otherwise been entitled to a fraction of one share of common stock as a result of the Reverse Stock Split instead received a proportional cash payment.

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.

Liquidity and Capital Resources

The Company has incurred substantial operating losses and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. To date, the Company has funded its operations primarily with the proceeds from equity securities. As of December 31, 2025, the Company had an accumulated deficit of \$398.6 million and cash and cash equivalents of \$17.3 million.

The Company has previously disclosed in its financial statements for the year ended December 31, 2024, and its most recent quarterly report on Form 10-Q for the period ended September 30, 2025, that substantial doubt existed regarding its ability to continue as a going concern. Although it has a history of negative cash flows from operations and operating losses, the Company has raised approximately \$14.5 million in net proceeds from the February 2025 Equity Offering, the ATM Agreement and the July 2025 warrant exercises (see Note 8) during the year ended December 31, 2025. In addition to these net proceeds, the Company has been actively negotiating settlements of aged payables and has recognized approximately \$2.1 million in savings during the year ended December 31, 2025, and it has significantly reduced its operating costs.

The Company expects to continue generating operating losses and negative operating cash flows as it develops its products through to potential approval, however, based on the improvement in its cash position for the year ended December 31, 2025, the Company believes it has sufficient cash and cash equivalents to fund its operations for at least twelve months from the date of this annual report on Form 10-K. Therefore, the Company has concluded that substantial doubt about its ability to continue as a going concern no longer exists.

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.

Segment Reporting

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

The CODM assesses performance for the research and development segment and decides how to allocate resources based on net loss, which is reported on the Statements of Operations. The CODM uses net loss to evaluate costs to develop its pipeline. The accounting policies of the segment are the same as those described in this Note 2.

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, 2025 and 2024, 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 Insured Cash Sweep ("ICS") accounts to maximize FDIC insurance coverage across its holdings. As of December 31, 2025, 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.

Property, plant and equipment, net

Property, plant and equipment, net, consisting 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, plant and equipment, held for sale

Property, plant and equipment, 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." In February 2025, the Company

completed the sale of the lab and cell processing equipment, furniture and fixtures and computer equipment that were recorded as assets held for sale as of December 31, 2024.

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.

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. Additionally, consideration received or due from research and development vendors, inclusive of credits on existing invoices, is recorded as a reduction of research and development expenses in the period that the related amounts are probable and reasonably estimable.

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 expenses in the Company's Statements of Operations.

Annual Stock Dividend to Fortress

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 3). The Company considers the Annual Stock Dividend as contingent consideration for the license contributed to Mustang by Fortress. Since the ultimate amount of the Annual Stock Dividend is highly uncertain and cannot be reasonable estimable, in accordance with ASC 450-20, *Loss Contingencies*, the Company records the Annual Stock Dividend in Research and development expense in the Company's Statements of Operations, when the shares are issued.

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

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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. As of December 31, 2025, the Company is no longer party to any operating or financing leases.

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. 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

Basic and diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding, including prefunded warrants and shares held in abeyance, during the period, without consideration of potential dilutive securities. For periods in which the Company generated a net loss, the Company does not include potential shares of common stock in diluted net loss per share when the impact of these items is anti-dilutive. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potentially dilutive securities would be anti-dilutive.

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

	For the year ended December 31.	
	2025	2024
Warrants	4,678,646	1,576,919
Options	1,521	1,521
Class A preferred shares ⁽¹⁾	333	333
Unvested restricted stock awards	720	1,195
Unvested restricted stock units	96	226
Total	4,681,316	1,580,194

(1) Class A Preferred Shares are reflected on an as-if converted basis.

The Company considers Class A common stock and Class A preferred stock to be additional classes of common stock for the purpose of calculating net loss per share, as they do not have preferential rights when compared to the Company's common stock, and therefore losses are allocated to these additional classes using the two-class method. The two-class method is an earnings allocation formula that treats participating securities as having rights that would otherwise have been available to common stockholders. At December 31, 2025, the Class A common stock and Class A preferred stock have rights to convert to a total of 1,461 common shares.

In connection with the exercise of certain existing warrants in October 2024 (see Note 8), the Company recorded a deemed dividend of approximately \$7.8 million for the issuance of new warrants. For the year ended December 31, 2024, net loss attributable to common stockholders consisted of net loss, as adjusted for deemed dividends.

