

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, 2023

or

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

For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File 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.)

377 Plantation Street  
Worcester, Massachusetts 01605  
(Address including zip code of principal executive offices)

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

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

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

**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: \$38.7 million.

Class of Common Stock	Outstanding Shares as of March 8, 2024
Class A Common Stock, \$0.0001 par value	845,385
Common Stock, \$0.0001 par value	9,544,747

**MUSTANG BIO, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
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## SPECIAL CAUTIONARY NOTICE 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:

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

We have based these forward-looking statements largely on our current expectations, estimates, forecasts, and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. 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.

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## SUMMARY OF RISK FACTORS

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described in 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 (“SEC”).

### Risks Related to our Finances and Capital Requirements

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

### Risks Inherent in Drug Development and Commercialization

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

### 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.

**Risks Relating to the Sale of Our Manufacturing Facility**

- We may be unable to complete the sale of our manufacturing facility as contemplated if the Committee on Foreign Investment in the United States ("CFIUS") determines to implement mitigation measures, including the potential divestment of some or all of the transferred assets by the buyer, which may limit our ability to realize the anticipated cost savings of the sale of the facility and may have a material adverse effect on our financial condition.
- Our receipt of the contingent portion of the consideration for the sale of the manufacturing facility is subject to receipt of the consent of the landlord of the facility to the transfer of such lease to the buyer and our ability to raise additional capital.
- Because the manufacturing facility was not transferred to the buyer within 120 days after Closing (as defined in the transaction documents), the buyer may provide us with notice of its intentions to enter into negotiations for our repurchase of the facility, following which we will be obligated to negotiate the repurchase of the facility from the buyer; there can be no guarantee that this repurchase happens on terms favorable to us, or at all.
- The landlord may object to certain aspects of the transaction, which could result in expensive and time-consuming litigation and could prevent us from realizing the intended benefits of the transaction.
- If the sale of the facility is fully consummated, we will rely on the buyer for the manufacture of our lead product candidates, which may subject us to additional manufacturing risks.
- We may incur substantial expenses related to the transaction and the consummation of the sale of the facility.
- Certain key personnel may depart the Company upon the completion of the sale of the facility, which may adversely affect our ability to realize the anticipated benefits of the transaction; unfortunately, key personnel may also depart our Company in the event that we are unable to complete the transaction.
- Our strategic pivot to our lead product candidate, MB-106, and our disposal of non-core assets, including our facility, may not result in the cost savings we anticipate and could result in total costs and expenses that are greater than expected.

## **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 in cell and gene therapies into potential cures for hematologic cancers, solid tumors and rare genetic diseases. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

Our pipeline is currently focused in three core areas: CAR T therapies for hematologic malignancies, CAR T therapies for solid tumors and gene therapies for rare genetic disorders. For each therapy we have partnered with world class research institutions. For our CAR T therapies we have partnered with the City of Hope National Medical Center (“COH” or “City of Hope”), Fred Hutchinson Cancer Center (“Fred Hutch”), Nationwide Children’s Hospital (“Nationwide”) and the Mayo Foundation for Medical Education and Research (“Mayo Clinic”). For our gene therapies, we have partnered with St. Jude Children’s Research Hospital (“St. Jude”) and with Leiden University Medical Centre (“LUMC”) in the development of first-in-class *ex vivo* lentiviral (“LV”) treatments for X-linked severe combined immunodeficiency (“XSCID”) and RAG1 severe combined immunodeficiency (“RAG1-SCID”), respectively.

#### **CAR T Therapies**

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

We are developing CAR T therapy for hematologic malignancies in partnership with Fred Hutch targeting CD20 (MB-106). In May 2021, we announced that the U.S. Food and Drug Administration (“FDA”) accepted our Investigational New Drug (“IND”) Application for MB-106. As of December 2023, approximately 40 patients have been treated in an ongoing phase 1 clinical trial sponsored by Fred Hutch (ClinicalTrials.gov Identifier: NCT03277729), and approximately 20 patients have been treated in an ongoing phase 1 clinical trial sponsored by us (ClinicalTrials.gov Identifier: NCT05360238). In 2023, we received Safety Review Committee approval to continue dose escalation in all three active arms of the ongoing Mustang-sponsored phase 1 trial. We presented the latest results, demonstrating a favorable safety profile, complete response rate, and durability, from the ongoing Mustang-sponsored phase 1 trial at the 2023 American Society of Hematology (“ASH”) Annual Meeting. As of December 31, 2023, the MB-106 Mustang-sponsored phase 1 trial is pending one patient to complete the final dose level required to advance to phase 2 pivotal studies for treatment of patients with relapsed or refractory indolent B-cell non-Hodgkin lymphoma.

We are also developing CAR T therapy for solid tumors in partnership with COH targeting IL13R $\alpha$ 2 (MB-101). In addition, we have partnered with Nationwide for a herpes simplex virus type 1 (“HSV-1”) oncolytic virus (MB-108) in order to enhance the activity of MB-101 for the treatment of patients with high-grade malignant brain tumors. The Phase 1 clinical trial sponsored by COH for MB-101 (ClinicalTrials.gov Identifier: NCT02208362) has completed the treatment phase and patients continue to be assessed for long-term safety. A Phase 1 clinical trial sponsored by the University of Alabama at Birmingham (“UAB”) for MB-108 (ClinicalTrials.gov Identifier: NCT03657576) began during the third quarter of 2019. In October 2023, we announced that the FDA accepted our IND application for the combination of MB-101 and MB-108 – which is referred to as MB-109 – for the treatment of patients with *IL13R $\alpha$ 2*+relapsed or refractory glioblastoma (“GBM”) and high-grade astrocytoma.

Finally, we are collaborating with the Mayo Clinic to develop a novel technology that may be able to transform the administration of CAR T therapies and potentially be used as an off-the-shelf therapy. We are evaluating plans to file an IND application for a multicenter Phase 1 clinical trial once a lead construct has been identified, subject to allocation of resources.

On May 18, 2023, we announced a series of changes resulting from a review of our portfolio of product candidates to determine the future strategy of our programs and the proper allocation of our resources. Following this review, we determined to discontinue development of our MB-102 (CD123), MB-103 (HER2), MB-104 (CS1) and MB-105 (PSCA) programs (such programs, the “Discontinued Programs”), all of which were CAR T therapies being developed in partnership with City of Hope.

## **Gene Therapies**

In partnership with St. Jude, our XSCID gene therapy programs (MB-117 and MB-217) are being developed under an exclusive license to develop a potentially curative treatment for XSCID, a rare genetic immune system condition in which affected patients do not live beyond infancy without treatment. For these programs, the same lentiviral vector (LVV) will be used to transduce patients' hematopoietic stem cells *ex vivo*. However, since the respective cell processing is different for each cell product, the FDA considers them different products, and we have therefore assigned a different designation to each: MB-117 designates the cell product for newborn patients, and MB-217 designates the cell product for previously transplanted patients.

The LVV used for MB-117 and MB-217 has been modified from a predecessor LVV in order to address concerns regarding detection of an increased percentage of clones in patients' myeloid lineage following treatment with the predecessor products (designated MB-107 and MB-207, respectively) engineered using the predecessor LVV. Although a safety signal has not been observed in over 40 patients treated with the two predecessor products, nevertheless, out of an abundance of caution, we and our academic partners decided to replace the predecessor LVV with the modified LVV. We anticipate that the NIH and St. Jude will initiate phase 1 trials in newborn and previously transplanted patients, respectively, in 2024 using the modified LVV to produce MB-117 and MB-217, respectively.

The predecessor LVV has been utilized in two Phase 1/2 clinical trials involving two different autologous cell products produced via transduction of patients' hematopoietic stem cells. As noted above, these cell products were designated MB-107 and MB-207, and the respective Phase 1/2 clinical trials were: a multicenter trial of the MB-107 product in newly diagnosed infants sponsored by St. Jude (ClinicalTrials.gov Identifier: NCT01512888) and a single-center trial of the MB-207 product in previously transplanted patients sponsored by the National Institutes of Health ("NIH") (ClinicalTrials.gov Identifier: NCT01306019).

In January 2021, we received a safe to proceed "approval" from the FDA for our MB-107 IND application allowing us to initiate a pivotal non-randomized multicenter Phase 2 clinical trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two. In January 2022, the FDA issued a clinical hold, pending additional Chemistry, Manufacturing and Controls ("CMC") data, on our IND application to allow for the initiation of a pivotal non-randomized multicenter Phase 2 clinical trial of MB-207 in previously transplanted XSCID patients.

In 2022, the NIH study was suspended as a result of the study stopping rules triggered by the increased percentage of clones noted above. St. Jude elected to voluntarily place their study on hold in April 2023, and we elected to voluntarily discontinue development of MB-107 and MB-207 in favor of MB-117 and MB-217 prior to treating any patients with either predecessor product. Both St. Jude and NIH intend to initiate their respective studies of MB-117 and MB-217 in 2024 following availability of the modified LVV.

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

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, 2023, we have an accumulated deficit of \$381.0 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 377 Plantation Street, Worcester, Massachusetts 01605. Our telephone number is (781) 652-4500, and our email address is [info@mustangbio.com](mailto:info@mustangbio.com).