Comprehensive Loss

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

Recent Accounting Pronouncements

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. The Company adopted the accounting standard on its annual report on Form 10-K for the year ended December 31, 2025, and determined that the guidance does not have a material impact on its financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Topic 220-40)*. The amendments in this update require new disclosures to disaggregate prescribed natural expenses underlying any income statement caption. ASU 2024-03 is effective for annual periods in fiscal years beginning after December 15, 2026, and interim periods thereafter. Early adoption is permitted. ASU 2024-03 applies on a prospective basis for periods beginning after the effective date. However, retrospective application to any or all prior periods presented is permitted. The Company is currently assessing the impact ASU 2024-03 will have on the financial statements and disclosures.

Note 3 - 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 9,333 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 278,385 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, 2026. The value of these shares is shown in the Statement of Stockholders’ Equity at December 31, 2025, as Common stock issuable – Annual Stock Dividend. The Company recorded an expense of approximately \$0.3 million in research and development expense related to these issuable shares during the year ended December 31, 2025.

Pursuant to the Amended and Restated Articles of Incorporation, the Company issued 69,046 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, 2025. The value of these shares is shown in the Statement of Stockholders’ Equity at December 31, 2024, as Common stock issuable – Annual Stock Dividend. The Company recorded an expense of approximately \$0.6 million in research and development expense acquired related to these issuable shares during the year ended December 31, 2024.

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, with the number of shares issuable based on the share price of the equity round or, in the instance of debt financing, the closing price of the Company’s common shares on the day prior to the closing; 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%). 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.

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For the year ended December 31, 2025, the Company issued 127,140 shares of common stock to Fortress, which equaled 2.5% of the sum of the gross proceeds of \$0.6 million from the sale of shares of common stock under Mustang's At-the-Market Offering, \$8.0 million gross proceeds from the February 2025 Equity Offering, and \$7.1 million from the July 2025 Series C-2 warrant exercises. The Company recorded an expense of approximately \$0.4 million in general and administrative expenses related to these shares for the year ended December 31, 2025.

For the year ended December 31, 2024, the Company issued 23,450 shares of common stock to Fortress, which equaled 2.5% of the sum of the gross proceeds of \$2.6 million from the sale of shares of common stock under Mustang's At-the-Market Offering, \$4.0 million gross proceeds from the May 2024 Public Offering, \$2.5 million from the June 2024 PIPE, and \$4.0 million from the October 2024 warrant exercise. The Company recorded an expense of approximately \$0.3 million in general and administrative expenses related to these shares for the year ended December 31, 2024.

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, 2025 and 2024, the Company recorded expense of \$0.5 million and \$0.5 million, respectively, related to this agreement.

Payables and Accrued Expenses Related Party

In the normal course of business, Fortress pays certain expenses on behalf of the Company. Such expenses are recorded as payables and accrued expenses - related party.

Director Compensation

Dr. Rosenwald and David Jin

Pursuant to the terms of the Director 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 on such date.

For the year ended December 31, 2025, the Company recognized \$50,000 and \$50,000 for Dr. Rosenwald and Mr. Jin, respectively, in expense in its Statements of Operations related to the director compensation. For the year ended December 31, 2024, the Company recognized \$50,000 and \$12,500 for Dr. Rosenwald and Mr. Jin, respectively, in expense in its Statements of Operations related to the director compensation. No restricted stock awards were granted in 2025 and 2024.

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, 2025, the Company recognized \$60,000 in expense in its Statements of Operations related to the advisory agreement. For the year ended December 31, 2024, the Company recognized \$60,000 in expense in its Statements of Operations related to the advisory agreement. No restricted stock awards were granted in 2025 and 2024.

Note 4 – Asset Purchase Agreements

In May 2023, the Company agreed to sell its Worcester, Massachusetts cell-processing facility assets to uBriGene (Boston) Biosciences, Inc. (“uBriGene”) under an Asset Purchase Agreement, as later amended. The sale closed on July 28, 2023, for \$6.0 million in cash, and the Company recorded a gain of \$1.4 million in connection with the equipment and facility assets transferred (excluding the facility lease) and recorded \$0.3 million of the base consideration as deferred income that would have been recognized upon transfer of the facility lease. 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, the Company, together with uBriGene and CFIUS, entered into a National Security Agreement (“NSA”) on May 13, 2024, requiring the Company and uBriGene to terminate of all related agreements and abandon the original transaction. The NSA also obligated uBriGene to sell or otherwise dispose of the equipment assets purchased within 180 days after the execution of the NSA.