Our website address is [www.mustangbio.com](http://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**

### **Therapies for Oncology and Hematologic Malignancies**

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

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

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

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

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

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

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

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

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



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

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

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

In the first quarter of 2024, the Company expects to receive FDA feedback in an End-of-Phase 1 Meeting on its strategy to conduct a non-randomized registrational multicenter trial in relapsed or refractory WM. In the second half of 2024, the Company expects to treat the first patient in that trial, which could enable top-line results in the second half of 2026. In order to facilitate interactions with the FDA throughout this process, we anticipate requesting Regenerative Medicine Advanced Therapy (“RMAT”) designation for indolent lymphoma – which includes WM – from the FDA in the first half of 2024. We are currently evaluating the extent to which we can continue the development of MB-106 in other NHL subtypes, subject to allocation of resources.

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

### ***MB-101 (IL13Ra2 CAR T Cell Program for Glioblastoma)***

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

radiation, and chemotherapy with temozolomide, which, while rarely curative, is shown to extend median overall survival from 4.5 to 15 months. GBM remains difficult to treat due to the inherent resistance of the tumor to conventional therapies.

Immunotherapy approaches targeting brain tumors offer promise over conventional treatments. IL13R $\alpha$ 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 $\alpha$ 2 and reduced binding to IL13R $\alpha$ 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<sub>CM</sub>) or enriched CD62L+ naïve and memory T cells (T<sub>N/MEM</sub>) are isolated and enriched. Our manufacturing process limits *ex vivo* expansion, which is designed to reduce T cell exhaustion and maintain a T<sub>CM</sub> or T<sub>N/MEM</sub> phenotype. Based on experiments with CAR-Ts in mouse xenograft models of GBM, these CAR-modified T<sub>CM</sub> and T<sub>N/MEM</sub> cells have been shown to be more potent and persistent than earlier generations of CAR-T cells.

Our academic partners at COH have recently completed the treatment phase of their Phase 1 study, which was designed to assess the feasibility and safety of using T<sub>CM</sub> or T<sub>N/MEM</sub> enriched IL13R $\alpha$ 2-specific CAR-engineered T cells for clinical study participants with IL13R $\alpha$ 2 recurrent/refractory malignant glioma (ClinicalTrials.gov Identifier: NCT02208362). In this study, COH enrolled and treated 65 patients, with 58 patients receiving 3 cycles of CAR T cells per the study protocol. In March 2024, results from this study were published in *Nature Medicine*. Preliminary data indicated that the CAR-T cells were well tolerated, and no dose-limiting toxicities were observed in any of the study arms nor where there any occurrences of CRS or treatment-related deaths. Of the 58 patients evaluable for disease response, 50% achieved stable disease (SD) or better; 22%, including 8 patients with grade 4 gliomas, achieved SD or better for at least 90 days. Two patients achieved partial response, and one patient achieved complete response on the study. In 2016 COH reported that a patient had achieved a complete response to treatment based on the imaging and clinical features set forth by the Response Assessment in Neuro-Oncology Criteria (“RANO”). This result was published as a case report in the *New England Journal of Medicine* (Brown CE *et al. NEJM*. 2016;375:2561-9). As described in the paper, this patient diagnosed with recurrent multifocal glioblastoma received multiple infusions of IL13R $\alpha$ 2-specific CAR-T cells over 220 days through two intracranial delivery routes – infusions into the resected tumor cavity followed by infusions into the ventricular system. Intracranial infusions of IL13R $\alpha$ 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 $\alpha$ 2.

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

1. MB-101 with or without nivolumab and ipilimumab in treating patients with recurrent or refractory glioblastoma (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04003649) sponsored by COH;
2. MB-101 in treating patients with recurrent or refractory glioblastoma with a substantial component of leptomeningeal disease (currently enrolling patients; ClinicalTrials.gov Identifier: NCT04661384) sponsored by COH;
3. MB101 in combination with the herpes simplex virus type 1 oncolytic virus (MB108) in treating patients with recurrent or refractory glioblastoma or high-grade astrocytoma, as described above. This combination therapy, to be administered in a phase 1 two-center trial under our IND, will be referred to as MB-109.

#### **MB-108 (HSV-1 oncolytic virus C134)**

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

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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 $\alpha$ 2-directed CAR T for the treatment of GBM and high-grade astrocytoma.

The O'Neal Comprehensive Cancer Center at the UAB is the single clinical trial site for the Phase 1 trial of MB-108, and this site has initiated a Phase 1 trial that began enrolling patients in 2019 (ClinicalTrials.gov Identifier: NCT03657576). The primary objective of this study is to determine the safety and tolerability of a single dose of MB-108 administered via a stereotactic intracerebral injection and to determine the maximally tolerated dose ("MTD") of the oncolytic virus. Secondary objectives are to obtain preliminary information about the potential benefit of MB-108 in the treatment of patients with recurrent malignant gliomas, including relevant data on markers of efficacy, including time to tumor progression and patient survival. As of April 2023, 9 patients had been enrolled in this study.

### **In Vivo CAR T Platform Technology.**

We are collaborating with the Mayo Clinic to develop a novel technology that may be able to transform the administration of CAR T therapies and potentially be used as an off-the-shelf therapy. The technology, developed by Larry R. Pease, Ph.D., principal investigator and former director of the Center for Immunology and Immune Therapies at Mayo Clinic, is a new platform to administer CAR T therapy using a two-step approach. First, a peptide is administered to the patient to drive the proliferation of the patient's resident T cells. This is followed by the administration of a viral CAR construct directly into the lymph nodes of the patient. In turn, the viral construct infects the activated T cells and effectively forms CAR T cells *in vivo* in the patient. Successful implementation may lead to an off-the-shelf product with no need to isolate and expand patient T cells *ex vivo* in a cell processing facility.

Preclinical proof-of-concept has been established, and the ongoing development of this technology will take place at Mayo Clinic. We are evaluating plans to file an IND application for a multicenter Phase 1 clinical trial once a lead construct has been identified, subject to allocation of resources.

### **Gene Therapies for Rare Genetic Disorders**

***MB-117 and MB-217 (designation of MB-107 and MB-207, respectively, following replacement of the predecessor LVV with a modified LVV) (Ex vivo Lentiviral Therapy for X-linked Severe Combined Immunodeficiency (XSCID))***

XSCID is a rare genetic immune system condition that occurs almost exclusively in males, in which affected patients do not live beyond infancy without treatment. Mustang Bio's first-in-class *ex vivo* lentiviral gene therapy for XSCID has been administered as two distinct cellular products using the same predecessor lentiviral vector in two phase 1/2 clinical trials: (1) a multicenter trial of MB-107 in newly diagnosed patients being led by St. Jude and including also UCSF Benioff Children's Hospital San Francisco ("UCSF") and Seattle Children's Hospital ("Seattle Children's") (ClinicalTrials.gov Identifier: NCT01512888) and (2) a single center trial of MB-207 at the NIH in patients who have previously undergone hematopoietic stem cell transplantation (ClinicalTrials.gov Identifier: NCT01306019). In 2022, the NIH study was suspended as a result of the study stopping rules triggered by the increased percentage of clones in patients' myeloid lineage, as noted above. St. Jude elected to voluntarily place their study on hold in April 2023, and we elected to voluntarily discontinue development of MB-107 and MB-207 in favor of MB-117 and MB-217 prior to treating any patients with either predecessor product. All patients treated in the St. Jude and NIH clinical trials continue to be followed and remain clinically stable with no significant hematological anomalies, including no observations of insertional mutagenesis and/or malignancies. Both St. Jude and NIH intend to initiate their respective studies of MB-117 and MB-217 in 2024 following availability of the modified LVV.

As part of addressing concerns relating to clonal expansion, the joint team existing of St. Jude, UCSF, Seattle Children's and the NIH decided to suspend use of the primary lentiviral vector. Going forward, this predecessor LV vector will be replaced by a modified LV vector which will be used to produce the MB-117 and MB-217 cell products. St. Jude has informed us that it intends to initiate a new Phase 1 trial in newly diagnosed infants using MB-117, and the NIH has informed us that it intends to initiate a new Phase 1 trial in previously transplanted patients using MB-217, each in 2024.

### **MB-110 (Ex vivo Lentiviral Therapy for RAG1 Severe Combined Immunodeficiency (SCID))**

Under an exclusive license and in partnership with LUMC, MB-110, a first-in-class *ex vivo* treatment for RAG1 SCID, is under development. Severe combined immunodeficiency (“SCID”) due to complete recombinase-activating gene-1 (RAG1) deficiency is a rare, genetic disorder due to null mutations in the RAG1 gene resulting in less than 1% of wild type V(D)J recombination activity. Neonatal patients present with life-threatening, severe, recurrent infections by opportunistic fungal, viral and bacterial micro-organisms, as well as skin rashes, chronic diarrhea, failure to thrive and fever. Immunologic observations include profound T and B cell lymphopenia, low or absent serum immunoglobulins, and normal natural killer cell counts. As is the case with other types of SCID, RAG1-SCID is fatal in infancy unless immune reconstitution is achieved with hematopoietic stem cell transplantation (HSCT).

MB-110, which includes low-dose conditioning prior to reinfusion of the patients’ own gene-modified blood stem cells, is currently being evaluated in a Phase 1/2 multicenter clinical trial in Europe. The ongoing clinical trial has enrolled its first patient, and additional clinical sites are expected to be added in the near future. The RAG1-SCID program has been granted Orphan Drug Designation by the European Medicines Agency.

We also established an ongoing partnership with Frank J. Staal, Ph.D., professor of Molecular Stem Cell Biology and molecular immunologist at LUMC, whose laboratory developed the MB-110 therapy. Dr. Staal will continue the development of additional LV gene therapies in his lab, to which we have certain rights under the agreement.

## **INTELLECTUAL PROPERTY AND PATENTS**

### **General**

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

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

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

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

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

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

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

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

In March 2017, we licensed intellectual property related to antibodies and binding agents that specifically bind to PSCA from the University of California Los Angeles (“UCLA”). In August 2023, we terminated the license agreement with UCLA.

In August 2018, we licensed from St. Jude Children’s Research Hospital XSCID Technology related to an *ex vivo* lentiviral vector gene therapy program to provide a normal copy of the *IL2RG* gene to patients born with XSCID.

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

In August 2019, we licensed from CSL Behring (Calimmune) the Cytegrity™ stable producer cell line developed and used by St. Jude. The Cytegrity™ stable producer cell line was developed in order to be used to produce the viral vector for MB-107 and MB-207. However, the decision to modify the LVV used to transduce the hematopoietic stem cells of XSCID patients and thereby replace MB-107 and MB-207 with MB-117 and MB-217, respectively, rendered the stable producer cell no longer useful. Therefore, on August 14, 2023, we notified Calimmune that we were terminating the Calimmune license, which took effect 60 days following notification.

In September 2020, we entered into an exclusive, worldwide licensing agreement with SIRION Biotech for the rights to SIRION’s LentiBOOST™ technology for the development of MB-207. This license includes right to granted patents and pending applications in the U.S., Europe, Japan, and Israel. In December 2021 this licensing agreement was amended to include CD20-directed CAR Ts in addition to lentiviral stem cell gene therapy for the treatment of XSCID. We eventually expect to use this technology for the development of MB-217.

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In November 2021, we entered into an exclusive, worldwide licensing agreement with Leiden University Medical Centre for a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1 severe combined immunodeficiency (“RAG1-SCID”).

In August 2021, we entered into an exclusive license agreement with Mayo Clinic for a novel technology that may be able to transform the administration of CAR T therapies and potentially allow such therapies to be used as an off-the-shelf therapy.

In addition to the technology we have in-licensed, we also developed our own proprietary intellectual property, both alone and in conjunction with COH. In particular, we filed a U.S. provisional application directed to optimized methods for manufacturing cell-based therapeutics, and we and COH, as co-applicants, filed a U.S. provisional application directed to methods of treating hematological cancers.

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

***Other Intellectual Property Rights***

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

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

**LICENSE, CLINICAL TRIAL AND SPONSORED RESEARCH AGREEMENTS**

**St. Jude Children’s Research Hospital**

*XSCID License*

On August 2, 2018, we entered into an exclusive worldwide license agreement with St. Jude for the development of a first-in-class *ex vivo* lentiviral gene therapy for the treatment of XSCID. We paid \$1.0 million in consideration for the exclusive license in addition to an annual maintenance fee of \$0.1 million (beginning in 2019). St. Jude is eligible to receive payments totaling \$13.5 million upon the achievement of five development and commercialization milestones. Royalty payments in the mid-single digits are due on net sales of licensed products (e.g. MB-117 and MB-217).

*XSCID Non-interventional Services Agreement*

In December 2019, we entered into a Non-Interventional Services Agreement with Children’s CGMP, LLC (“Children’s”), an affiliate of St. Jude Children’s Research Hospital, pursuant to which Children’s provides lentiviral vector for non-clinical XSCID research purposes, as well as related advisory services, and we agreed to fund approximately \$0.8 million upon execution.

*XSCID Data Transfer Agreement*

In June 2020, we entered into a Data Transfer Agreement for the XSCID program (the “XSCID DTA”). Pursuant to the terms of the XSCID DTA, we made an upfront payment of approximately \$1.1 million and will reimburse St. Jude for additional costs in connection with the on-going investigator-initiated study.

**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 $\alpha$ 2-directed CAR T program, and one relating to the Spacer technology (described below). As of December 31, 2023, COH owns 845,385 shares of our Class A common stock, which are convertible into 56,359 shares of Common Stock, and has the right to appoint a member to our Board of Directors (the “Board”).

In addition, we entered into a sponsored research agreement with COH under which we have funded continued research in the amount of \$2.0 million per year, payable in four equal installments, which ended in the first quarter of 2020. The research covered under this arrangement was for the IL13R $\alpha$ 2-directed CAR T program, the CD123-directed CAR T program, and the Spacer technology.

In May 2023, we announced a series of changes resulting from a review of our portfolio of product candidates to determine the future strategy of our programs and the proper allocation of our resources. Following this review, we determined to discontinue development of the Discontinued Programs, which included a portion of our portfolio of CAR T therapies being developed by us in partnership with the City of Hope.

*IL13R $\alpha$ 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 $\alpha$ 2-directed CAR T program (the “IL13R $\alpha$ 2 License”). Pursuant to the IL13R $\alpha$ 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 $\alpha$ 2 CRA (Glioblastoma)*

In February 2017, we entered into a Clinical Research Support Agreement for the IL13R $\alpha$ 2-directed CAR T program (the “IL13R $\alpha$ 2 GBM CRA”). Pursuant to the terms of the IL13R $\alpha$ 2 CRA, we made an upfront payment of approximately \$9,000 and will contribute an additional \$140,000 per patient in connection with the on-going investigator-initiated study. Further, we agreed to fund approximately \$66,000 annually pertaining to the clinical development of the IL13R $\alpha$ 2-directed CAR T therapy (also known as MB-101).

*IL13R $\alpha$ 2 CRA (Leptomeningeal Glioblastoma)*

In October 2020, we entered into a Clinical Research Support Agreement for the IL13R $\alpha$ 2-directed CAR T program for adult patients with leptomeningeal glioblastoma, ependymoma or medulloblastoma (the “IL13R $\alpha$ 2 Leptomeningeal CRA”). Pursuant to the terms of the IL13R $\alpha$ 2 Leptomeningeal CRA, we made an upfront payment of approximately \$29,000 and will contribute an additional \$150,000 per patient in connection with the on-going investigator-initiated study. Further, we agreed to fund approximately \$200,000 annually pertaining to the clinical development of the IL13R $\alpha$ 2-directed CAR T therapy.

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### *Sponsored Research Agreement - IL13R $\alpha$ 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 $\alpha$ 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 $\alpha$ 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.

### **University of California License**

On March 17, 2017, we entered into an exclusive license agreement with the Regents of UCLA (the “UCLA License”) to acquire intellectual property rights in patent applications related to the engineered anti-prostate stem cell antigen antibodies for cancer targeting and detection. Pursuant to the UCLA License, we paid UCLA an upfront fee of \$0.2 million and owed annual maintenance fees. In addition, UCLA was eligible to receive milestone payments totaling up to \$14.3 million, and royalty payments in the mid-single digits are due on net sales of licensed products. On July 10, 2023, we notified UCLA that we were terminating the UCLA license, which took effect on August 9, 2023.

### **Fred Hutchinson Cancer Center**

#### *CD20 Technology License*

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

#### *CD20 CTA (NHL and CLL)*

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



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

**Nationwide Children’s Hospital License**

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

**CSL Behring (Calimmune) License**

On August 23, 2019, we entered into a non-exclusive license agreement with CSL Behring (Calimmune) for the Cytegrity™ stable producer cell line for the production of lentiviral gene therapy for the XSCID gene therapy program. The Cytegrit™ stable producer cell line was used to produce the predecessor LVV for our MB-107 and MB-207 lentiviral gene therapies for the treatment of XSCID. We paid \$0.2 million in consideration for the license. CSL Behring (Calimmune) was eligible to receive additional payments totaling \$1.2 million upon the achievement of development and commercialization milestones. Royalty payments in the low-single digits were due on net sales of licensed products. However, the decision to modify the LVV used to transduce the hematopoietic stem cells of XSCID patients and thereby replace MB-107 and MB-207 with MB-117 and MB-217, respectively, rendered the stable producer cell no longer useful. Therefore, on August 14, 2023, we notified Calimmune that we were terminating the Calimmune license, which took effect 60 days following notification.

**SIRION Biotech License**

On October 6, 2020, we announced a licensing agreement under which we acquired technology rights from SIRION Biotech GmbH (“SIRION”) for LentiBOOST™ technology for the development of MB-207, our predecessor lentiviral gene therapy for the treatment of patients with XSCID, who have been previously treated with a hematopoietic stem cell transplantation (“HSCT”) and for whom re-treatment is indicated. LentiBOOST™ is SIRION’s proprietary non-cytotoxic transduction enhancer for lentiviral vectors. We eventually expect to use this technology for the development of MB-217, the cell product that uses a modified LVV to transduce the hematopoietic stem cells of patients previously treated with an HSCT.

Pursuant to the agreement, we paid SIRION a one-time upfront fee of \$0.1 million. In addition, SIRION is eligible to receive additional payments totaling up to approximately \$9.1 million upon the achievement of certain development and commercialization milestones. Royalty payments in the low- to mid-single digits are due on aggregate cumulative worldwide net sales of licensed products.

In December 2021, this licensing agreement was amended to include CD20-directed CAR Ts. SIRION is eligible to receive additional payments totaling up to approximately \$9.1 million upon the achievement of certain development and commercialization milestones for the additional product.