In June 2024, the Company entered into a new Asset Purchase Agreement with uBriGene to repurchase the previously transferred equipment assets and supplies for total consideration of approximately \$4.7 million. The Company agreed to pay uBriGene a total purchase price of \$1.4 million consisting of (i) an upfront payment of \$0.1 million due and (ii) \$1.3 million due twelve (12) months after the closing date (the “Deferred Amount”). In the event that on the date the Deferred Amount is payable, the Company has net assets below \$20 million, the Company may, upon written notice to uBriGene, elect to delay its payment obligation by an additional six (6) months, and the Deferred Amount will accrue interest at a rate of 5% per annum beginning on that date twelve months after closing and until the Deferred Amount is paid in full. As of December 31, 2025, the Company’s net assets were below \$20.0 million and the Deferred Amount of approximately \$1.3 million, including approximately \$33,000 of accrued interest, continued to be deferred and remained recorded in Accrued Other Expenses (see Note 6).

The \$4.7 million purchase consideration was allocated to the repurchased equipment and supplies based on a relative fair value basis. The Company used a third-party to perform a valuation of the repurchase equipment, which resulted in fair value less costs to sell of approximately \$2.2 million. The remaining \$2.5 million was allocated to the supplies repurchased, the Company determined that there was no alternative future use, and therefore, the \$2.5 million was recorded as research and development expense at closing. The repurchased equipment was classified as held for sale at the acquisition date. In February 2025, the Company completed the sale of these assets to an unrelated third party.

Note 5 – Property, Plant and Equipment, Net and Held for Sale, and Asset Impairment

In June 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

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impairment loss was allocated to the leasehold improvements, with the remaining \$0.4 million allocated to the right-of-use asset.

In February 2025, the Company terminated the lease of its Plantation Street Facility. The remaining lease liability of approximately \$0.8 million was reversed, and the remaining leasehold improvements of approximately \$0.3 million and right of use assets of approximately \$0.1 million were written off, resulting in a net gain of \$0.4 million recorded in research and development expense in the Statements of Operations.

In conjunction with the termination of the lease, the Company also completed the sale of the remaining equipment for approximately \$1.2 million, which had been classified as held for sale on the Balance Sheet at December 31, 2024.

Note 6 - Accounts Payable and Accrued Expenses

At December 31, 2025 and 2024, accounts payable and accrued expenses consisted of the following:

<i>(\$ in thousands)</i>	December 31,	
	2025	2024
Accounts payable	\$ 3,510	\$ 7,464
Accrued research and development	250	330
Accrued compensation	24	93
Other ⁽¹⁾	1,627	1,599
Total accounts payable and accrued expenses	<u>\$ 5,411</u>	<u>\$ 9,486</u>

⁽¹⁾ Other includes approximately \$1.3 million of accrued consideration for the uBriGene Asset Purchase Agreement, see Note 4.

Note 7 - Commitments and Contingencies

Leases

On February 7, 2025, the Company entered into the First Amendment to the Lease Agreement with WCS – 377 Plantation Street, Inc. (the “Landlord”), pursuant to which the Company’s lease of its Plantation Street Facility was terminated. Following the termination of the lease, the Company is no longer party to any leases for office space or equipment. Upon termination of the lease, the Company moved its headquarters to 95 Sawyer Road, Suite 110, Waltham, MA, which is office space leased by Fortress. Fortress allocates a small portion of its rent and office related costs to the Company on a monthly basis which is recorded in general and administrative expenses in the Statements of Operations.

Upon termination of the lease, the Company wrote off the remaining right of use assets, operating lease liabilities, and associated leasehold improvements and recorded a net gain of approximately \$0.4 million in research and development expenses in the Statements of Operations. As of December 31, 2025, the Company had no operating lease liabilities or right of use assets. At December 31, 2024, the Company had operating lease liabilities of \$0.9 million and right of use assets of \$0.1 million, which were included in the Balance Sheet.