**Mayo Foundation for Medical Education and Research**

*CAR T Technology License*

On August 12, 2021, we announced that we executed an exclusive license agreement with Mayo Clinic for a novel technology that may be able to transform the administration of CAR T therapies and potentially allow such therapies to be used as an off-the-shelf therapy.

The technology, developed by Larry R. Pease, Ph.D., principal investigator and former director of the Center for Immunology and Immune Therapies at Mayo Clinic, is a new platform to administer CAR T therapy using a two-step approach. First, a peptide is administered to the patient to drive the proliferation of the patient’s resident T cells. This is followed by the administration of a viral CAR construct directly into the lymph nodes of the patient. In turn, the viral construct infects the activated T cells and effectively forms CAR T cells *in vivo* in the patient. Successful implementation may lead to an off-the-shelf product with no need to isolate and expand patient T cells *ex vivo*.

Preclinical proof-of-concept has been established, and the ongoing development of this technology will take place at Mayo Clinic. We are evaluating plans to file an IND application for a multicenter Phase 1 clinical trial once a lead construct has been identified, subject to allocation of resources.

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Pursuant to this agreement, we paid an upfront fee of \$0.8 million and will pay an annual maintenance fee of \$25,000. Additional payments are due for each of two licensed products upon the achievement of development and commercial milestones totaling up to \$92.6 million per product, and royalty payments in the mid-single digits are due on net sales of licensed products.

### *Sponsored Research Agreement*

In connection with the Mayo Clinic license agreement, we entered into an SRA under which we will fund research supporting the CAR T Technology License in the amount of \$2.1 million over a period of two years. In October 2022, the SRA was amended to include additional funding of \$0.1 million.

### **Leiden University Medical Centre**

#### *RAG1-SCID Technology License*

On November 10, 2021, we announced an exclusive license agreement with Leiden University Medical Centre (“LUMC”) for a novel *ex vivo* lentiviral gene therapy for the treatment of RAG1 severe combined immunodeficiency (“RAG1-SCID”).

Pursuant to this agreement, we paid an upfront fee of \$0.4 million. Additional payments are due for the achievement of development and commercial milestones totaling up to \$31.0 million, and royalty payments in the low to mid-single digits are due on net sales of licensed products.

### *Sponsored Research Agreement*

In connection with the RAG1-SCID license, we entered into an SRA with LUMC under which we fund research supporting the program in the amount of 2.3 million euros over a period of five years.

## **COMPETITION**

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

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

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

The gene therapy field is characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. We are aware of companies currently engaged in developing gene therapies in various indications, including Abeona Therapeutics, Adverum Biotechnologies, Astellas, AVROBIO, Sio Gene, Biogen, bluebird bio, BioMarin Pharmaceutical, Krystal Biotech, MeiraGTx, Novartis Pharmaceuticals, Orchard Therapeutics, Passage Bio, Prevail Therapeutics, REGENXBIO, Rocket Pharmaceuticals, Roche, Sangamo Therapeutics, Sarepta Therapeutics, Solid Biosciences, Ultragenyx Pharmaceuticals, uniQure and Voyager Therapeutics, as well as several companies addressing other methods for delivering or modifying genes and regulating gene expression.

## **EMPLOYEES**

As of December 31, 2023, we had 80 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, scientific and other strategic contributions to our Company on a regular basis.

## **SUPPLY AND MANUFACTURING**

As an early-stage development company, we rely on our research partners to manufacture or have manufactured all LV vectors used in the clinical development programs currently in progress at COH, Fred Hutch, St. Jude, the NIH, and LUMC under the IND applications filed by these institutions. In addition, we rely on the NIH to produce oncolytic virus for UAB, the clinical trial site for the Phase 1 trial of Nationwide's herpes simplex virus type 1 oncolytic virus (MB-108). We will continue to rely on our research partners to manufacture lentiviral vectors and oncolytic virus for our IND trials until such time as material is available from our contract manufacturing organizations.

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

We have limited experience in processing cells for clinical or commercial purposes. In 2018, we opened our own cell processing facility in Worcester, Massachusetts, in order to manufacture and supply cellular product candidates for all clinical trials that will be conducted under IND applications to be filed by us. In May 2023, we entered into an Asset Purchase Agreement with uBriGene (Boston) Biosciences, Inc., pursuant to which we agreed to sell our leasehold interests in our cell processing facility and associated assets relating to the manufacturing and production of cell and gene therapies. On July 28, 2023, we completed the sale of all of our assets relating to our operations primarily relating to the manufacturing and production of cell and gene therapies. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments."

In May 2021, the FDA accepted our IND to initiate a multi-center Phase 1/2 clinical trial of MB-106 (CD20) under our IND. In October 2023, the FDA accepted our IND application to initiate a Phase 1 clinical trial of MB-109. As with any supply program, obtaining raw materials of the correct quality cannot be guaranteed, and we cannot ensure that we will be successful in this endeavor.

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

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

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

## **GOVERNMENT AND INDUSTRY REGULATIONS**

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and, if approved, marketing of our product candidates, as well as our ongoing research and development activities. None of our product candidates has been approved for sale in any market. Before marketing in the U.S.,

any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, and the sale and distribution of biopharmaceutical products.

### ***U.S. Drug Development***

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

### ***FDA Expedited Review and Approval Programs***

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

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

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

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

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

In addition, studies for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Approval is determined on the basis of adequate and well-controlled clinical trials that establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the

availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint and under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

### ***Clinical Trials***

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

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

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

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

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

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

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

#### ***FDA Review and Approval***

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

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

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

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

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

### ***Post-Marketing Requirements***

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

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

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

### ***Pediatric Information***

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

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

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

### ***Orphan Drug Designation and Exclusivity***

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

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

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

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

### ***Other Healthcare Laws and Compliance Requirements***

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

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

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal health care program;
- The False Claims Act and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from the federal government or making or using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;
- The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the health care benefit program through false representations or knowingly and willingly falsifying, concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of, or payment for, health care benefits or services;



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- 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***

In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for any product for which we obtain regulatory approval to enable us to realize an appropriate return on our investment in research and product development. We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the health care reform legislation enacted in 2010, known as the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework could have a material adverse effect on our business.

### ***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 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 or clinical 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 \$51.6 million and \$77.5 million for the years ended December 31, 2023 and 2022, respectively, and we had an accumulated deficit of \$381.0 million as of December 31, 2023. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

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

- one or more of our product candidates receive regulatory approval and are approved for commercial sale, due to our need to establish the necessary commercial infrastructure to launch and commercialize this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for manufacturing, testing, warehousing, distribution, cash collection and related commercial activities;
- we are required by the FDA or foreign regulatory authorities to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements that require us to make payments to collaborators or licensors;
- there are variations in the level of expenses related to our future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved; and
- there are any regulatory developments affecting product candidates of our competitors.

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

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

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

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

We are currently advancing our programs in hematologic cancers, solid tumors and rare genetic diseases through clinical development. Developing and commercializing CAR T and gene therapy products is expensive, and we do not expect to generate meaningful product

revenues in the foreseeable future until we obtain marketing approval for products in the United States and following any potential commercial launch.

As of December 31, 2023, our cash and cash equivalents were \$6.2 million. Based on our current business plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31, 2023 are issued. Our fundraising efforts to raise additional funding may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our potential products following marketing approval if and when obtained. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. Potential indebtedness, if incurred, would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

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

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

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

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

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

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

Our operations have consumed substantial amounts of cash since inception. We will need to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we may receive regulatory approval, including building our own commercial organizations to address certain markets. We will require substantial additional capital for the further development and, if approved, commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. As of December 31, 2023, we had \$7.0 million in cash and restricted cash and have not generated positive cash flows from operations. We cannot provide any assurance that we will be able to raise funds to complete the development of our product candidates. Additionally, if we are unable to secure additional funding, it is likely that we will need to delay or terminate the development of certain product candidates; any such delay or termination, or the announcement of any such delay or termination, may impact our potential growth and have a material adverse effect on the value of our Securities.

In order to carry out our business plan and implement our strategy, we will need to obtain substantial additional financing and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be certain that additional funding will be available on acceptable

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terms, or at all. Additional funding may be more difficult to obtain, or may be more expensive, as a result of recent increases in inflation and interest rates in the U.S. economy generally. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or, if approved, commercialization of one or more of our product candidates. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Risks Related to Our Business Strategy, Structure, and Organization**

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

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

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

- developing our technology platform;
- identifying, developing, formulating, manufacturing and, if approved, commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- participating in regulatory approval processes, including ultimately gaining approval to market a drug product, which may not occur;
- obtaining sufficient quantities of our product candidates from our third-party manufacturers to meet clinical trial needs and, if approved, to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- conducting sales and marketing activities including hiring, training, deploying and supporting our sales force and creating market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote our product candidates that we may establish;
- maintaining patent protection and regulatory exclusivity for our product candidates; and
- raising additional required capital on acceptable terms.

Our operations have historically been limited to organizing, 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 to assess our ability to continue to develop our technology, identify product candidates, develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies, as well as for you to assess the advisability of investing in our securities. Each of these requirements will require substantial time, effort and financial resources.