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The following summarizes quantitative information about the Company's operating leases, which were terminated in February 2025, and the nominal rent allocation from Fortress:

(\$ in thousands)	For the Year Ended	
	December 31, 2025	December 31, 2024
Lease cost		
Operating lease cost	\$ 20	\$ 145
Variable lease cost	175	324
Total	\$ 195	\$ 469

(\$ in thousands)	For the Year Ended	
	December 31, 2025	December 31, 2024
Operating cash outflows from operating leases	\$ 86	\$ 534
Gain on lease termination	\$ 394	\$ 314
Weighted-average remaining lease term – operating leases	—	1.8
Weighted-average discount rate – operating leases	9.0 %	9.0 %

Note 8 - 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 2,666 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. In March 2025, the right expired, and the holders of Class A Common Stock had not appointed such director.

At-the-Market Offering of Common Stock

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 year ended December 31, 2025, the Company issued approximately 54,000 shares of common stock at an average price of \$11.55 per share for gross proceeds of \$0.6 million under the Mustang ATM Agreement. In connection

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with these sales, the Company paid aggregate fees of approximately \$27,000 for net proceeds of approximately \$0.6 million.

During the year ended December 31, 2024, the Company issued approximately 140,000 shares of common stock at an average price of \$18.78 per share for gross proceeds of \$2.6 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 \$2.5 million.

Pursuant to the Founders Agreement, the Company issued 1,361 shares of common stock to Fortress at a weighted average price of \$11.55 per share for the year ended December 31, 2025. For the year ended December 31, 2024, the Company issued 3,509 shares of common stock to Fortress at a weighted average price of \$18.78 per share for the year ended December 31, 2024.

February 2025 Equity Offering

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

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

In July 2025, the remaining approximately 0.5 million of the Pre-Funded Warrants and approximately 2.4 million of the Series C-2 Warrants were exercised. In connection with these exercises, the Company received approximately \$7.1 million in proceeds and issued approximately 2.9 million shares of its common stock. As of December 31, 2025, all of the Series C-1 Warrants and 284,452 of the Series C-2 Warrants remain outstanding.

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

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

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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) 23,200 shares of common stock, (ii) pre-funded warrants (the “May 2024 Pre-Funded Warrants”) to purchase up to an aggregate of 314,352 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 337,552 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 337,552 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 337,552 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 \$11.85, and the public offering price for each May 2024 Pre-Funded Warrant and accompanying Warrants was \$11.845. The May 2024 Pre-Funded Warrants have an exercise price of \$0.005 per share, were exercisable immediately and will expire when exercised in full. Each Warrant has an exercise price of \$11.85 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 July 30, 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 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 51,764 shares of common stock that were previously issued in October 2023 to the Investor, with an exercise price of \$79.00 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 \$11.85 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) 60,500 shares of common stock, at a price per Share of \$20.50 and (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 62,100 shares of our common stock, at a price per Pre-Funded Warrant equal to \$20.495, the price per share of common stock, less \$0.005.

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 \$0.005 per share, became exercisable upon issuance and remain exercisable until exercised in full.

The net proceeds from the June 2024 Offering, after deducting the fees and expenses of the Placement Agent and other offering expenses payable by us, but excluding the net proceeds, if any, from the exercise of the Warrants, was approximately \$2.1 million. The June 2024 Offering closed on June 21, 2024.

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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 122,600 shares of common stock, at an offering price of \$20.50 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 \$20.50 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).

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 7,355 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 \$25.625 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.

Induced Warrant Exercise

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 337,552 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 \$11.85 per share in exchange for our agreement to issue in a private placement new Series B Common Stock purchase warrants to purchase up to (i) 337,552 shares of common stock (the “New Series B-1 Warrant Shares”) and (ii) 337,552 shares of common stock (the “New Series B-2 Warrant Shares” and collectively, the “New Warrants”). Each Warrant has an exercise price of \$13.50 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”), which was obtained on February 11, 2025. 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 of approximately \$0.4 million.

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 “Wainwright Warrants”) to purchase up to 20,251 shares of Common Stock (the “Wainwright Warrant Shares”). The Wainwright Warrants have the same terms as the New Series B-1 Warrants, except that the Wainwright Warrants have an exercise price equal to \$14.815 per share.

The issuance of the New Warrants was accounted for as an equity issuance cost associated with the exercise of the Existing Warrants, which had no net impact on equity as the New Warrants conveyed were determined to be equity classified.