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

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

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

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

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

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

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

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

### **Risks Inherent in Drug Development and Commercialization**

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

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

- commencing a clinical trial as a result of regulatory authority action;
- identifying, recruiting and training suitable clinical investigators;
- reaching and preserving agreements on acceptable terms with prospective clinical research organizations (“CROs”) and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Institutional Review Board (“IRB”) or ethics committee approval to conduct a clinical trial at a prospective site;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical sites once a trial has begun;
- change in the principal investigator or other key staff overseeing the clinical trial at a given site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; or
- retaining (or replacing) patients who have initiated a clinical trial but who may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process, personal issues, or other reasons.

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

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

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

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



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

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

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the trial design or implementation of our clinical trials, including proper use of clinical trial methods and methods of data analysis;
- an inability to establish sufficient data and information to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for an indication;
- the FDA may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from that of the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- the FDA may disagree with the interpretation of data from preclinical studies or clinical trials;

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- the FDA may determine that our manufacturing processes or facilities or those of third-party manufacturers with which we or our respective collaborators currently contract for clinical supplies and plan to contract for commercial supplies do not satisfactorily comply with cGMPs; or
- the approval policies or interpretation of regulations of the FDA may significantly change in a manner rendering the clinical data insufficient for approval or the product characteristics or benefit-risk profile unfavorable for approval.

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

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

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

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

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

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

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

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

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

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

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

- regulatory authorities may require the addition of unfavorable labeling statements, including specific warnings, black box warnings, adverse reactions, precautions, and/or contraindications;
- regulatory authorities may suspend or withdraw their approval of the product, and/or require it to be removed from the market;
- we may be required to recall a product, be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

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

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

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

The FDA, or other regulatory authorities, may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA and other applicable regulatory authorities closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other applicable regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market any approved product for only their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetics Act ("FDCA") relating to the promotion of prescription

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drugs may lead to investigations, civil claims, and/or criminal charges alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

- restrictions on such products, operations, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters, untitled letters, Form 483s, import alerts, and/or inspection observations;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits;
- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions, consent decrees, and/or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

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

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

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

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

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

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize one or more of our product candidates. Our competitors may also develop drugs that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We will also face competition from these third parties in establishing clinical trial sites, in patient registration for clinical trials, and in identifying and in-licensing new product candidates.

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

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

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally would also be necessary for commercial success. The degree of market acceptance of any approved products would depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such approved product as well as competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the product as a safe and effective treatment;

- the safety of such product candidates seen in a broader patient group, (i.e., based on actual use);
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- changes in regulatory requirements by government authorities for our product candidates;
- the relative convenience and ease of administration of the product candidate for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contradictions, warnings, drug interactions, or other precautions;
- changes in the standard of care for the targeted indications for our product candidate or future product candidates, which could reduce the marketing impact of any labeling or marketing claims that we could make following FDA approval;
- the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

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

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

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

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

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

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

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

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

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

***We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for one or more of our product candidates or a future product candidate we may license or acquire and, if approved, 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



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- 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.

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

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

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

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

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

***Negative public opinion and increased regulatory scrutiny of the therapies that underpin many of our product candidates may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.***

Public perception may be influenced by claims that one or more of the therapies underpinning our product candidates, including without limitation gene therapy, is unsafe, and such therapy may not gain the acceptance of the public or the medical community. In particular, the success of our gene therapy platforms will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity, could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that do obtain approval and/or a decrease in demand for any such product candidates. Concern about environmental spread of our products, whether real or anticipated, may also hinder the commercialization of our products.

#### **Risks Related to Reliance on Third Parties**

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

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

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

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

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

***We are currently reliant on COH, Fred Hutch, St. Jude, the NIH, UAB, Mayo Clinic, and LUMC for a substantial portion of our research and development efforts and the early clinical testing of our product candidates.***

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

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

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

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

We rely on our third-party manufacturers to produce or purchase from third-party suppliers the materials and equipment necessary to produce our product candidates for our preclinical and clinical trials. Forces beyond our control, including the continuing effects of the COVID-19 pandemic, could disrupt the global supply chain and impact our or our third-party manufacturers' ability to obtain raw materials or other products necessary to manufacture our product candidates. There are a limited number of suppliers for raw materials and equipment that we use (or that are used on our behalf) to manufacture our product candidates, and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials and equipment necessary to produce our product candidates for our preclinical and clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials or equipment by our third-party manufacturers. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing preclinical or clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials or equipment after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

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

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

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

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

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

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

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

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

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

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties, who may or may not be interested

in granting such a license, to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

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

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

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

***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 candidate, 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 on March 14, 2021 includes a provision that will eliminate 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 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 Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 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 Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

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

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

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

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

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

Disruptions at the FDA 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,

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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.

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these

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

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

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

#### **Risks Related to Intellectual Property and Potential Disputes Thereof**

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

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

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

In addition, patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent positions. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technologies or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Third parties are often responsible for maintaining patent protection for our product candidates, at our and their expense. If that party fails to appropriately prosecute and maintain patent protection for a product candidate, our abilities to develop and commercialize products may be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. Such a failure to properly protect intellectual property rights relating to any of our product candidates could have a material adverse effect on our financial condition and results of operations. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to



protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents.

We and our licensors also rely on trade secrets and proprietary know-how to protect product candidates. Although we have taken steps to protect our and their trade secrets and unpatented know-how, including entering into confidentiality and non-use agreements with third parties, and proprietary information and invention assignment agreements with employees, consultants and advisers, third parties may still come upon this same or similar information independently. Despite these efforts, any of these parties may also breach the agreements and may unintentionally or willfully disclose our or our licensors' proprietary information, including our trade secrets, and we may not be able to identify such breaches or obtain adequate remedies. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our or our licensors' trade secrets were to be lawfully obtained or independently developed by a competitor, we and our licensors would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our or our licensors' trade secrets were to be disclosed to or independently developed by a competitor, our competitive positions would be harmed.

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

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

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

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

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

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

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

***Protecting our proprietary rights is difficult and costly, and we may be unable to ensure their protection.***

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

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate our product candidates or any future product candidate technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the scope of our issued patents may not extend to competitive products developed or produced by others;

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- the issued patents covering our product candidates or any future product candidate may not provide a basis for market exclusivity for active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- intellectual property rights of others may have an adverse effect on our business.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful, and an unfavorable outcome in any litigation would harm our business.***

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

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

Our success also depends on our ability, and the abilities of any of our respective current or future collaborators, to develop, manufacture, market and sell product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our or our licensors' intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we or our licensors are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or such licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we and our licensors were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, depending upon the priority dates claimed by the competing parties, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain.

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

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

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

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

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

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

***We may be subject to claims that our employees and/or consultants have wrongfully used or disclosed to us alleged trade secrets of their former employers or other clients.***

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

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

In addition to seeking patent protection for our product candidates or any future product candidate, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We limit disclosure of such trade secrets where possible but we also seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who do have access to them, such as our employees, our licensors, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

- the scope of rights granted under such license agreements and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to such license agreements;
- the scope and interpretation of the representations and warranties made to us by our licensors, including those pertaining to the licensors' right title and interest in the licensed technology and the licensors' right to grant the licenses contemplated by such agreements;
- the sublicensing of patent and other rights under our license agreements and/or collaborative development relationships, and the rights and obligations associated with such sublicensing, including whether or not a given transaction constitutes a sublicense under such license agreement;
- the diligence and development obligations under license agreements (which may include specific diligence milestones) and what activities or achievements satisfy those diligence obligations;
- whether or not the milestones associated with certain milestone payment obligations have been achieved or satisfied;
- the applicability or scope of indemnification claims or obligations under such license agreements;
- the permissibility and advisability of, and strategy regarding, the pursuit of potential third-party infringers of the intellectual property that is the subject of such license agreements;
- the calculation of royalty, sublicense revenue and other payment obligations under such license agreements;
- the extent to which license rights, if any, are retained by licensors under such license agreements;
- whether or not a material breach has occurred under such license agreements and the extent to which such breach, if deemed to have occurred, is or can be cured within applicable cure periods, if any;
- disputes regarding patent filing and prosecution decisions, as well as payment obligations regarding past and ongoing patent expenses;
- intellectual property rights resulting from the joint creation or use of intellectual property (including improvements made to licensed intellectual property) by our and our partners' licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations or may conflict in such a way that puts us in breach of one or more agreements, which would make us susceptible to lengthy and expensive disputes with one or more of such third-party licensing partners. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreements, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

## **Risks Relating to Our Control by Fortress**

### ***Fortress controls a voting majority of our common stock.***

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

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

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information, including, but not limited to, information related to our intellectual property and proprietary business information, personal information, and other confidential information. It is critical that we maintain such

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confidential information in a manner that preserves its confidentiality and integrity. Furthermore, we have outsourced elements of our operations to third party vendors, who each have access to our confidential information, which increases our disclosure risk.

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

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

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

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

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

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

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

***Our growth is subject to economic and geopolitical conditions.***

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

- announcements concerning the progress of our efforts to obtain regulatory approval for and, if approved, commercialize our product candidates or any future product candidate, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching these product candidates, if approved;

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

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

### **Risks Relating to Sale of Our Manufacturing Facility**

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

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

Pursuant to the Amended Asset Purchase Agreement, we and uBriGene agreed to cause our respective affiliates to use their reasonable best efforts to obtain clearance for the Transaction from CFIUS, although obtaining such clearance was not a condition to closing the Transaction. In accordance with the Amended Asset Purchase Agreement, together with uBriGene, we submitted a joint notice to CFIUS on August 10, 2023.