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Registration Statements

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 December 31, 2025, approximately \$34.2 million of the 2024 S-3 remains available for sales of securities.

As of the filing of this Form 10-K, 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.

Stock Issuances to Fortress

During the year, the Company issues shares of common stock to Fortress in connection with the Founders Agreement, see Note 3.

Stock Warrants

A summary of warrant activities for the years ended December 31, 2025 and 2024, is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2023	89,618	\$ 67.16	5.34
Granted	2,234,669	10.93	2.10
Exercised	(747,368)	5.35	—
Outstanding as of December 31, 2024	1,576,919	\$ 14.56	3.14
Granted	7,637,889	2.17	1.99
Exercised	(4,536,162)	1.57	—
Outstanding as of December 31, 2025	4,678,646	\$ 6.93	3.37

Upon the exercise of warrants, the Company will issue new shares of common stock. In connection with the February 2025 Equity Offering on February 10, 2025, the Company issued Pre-Funded Warrants to purchase up to 2,162,807 shares of common stock and issued two series of warrants to purchase up to 5,315,614 shares of common stock. In connection with this offering, Wainwright received Placement Agent Warrants to purchase up to 159,468 shares of common stock.

During the year ended December 31, 2025, all of the Pre-Funded Warrants were exercised at an exercise price of \$0.0001 per share and 2,373,355 of the Series C-2 Warrants were exercised at an exercise price of \$3.01 per share.

In connection with the May 2024 Offering, the Company issued pre-funded warrants to purchase up to 314,352 shares of common stock and issued three series of warrants (the “Series A-1,” “Series A-2,” and “Series A-3”) to purchase up to 1,012,656 shares of common stock. In connection with these offerings, Wainwright received Placement Agent Warrants to purchase up to 20,251 shares of common stock.

In connection with the June 2024 Registered Direct Offering, the Company issued pre-funded warrants to purchase up to 62,100 shares of common stock, and in the concurrent Private Placement, the Company issued unregistered warrants to purchase up to 122,600 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 7,355 shares of common stock.

In connection with the induced warrant exercise in October 2024, the holder of the Series A-3 warrants from the May 2024 Offering agreed to exercise for cash 337,552 warrants in partial consideration for the Company to issued two series of unregistered warrants (the “New Series B-1” and “New Series B-2”) to purchase up to 675,104 shares of common stock. Upon exercise of the Series A-3 warrants, the Company issued to the holder 82,000 of the 337,552 shares of common stock. Due to beneficial ownership limitation provisions in the inducement letter agreement, the remaining 255,552 shares

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were initially unissued and held in abeyance for the benefit of the holder until notice from the holder that the shares may be issued in compliance with the agreement. As of December 31, 2024, 185,880 shares remained in abeyance. In connection with the issuance of the New Series B-1 and New Series B-2 warrants, approximately \$7.8 million of the aggregate fair value was deemed to be a dividend and recorded to additional paid-in-capital because the Company had an accumulated deficit on the exercise date. The deemed dividend was included in the net loss attributable to Class A common and common stockholders in the calculation of net loss per share in the Statements of Operations (see Note 2). The resale of the underlying shares of common stock were subsequently registered in November 2024 on Form S-3 (File No. 333-283420). In connection with these offerings, Wainwright received Placement Agent Warrants to purchase up to 20,251 shares of common stock.

The key inputs used for the Black-Scholes Model calculation on October 25, 2024, to measure the fair value of the New Warrants, were as follows:

	New Series B-1 Warrants	New Series B-2 Warrants
Stock Price	14.50	14.50
Risk-free interest rate	4.1 %	4.3 %
Expected dividend yield	—	—
Expected term in years	5	1
Expected volatility	122.2 %	213.2 %

Equity Incentive Plan

The Company has in effect the 2016 Incentive Plan (the “Incentive Plan”). The Incentive Plan was adopted in 2016 and enables the grant of stock-based awards to directors, officers, employees and consultants. The plan initially authorized grants with respect to 2,666 shares of 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 4,000 shares, for a total of 6,666 shares. In June 2021, the Company’s stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 4,000 shares, for a total of 10,666 shares. In June 2022, the Company’s stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 4,000 shares, for a total of 14,666 shares. In December 2025, the Company’s stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 2,500,000 shares, for a total of 2,514,666 shares.

As of December 31, 2025, 2,506,958 shares are available for issuance under the Incentive Plan.

Stock Options

The following table summarizes stock option activities for the years ended December 31, 2025 and 2024:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding at December 31, 2024	1,521	\$ 4,297.50	2.31
Outstanding at December 31, 2025	1,521	\$ 4,297.50	1.31
Options vested and exercisable at December 31, 2025	951	\$ 4,297.50	1.31

As of December 31, 2025, 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, 2025 and 2024:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2023	1,285	\$ 577.50
Vested	(90)	2,722.50
Nonvested at December 31, 2024	1,195	\$ 415.95
Vested	(475)	523.50
Nonvested at December 31, 2025	720	\$ 345.00

As of December 31, 2025, the Company had unrecognized stock-based compensation expense related to restricted stock of approximately \$42,000, which is expected to be recognized over a weighted average period of approximately 0.5 years.

Restricted Stock Units

The following table summarizes restricted stock units' activities for the year ended December 31, 2025 and 2024:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2023	1,911	\$ 948.25
Forfeited	(1,320)	911.70
Vested	(365)	1,205.20
Nonvested at December 31, 2024	226	\$ 746.70
Forfeited	(12)	1,321.25
Vested	(118)	1,042.90
Nonvested at December 31, 2025	96	\$ 310.81

As of December 31, 2025, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately \$4,000, which is expected to be recognized over a weighted average period of approximately one year.

The following table summarizes stock-based compensation expense for the years ended December 31, 2025 and 2024 (in thousands).

	For the year ended December 31,	
	2025	2024
General and administrative	\$ 139	\$ 200
Research and development ⁽¹⁾	(10)	(650)
Total stock-based compensation expense	\$ 129	\$ (450)

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. In December 2025, the Company's stockholders approved an amendment to the ESPP to increase the number of shares issuable by 250,000 shares.

As of December 31, 2025, 2,762 shares have been purchased, and 256,571 shares are available for future sale under the Company's ESPP.

Note 9 - 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, 2025 and 2024.

The Company adopted ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, on a prospective basis. As a result, the 2025 rate reconciliation is presented in accordance with the new disclosure requirements, while the 2024 reconciliation continues to be presented under the disclosure requirements in effect for that period.

A reconciliation of income tax computed at the federal statutory rate to the provision for income taxes pursuant to the disclosure requirements of ASU 2023-09 for the year ended December 31, 2025, was as follows:

<i>(\$ in thousands)</i>	<u>For the year ended December 31,</u>	
	<u>2025</u>	
	<u>Amount</u>	<u>Percent</u>
U.S. federal statutory tax rate	\$ (396)	21.0 %
State and local income taxes, net of federal income tax effect ⁽¹⁾	21	(1.1)%
Change in valuation allowance	(130)	6.9 %
Non-deductible items:		
Share-based compensation	70	(3.7)%
Non-deductible compensation	170	(9.0)%
Stock issuance costs	83	(4.4)%
Other adjustments:		
Federal net operating loss	274	(14.5)%
Other true-ups	(65)	3.5 %
Provision for income taxes and effective income tax rate	<u>27</u>	<u>(1.4)%</u>

(1) During the year ended December 31, 2025, state taxes in Massachusetts, New York and New York City comprised greater than 50% of the tax effect in this category.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate for the year ended December 31, 2024, was as follows:

	<u>For the year ended December 31,</u>	
	<u>2024</u>	
Statutory federal income tax rate		21 %
State taxes, net of federal tax benefit		16 %
Non-deductible items		(1)%
Tax credits		1 %
Other		(10)%
Change in valuation allowance		(27)%
Income taxes provision (benefit)		<u>—</u>

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The components of the net deferred tax asset as of December 31, 2025 and 2024 are the following:

<i>(\$ in thousands)</i>	For the year ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryovers	\$ 103,701	\$ 95,131
Stock compensation and other	1,267	1,537
Change in fair value of warrant liabilities	60	59
Amortization of license	8,735	9,672
Lease liability	—	326
Accruals and reserves	135	1,922
Startup costs	4	4
Tax credits	19,046	19,046
174 Capitalization	16,835	24,437
Other	56	—
Total deferred tax assets	<u>149,839</u>	<u>152,134</u>
Less: valuation allowance	<u>(149,839)</u>	<u>(152,104)</u>
Deferred tax assets, net	<u>\$ —</u>	<u>\$ 30</u>
Deferred tax liability:		
Right of use asset	—	(30)
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, 2025 and 2024. A valuation allowance of approximately \$149.8 million and \$152.1 million, respectively, was recorded for the years ended December 31, 2025 and 2024.