Following an initial 45-day review period and subsequent 45-day investigation period, on November 13, 2023, CFIUS requested that we and uBriGene withdraw and re-file our joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon CFIUS's request, we and uBriGene submitted a request to withdraw and re-file our

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joint voluntary notice to CFIUS, and on November 13, 2023, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period on November 14, 2023. CFIUS's 45-day review ended on December 28, 2023. Since CFIUS had not concluded its review by December 28, 2023, the proceeding transitioned to a subsequent 45-day investigation period, which ended on February 12, 2024.

Following the 45-day review period and subsequent 45-day investigation period described above, on February 12, 2024, we and uBriGene requested permission to withdraw and re-file their joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon our and uBriGene's request to withdraw and re-file their joint voluntary notice to CFIUS, on February 12, 2024, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period on February 13, 2024. The new 45-day review period will conclude no later than March 28, 2024. If CFIUS does not conclude its review by March 28, 2024, the proceeding will transition to a second 45-day phase as CFIUS further investigates the Transaction.

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

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

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

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

Certain key personnel may depart the Company upon the completion of the sale of the facility, which may adversely affect our ability to realize the anticipated benefits of the transaction; unfortunately, key personnel may also depart the Company in the event that we are unable to complete the facility transfer.

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

Pursuant to the Asset Purchase Agreement, in addition to the base purchase price paid to us upon closing of the Transaction, uBriGene will also pay a Contingent Amount to us as consideration of the Transaction once we (i) complete an issuance of equity securities in an amount equal to or greater than \$10,000,000 (the "Contingent Capital Raise") and (ii) obtains the consent of the Landlord to the Proposed Lease Transfer. As of December 31, 2023, we had completed issuances of equity securities for proceeds totaling approximately \$4.6 million following the Closing Date. If we are unable to close the full amount of the Contingent Capital Raise and/or do not receive the Landlord's

consent to the Proposed Lease Transfer within two years from the Closing Date, uBriGene will no longer be obligated to pay the Contingent Amount to us.

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

**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.

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 377 Plantation Street, Worcester, MA 01605.

On October 27, 2017, we entered into a lease agreement with WCS - 377 Plantation Street, Inc., a Massachusetts nonprofit corporation (“Landlord”). Pursuant to the terms of the lease agreement, we agreed to lease 27,043 sf from the Landlord, located at 377 Plantation Street

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in Worcester, MA (the “Plantation Street Facility”), through November 2026, subject to additional extensions at our option. Base rent, net of abatements of \$0.6 million over the lease term, totals approximately \$3.6 million, on a triple-net basis.

The Plantation Street Facility became operational for the production of personalized CAR T and gene therapies in 2018.

On June 14, 2022, we entered into a sublease agreement with The Paul Revere Life Insurance Company. Pursuant to the terms of the sublease agreement, we agreed to sublease 26,503 square feet, located at 1 Mercantile Street, Worcester, MA (the “Mercantile Street Facility”), through January 2030. Base rent, net of abatements of \$1.2 million, totals approximately \$3.4 million. On July 18, 2023, we executed, with a retroactive effective date of June 15, 2023, a Third Amendment to the Sublease, with the Paul Revere Life Insurance Company, pursuant to which we relocated from the 26,503 square feet of rentable space on the fourth floor of the Mercantile Street Facility to 11,916 square feet of rentable space on the second floor. There were no modifications to the lease term. The reduction of the rentable space resulted in a decrease in the base rent and abatements. Base rent, net of abatements of \$0.2 million, totals approximately \$1.6 million, for the reduced space.

**Item 3. Legal Proceedings**

We have submitted a joint voluntary notice to the U.S. Committee on Foreign Investment in the United States (“CFIUS”) in connection with the sale of manufacturing facility and associated assets to a third party. Such transaction is currently under review by CFIUS. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments” for additional information.

Except as set forth above, 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 publicly traded 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 8, 2024, there were approximately 71 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 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 "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 in cell and gene therapies into potential cures for hematologic cancers, solid tumors and rare genetic diseases. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

Our pipeline is currently focused in three core areas: CAR T therapies for hematologic malignancies, CAR T therapies for solid tumors and gene therapies for rare genetic disorders. For each therapy we have partnered with world class research institutions. For our CAR T therapies we have partnered with COH, Fred Hutch, Nationwide and Mayo Clinic. For our gene therapies, we have partnered with St. Jude in the development of a first-in-class *ex vivo* lentiviral treatment of XSCID and with LUMC in the development of a first-in-class *ex vivo* lentiviral treatment of RAG1-SCID.

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

#### **CAR T Therapies**

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

We are developing a CAR T therapy for hematologic malignancies in partnership with Fred Hutch targeting CD20 (MB-106). On May 18, 2023, we announced a series of changes resulting from a review of our portfolio of product candidates to determine the future strategy of our programs and the proper allocation of our resources. Following this review, we determined to discontinue development of our MB-102 (CD123), MB-103 (HER2), MB-104 (CS1) and MB-105 (PSCA) programs (such programs, the "Discontinued Programs"), comprising a portion of our portfolio of CAR T therapies being developed by us in partnership with City of Hope.

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

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

In December 2023, we presented interim Phase 1/2 data from our multicenter clinical trial at the 65<sup>th</sup> American Society of Hematology Annual Meeting, taking place December 8 through 12, 2023. At this meeting, we presented data for the 9 patients (5 FL, 3 WM and 1 hairy cell leukemia variant) treated in the indolent NHL arm of the multicenter clinical trial. As planned, 2 dose levels (DL1= $3.3 \times 10^6$  CAR T-cells/kg [n=4] and DL2= $1.0 \times 10^7$  CAR T-cells/kg [n=5]) were evaluated. All patients responded clinically, yielding an overall response rate of 100% among the FL and WM patients. All 5 FL patients, including 2 who had prior CD19 CAR T-cell therapy, achieved a complete response. Among the WM patients, 1 achieved a very good partial response and 2 achieved a partial response. The hairy cell leukemia variant patient experienced stable disease and achieved transfusion independence. The data demonstrate that MB-106 has a tolerable safety profile, with no occurrence of CRS above grade 1 and no occurrence of ICANS of any grade, despite not using prophylactic tocilizumab or dexamethasone. MB-106 expansion and persistence was demonstrated in these patients. Additionally, outpatient administration of MB-106 was allowed and found to be feasible.

In the first quarter of 2024, the Company expects to receive FDA feedback in an End-of-Phase 1 Meeting on its strategy to conduct a non-randomized registrational multicenter trial in relapsed or refractory WM. In the second half of 2024, the Company expects to treat the first patient in that trial, which could enable top-line results in the second half of 2026. In order to facilitate interactions with the FDA throughout this process, we anticipate requesting Regenerative Medicine Advanced Therapy (“RMAT”) designation for indolent lymphoma – which includes WM – from the FDA in the first half of 2024. We are currently evaluating the extent to which we can continue the development of MB-106 in other NHL subtypes, subject to allocation of resources.

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

In April 2022, we announced interim data from two ongoing investigator-sponsored Phase 1 clinical trials evaluating two clinical candidates, MB-101 (IL13R $\alpha$ 2-targeted CAR T cell therapy licensed from City of Hope) and MB-108 (herpes simplex virus type 1 oncolytic virus licensed from Nationwide Children’s Hospital) for the treatment of recurrent glioblastoma.

On October 26, 2023, we announced that the FDA accepted our IND application for MB-109 for the treatment of recurrent glioblastoma (“GBM”) and high-grade astrocytoma. We are evaluating the timing for initiation of a Phase 1 multicenter clinical trial at City of Hope and the University of Alabama at Birmingham (“UAB”) to assess the safety, tolerability and efficacy of MB-109 in adult patients with recurrent GBM and high-grade astrocytomas that express IL13R $\alpha$ 2 on the surface of the tumor cells, subject to allocation of resources.

In March 2024, we announced the publication of Phase 1 data demonstrating the safety and promising clinical activity of MB-101 in patients with recurrent and refractory malignant glioma, including glioblastoma, in *Nature Medicine*. Stable disease or better was achieved in 50% (29/58) of heavily pretreated patients lasting at least 2 months, with 2 partial responses, 1 complete response, and a second complete response in a patient with recurrent glioblastoma who received additional CAR T-cell cycles off-protocol. Patients with recurrent glioblastoma who received MB-101, manufactured using an optimized process, via dual intratumoral (ICT)/ intraventricular (ICV) delivery exhibited a superior median overall survival of 10.2 months, compared the expected survival rate of 6.0 months in patients with recurrent GBM. MB-101 delivered via ICT, ICV or dual ICT/ICV delivery was generally well-tolerated, with no dose limiting toxicities observed at doses up to  $200 \times 10^6$  CAR T-cells. Higher levels of CD3+ T-cells in the tumor milieu prior to treatment was associated superior median overall survival, suggesting that immunologically “hot” tumors respond better to MB-101.

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### *In Vivo CAR T Platform Technology*

We are collaborating with the Mayo Clinic to develop a novel technology that may be able to transform the administration of CAR T therapies and potentially be used as an off-the-shelf therapy. In 2024, the Mayo Clinic expects to submit *in vivo* proof-of-concept data in a mouse model of cancer to a major scientific journal. We are evaluating plans to file an IND application for a multicenter Phase 1 clinical trial once a lead construct has been identified, subject to allocation of resources.

### **Gene Therapies**

*MB-117 (previously referred to as MB-107) (Ex vivo LV Gene Therapy for Newly Diagnosed X-linked Severe Combined Immunodeficiency (XSCID)) and MB-217 (previously referred to as MB-207) (Ex vivo LV Gene Therapy for Previously Transplanted XSCID)*

In partnership with St. Jude, our XSCID gene therapy programs are being conducted under an exclusive license to develop a potentially curative treatment for XSCID, a rare genetic immune system condition in which affected patients do not live beyond infancy without treatment. St. Jude's first-in-class *ex vivo* LV gene therapy has been utilized in two Phase 1/2 clinical trials involving two different autologous cell products produced via transduction of patients' hematopoietic stem cells using a predecessor LV vector. These cell products were designated MB-107 and MB-207, and the respective Phase 1/2 clinical trials were: a multicenter trial of the MB-107 product in newly diagnosed infants sponsored by St. Jude (ClinicalTrials.gov Identifier: NCT01512888; referred to as St. Jude as LVXSCID-ND) and a single-center trial of the MB-207 product in previously transplanted patients sponsored by the National Institutes of Health ("NIH") (ClinicalTrials.gov Identifier: NCT01306019; referred to as the NIH as LVXSCID-OC).

Going forward, this predecessor LV vector will be replaced by a modified LV vector which will be used to produce the MB-117 and MB-217 cell products. In 2024, following availability of the modified LVV, we expect that St. Jude will initiate its Phase 1 trial to treat newly diagnosed infants with MB-117 and that the NIH will initiate its Phase 1 trial to treat previously transplanted patients with MB-217.

### *LUMC License*

MB-110, a first-in-class *ex vivo* treatment for RAG1 SCID, is currently being evaluated at LUMC in a Phase 1/2 multicenter clinical trial in Europe. In 2022 the first patient was treated without any complications, after which the patient developed a functioning immune system which responded well to the standard vaccinations for newborns. We are evaluating the extent to which we will progress this program, subject to allocation of resources.

### **Recent Events**

#### *Sale of Manufacturing Facility – Overview of Transaction*

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

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



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Under the terms of the Asset Purchase Agreement, in addition to the Base Amount, uBriGene will be obligated to pay us a contingent amount (the “Contingent Amount”) if we, within two years from the Closing Date: (i) complete an issuance of equity securities in an aggregate amount equal to or greater than \$10.0 million after the closing (the “Contingent Capital Raise”) and (ii) obtain the consent of the landlord of the Facility to transfer the lease of the Facility to uBriGene (as discussed under “—Transfer of Lease of the Facility” below). As of December 31, 2023, we had completed issuances of equity securities for proceeds totaling approximately \$4.6 million following the Closing Date. If we are unable to close the full amount of the Contingent Capital Raise and/or do not receive the Landlord’s consent to the transfer the lease of the Facility to uBriGene within two years from the Closing Date, uBriGene will not be obligated to pay the Contingent Amount to us. The Contingent Amount to be paid to us upon the satisfaction of the conditions listed above will be an amount equal to \$5.0 million less (i) any severance payments or other monetary obligations to our employees who support the Transferred Operations and who have accepted offers of employment with uBriGene that arise between the Closing Date and the date the lease transfers to uBriGene and (ii) any payments payable by us under Transferred Contracts in connection with the consummation of the Transaction, including any payments necessary to obtain third party consents.

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

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

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

Following the 45-day review period and subsequent 45-day investigation period described above, on February 12, 2024, we and uBriGene requested permission to withdraw and re-file their joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon our and uBriGene’s request to withdraw and re-file their joint voluntary notice to CFIUS, on February 12, 2024, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period on February 13, 2024. The new 45-day review period will conclude no later than March 28, 2024. If CFIUS does not conclude its review by March 28, 2024, the proceeding will transition to a second 45-day phase as CFIUS further investigates the Transaction.

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

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

### *Transfer of Lease of the Facility*

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

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The Landlord has informed us that it will not consider our request for the Proposed Lease Transfer until we receive the final determination letter from CFIUS (the “CFIUS Letter”) with respect to the Transaction and provide the Landlord with a reasonably detailed summary of Mustang and uBriGene’s reaction to such final determination (the “Reaction Summary”). Upon the Landlord’s receipt of the CFIUS Letter and the Reaction Summary, the Landlord will have an additional thirty business days to make its determination on the Proposed Lease Transfer. If CFIUS conclude its action with respect to the Transaction by the end of its new 45-day review period ending March 28, 2024, then the landlord would be expected to deliver its decision regarding the Proposed Lease Transfer by April 27, 2024.

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

### *uBriGene’s Right to Deliver a Repurchase Notice with Respect to the Transferred Assets*

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

### *Transferred Employees and Transferred Contracts*

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

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

### *Manufacturing Services Agreement and Sub-Contracting CDMO Agreement*

As contemplated by the Asset Purchase Agreement, on the Closing Date, we and uBriGene entered into a Manufacturing Services Agreement (the “Manufacturing Services Agreement”). Under the Manufacturing Services Agreement, we contracted uBriGene to manufacture our lead product candidates, including MB-106, and we committed to spend at least \$8.0 million over a period of two years after the closing of the Transaction to purchase manufacturing and related services (the “Manufacturing Services”) from uBriGene (the “Minimum Commitment”). We paid uBriGene 25% of the Minimum Commitment at the time of signing of the Manufacturing Services Agreement and will pay the remainder of the Minimum Commitment over the following two years. Subject to our payment of our Minimum Commitment, uBriGene will provide to us a manufacturing rebate, payable in cash at the end of the second year of the Manufacturing Services Agreement term, for any amounts paid for Manufacturing Services in excess of the Minimum Commitment (but in no event will such rebate exceed \$3.0 million). In connection with the Manufacturing Services Agreement, we will provide uBriGene with the customary licenses to use intellectual property rights specific to our cell and gene therapies to the extent reasonably necessary for uBriGene’s performance under the Manufacturing Services Agreement.

In addition, as contemplated by the Asset Purchase Agreement, on the Closing Date, we and uBriGene entered into a sub-contracting Manufacturing Services Agreement (the “Sub-Contracting CDMO Agreement”), pursuant to which uBriGene contracted us to perform the Manufacturing Services to be performed by uBriGene under the Manufacturing Services Agreement and granted us a revocable, non-exclusive, royalty-free license to use the Transferred Assets in connection with the performance of such services. Under the terms of the Sub-Contracting CDMO Agreement, we will manufacture our lead product candidates, including MB-106 (the “Company CDMO Manufacturing Services”), and may from time to time manufacture other products as requested by uBriGene. Pursuant to the Sub-Contracting CDMO Agreement, the price to be paid by uBriGene in exchange for the Company CDMO Manufacturing Services will be an amount equal

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to the sum of: (i) the base salary and hourly wages for the Transferred Employees for time spent performing the Company CDMO Manufacturing Services, (ii) the fees, payments, costs and expenses payable by us to third parties under any of the Transferred Contracts used to perform the CDMO Manufacturing Services (so long as such amounts are generally consistent with amounts paid by us under such Transferred Contracts immediately prior to the Closing Date and such amounts did not become payable as a result of a breach of, a default under, a termination, a cancellation or an acceleration of any right or obligation under the Transferred Contracts), and (iii) any other amounts approved in advance in writing by uBriGene. As of the date hereof, uBriGene has not notified us of any plans to request any manufacturing services under the Sub-Contracting CDMO Agreement, other than the Company CDMO Manufacturing Services. In addition, under the Sub-Contracting CDMO Agreement, Mustang and uBriGene agreed to establish a joint steering committee comprising two representatives from each of Mustang and uBriGene to review, discuss and decide on operational matters relating to the services to be performed by us under such agreement, including matters relating to expenses. In addition, we agreed to permit uBriGene to locate up to three of uBriGene's personnel at the Facility so as to participate in meetings of the joint steering committee and allow for in-person feedback and decision-marking regarding the services to be performed by us.

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

We intend to expense manufacturing costs under the MSA and Sub-Contracting CDMO Agreement and account for reimbursed costs associated with the agreements as an offset to such expense. For the year ended December 31, 2023, we expensed \$4.1 million of manufacturing costs under the MSA and have a receivable of \$3.2 million, net of payments received of \$2.4 million, for reimbursed costs associated with the Sub-Contracting CDMO agreement.

### *Transition Services Agreement and Quality Services Agreement*

On the Closing Date, the parties also entered into a Quality Services Agreement, pursuant to which we and uBriGene agreed to specified duties for each party with respect to the contract manufacture by uBriGene of our product candidates. The Quality Services Agreement sets forth the quality activities associated with the production, analysis, and release of such products and assigns responsibility for each activity to us and/or uBriGene. The Quality Services Agreement terminates upon the earlier of: (i) the date of expiration of the MSA or (ii) the date of termination of the MSA.

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

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

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

### *Risks Relating to the Transaction*

We are exposed to a number of risks and uncertainties relating to the Transaction. Please see "Risk Factors—Risks Relating to the Sale of Our Manufacturing Facility" for a discussion of these risks and uncertainties.