As of December 31, 2025, the Company had federal and state net operating loss carryforwards of approximately \$306.9 million and \$654.8 million, respectively. Approximately \$283.3 million and \$0.6 million of the federal and state net operating loss carryforwards, respectively, can be carried forward indefinitely. As of December 31, 2025, the Company had federal and state income tax credits of approximately \$15.0 million and \$5.1 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, 2025. 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.

At December 31, 2025 and December 31, 2024, the Company did not have any significant uncertain tax positions. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company’s statement of operations.

The Company is subject to U.S. federal and various state taxes. Because of net operating losses, all federal tax years since inception remain open for the assessment of income taxes. The expiration of the statute of limitations related to the various state income and franchise tax returns varies by state.

On July 4, 2025, President Donald J. Trump signed the “One Big Beautiful Bill Act” (OBBBA) into law. Key corporate tax provisions include the restoration of 100% bonus depreciation, immediate expensing for domestic research and experimental expenditures, changes to interest limitation rules, and expanded aggregation requirements for compensation

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deductibility limits. In accordance with ASC 740, the Company recognized the effects of the new tax law in the period enacted. As a result, the Company immediately expensed current-year domestic research and experimental expenditures and elected to continue amortizing its existing domestic capitalized research and experimental expenditures over their remaining useful lives. Due to the Company having a full valuation allowance, there were no impacts to the effective tax rate.

Under ASC 2023-09, entities must disclose income taxes paid (net of refunds received), disaggregated between federal and state. This also requires disclosing income taxes paid (net of refunds) by individual jurisdictions that represent more than 5% of total income taxes paid (net of refunds).

Because the company does not have significant payments for the year ended December 31, 2025, no amounts are disclosed.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Mustang Bio, Inc.

By: /s/ Manuel Litchman, M.D.

Name: Manuel Litchman, M.D.

Title: President, Chief Executive Officer and Interim Chief Financial Officer

March 19, 2026

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Manuel Litchman</u> Manuel Litchman, M.D.	President, Chief Executive Officer, Interim Chief Financial Officer and Director (Principal Executive and Financial Officer)	March 19, 2026
<u>/s/ Michael S. Weiss</u> Michael S. Weiss	Chairman of the Board of Directors and Executive Chairman	March 19, 2026
<u>/s/ Adam Chill</u> Adam Chill	Director	March 19, 2026
<u>/s/ Neil Herskowitz</u> Neil Herskowitz	Director	March 19, 2026
<u>/s/ David Jin</u> David Jin	Director	March 19, 2026
<u>/s/ Lindsay A. Rosenwald</u> Lindsay A. Rosenwald, M.D.	Director	March 19, 2026
<u>/s/ Michael Zelefsky</u> Michael Zelefsky, M.D.	Director	March 19, 2026

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-284299, 333-280927, 333-275997 and 333-278006) on Form S-1, registration statements (Nos. 333-283420 and 333-279891) on Form S-3 and in the registration statements (Nos. 333-273549, 333-266176, 333-258310, 333-258311, 333-255007, and 333-221819) on Form S-8 of our report dated March 19, 2026 with respect to the financial statements of Mustang Bio, Inc.

/s/ KPMG LLP
Boston, Massachusetts
March 19, 2026

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

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

- (1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of Mustang Bio, Inc. (the “Registrant”);
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
- (4) I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the Registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the Registrant’s disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in the report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s most recent fiscal quarter (the Registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and
- (5) I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant’s auditors and the audit committee of the Registrant’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant’s internal control over financial reporting.

Dated: March 19, 2026

By: /s/ Manuel Litchman

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

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Mustang Bio, Inc. (the "Company") for the period ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Manuel Litchman, M.D., President, Chief Executive Officer and Interim Chief Financial Officer (Principal Executive and Financial Officer), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

Dated: March 19, 2026

By: /s/ Manuel Litchman

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