### **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.

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

### **Accrued Research and Development Expense**

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

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

### **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 consolidated 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, 2023, and 2022

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

### Research and Development Expenses

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

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

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

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

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

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

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

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

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

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

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

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

#### ***Gain on the Sale of Property and Equipment***

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

#### ***General and Administrative Expenses***

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

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General and administrative expense decreased by approximately \$2.5 million from \$12.2 million for the year ended December 31, 2022, to \$9.7 million for the year ended December 31, 2023. The decrease in general and administrative expense for the year ended December 31, 2023, was primarily attributable to the following:

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

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

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

### ***Other Income (Expense)***

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

### **Liquidity and Capital Resources**

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

We have funded our operations to date primarily through the sale of equity and our Term Loan. On April 11, 2023, we repaid the Term Loan, see Note 8 to the Financial Statements.

### **Sources of Liquidity**

#### *Registration Statements*

On December 12, 2023, we filed registration statement No. 333-275997 on Form S-1, which registered the offer and sale of common stock on behalf of the Selling Stockholders, of up to 2,743,530 shares of our common stock, issuable upon the exercise of certain warrants held by the Selling Stockholders.

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On October 23, 2020, we filed a shelf registration statement No. 333-249657 on Form S-3 (the “2020 S-3”), which was declared effective on December 4, 2020. Under the 2020 S-3, we may sell up to a total of \$100.0 million of our securities. The 2020 S-3 expired on October 23, 2023.

On April 23, 2021, we filed a shelf registration statement No. 333-255476 on Form S-3 (the “2021 S-3”), which was declared effective on May 24, 2021. Under the 2021 S-3, we may sell up to a total of \$200.0 million of our securities. As of December 31, 2023, approximately \$195.6 million of the 2021 S-3 remains available for sale of securities.

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

### *Term Loan*

On April 11, 2023, our long-term debt facility with Runway Growth Finance Corp. (the “Term Loan”) was terminated upon receipt by Runway of a payoff amount of \$30.4 million from us comprising principal, interest and the applicable final payment amount. The loss on extinguishment was recorded in interest expense in the Statements of Operations.

### *Registered Direct Offering*

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

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

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

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

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

Pursuant to the Founders Agreement, we did not issue any shares of common stock to Fortress for the year ended December 31, 2023, and recorded the value of 64,706 shares issuable to Fortress in connection with the shares issued under the Registered Direct Offering.

### *At-the-Market Offering*

In July 2018, we entered into an At-the-Market Issuance Sales Agreement (the “Mustang ATM”) with B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.), Cantor Fitzgerald & Co., National Securities Corporation (now B. Riley FBR, Inc.), and Oppenheimer & Co. Inc. (each an “Agent” and collectively, the “Agents”), relating to the sale of shares of common stock pursuant to the 2021 S-3. Under the Mustang ATM, we pay the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. On December



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31, 2020, the Mustang ATM was amended to add H.C. Wainwright & Co., LLC as an Agent. On April 14, 2023, the Mustang ATM was amended to add the limitations imposed by General Instruction I.B.6 to Form S-3 and remove Oppenheimer & Co., Inc. as an Agent.

During the year ended December 31, 2023, we issued approximately 52,000 shares of common stock at an average price of \$3.15 per share for gross proceeds of \$163,000 under the ATM Agreement. In connection with these sales, we paid aggregate fees of approximately \$3,000 for net proceeds of approximately \$160,000.

During the year ended December 31, 2022, we issued approximately 0.5 million shares of common stock at an average price of \$12.61 per share for gross proceeds of \$6.6 million under the ATM Agreement. In connection with these sales, we paid aggregate fees of approximately \$0.1 million for net proceeds of approximately \$6.5 million.

Pursuant to the Founders Agreement, we did not issue any shares of common stock to Fortress for the year ended December 31, 2023, and recorded the value of 1,297 shares issuable to Fortress in connection with the shares issued under the Mustang ATM. Pursuant to the Founders Agreement, we issued 13,131 shares of common stock to Fortress at a weighted average price of \$13.56 per share for the year ended December 31, 2022, in connection with the shares issued under the Mustang ATM.

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, 2023, and 2022:

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

#### *Operating Activities*

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

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

#### *Investing Activities*

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

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

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*Financing Activities*

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

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

As of December 31, 2023, we had cash and cash equivalents of \$6.2 million. Based on our current operating plan, we currently expect that such cash and cash equivalents will be sufficient to fund our operations and clinical trials through the first quarter of 2024. In the near term, our liquidity and capital resources will be significantly affected by our ability to raise additional equity capital, including receiving the Contingent Payment pursuant to the Amended Asset Purchase Agreement in connection with the sale of our Facility, as described under “Recent Developments” above. Receipt of the Contingent Payment is dependent upon our raising an additional \$5.4 million through issuances of equity securities in order to complete the Contingent Capital Raise and obtaining the Landlord’s consent to the Proposed Lease transfer. The lease transfer is subject to review and approval by CFIUS. The current 45-day review period will conclude no later than March 28, 2024. If we are not able to secure the Contingent Payment by the end of the first quarter of 2024, we will continue to seek addition funding through corporate partnerships and capital markets fundraising and may face significant difficulty in funding our operations in the short term and will need to pursue other options to reduce expenses. See “Risk Factors—Risks Related to Our Finances and Capital Requirements.”

The continuation of our business as a going concern is dependent upon raising additional capital and eventually attaining and maintaining profitable operations. As of December 31, 2023, there is substantial doubt about our ability to continue as a going concern for the next 12 months from the date of issuance of these financial statements. The financial statements included in this Form 10-K do not include any adjustments that might be necessary should operations discontinue.

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 shares 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.

*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 officer and principal financial officer, we conducted an evaluation of the effectiveness, as of December 31, 2023, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

**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 officer and principal financial officer, and effected by our Board, management and other personnel, 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, 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, 2023. 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, 2023, 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, 2023, 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)
<b>Executive Officers</b>		
Manuel Litchman, M.D.	70	President, Chief Executive Officer, and Director
James Murphy	67	Interim Chief Financial Officer
<b>Non-Employee Directors</b>		
Michael S. Weiss	58	Chairman of the Board of Directors and Executive Chairman
Adam J. Chill	56	Director
Neil Herskowitz	67	Director
Lindsay A. Rosenwald, M.D.	68	Director
Michael J. Zelefsky, M.D.	63	Director

**Information about our Executive Officers****Manuel Litchman, M.D. - President, Chief Executive Officer, and Director**

Dr. Litchman has served as our President and Chief Executive Officer, and as a member of our Board, since April 2017. 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.

**James Murphy - Interim Chief Financial Officer**

Mr. Murphy has served as our Interim Chief Financial Officer since January 2024. Mr. Murphy has served as a consultant to several companies through Danforth, an advisory firm that provides operational and strategic support services to life science companies. During Mr. Murphy’s tenure at Danforth, he has served as interim Chief Financial Officer in both public and private life science companies since 2012.

Prior to joining Danforth, Mr. Murphy served as the Chief Financial Officer at OxiGene, Inc., a publicly traded biotechnology company, from February 2004 to April 2012. Mr. Murphy began his career in the life sciences sector in 1990 when he joined Sepracor Inc., a publicly traded specialty pharmaceutical and device company. Mr. Murphy received his B.A. in economics and accounting from the College of the Holy Cross.

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

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

##### ***Adam J. Chill - Director***

Mr. Chill has served as a member of our Board 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 two of our affiliates, Checkpoint Therapeutics, Inc. and Avenue Therapeutics, Inc. Mr. Herskowitz received a B.B.A. in Finance from Bernard M. Baruch College in 1978. Based on Mr. Herskowitz's financial industry experience and in-depth understanding of our business, we believe that Mr. Herskowitz has the appropriate set of skills to serve as a member of the Board.

##### ***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. From November 2014 to August 2015, Dr. Rosenwald served as Interim President and CEO of Checkpoint Therapeutics, Inc. and remains on that company's board of directors. He also serves on the board of directors of Avenue Therapeutics, Inc. and Journey Medical Corporation. Prior to that, from 1991 to 2008, he served as the Chairman of Paramount BioCapital, Inc. Over the last 30 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and has been involved in the founding and recapitalization of numerous public and private

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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 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 six 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 2023, our Board held eleven meetings. During 2023, 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 The Nasdaq Stock Market LLC ("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 2023 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, 2023. 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](http://ir.mustangbio.com). Among other things, the duties and responsibilities of the Audit Committee include reviewing and monitoring our financial statements and internal accounting procedures, the selection of, consultation with and review of the services provided by our independent registered public accounting and identifying and assessing any related party transactions in collaboration with counsel, accountants and management. Our Audit Committee has sole discretion over the retention, compensation, evaluation and oversight of our independent registered public accounting firm.

The SEC and Nasdaq have established rules and regulations regarding the composition of audit committees and the qualifications of audit committee members. Our Board 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 two meetings during the fiscal year ended December 31, 2023. 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](http://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 Interim Chief Financial Officer, James Murphy, at our

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offices located at 377 Plantation Street, Worcester, Massachusetts 01605. 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 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.

We are not currently in compliance with Nasdaq's Board Diversity Rule, as we do not have a "Diverse Director" as defined by Nasdaq's rules. We evaluate all qualified candidates to serve on our Board, including those with diverse backgrounds, and will continue to do so in furtherance of efforts to gain compliance with Nasdaq's Board Diversity Rule.

### **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](http://www.mustangbio.com).

### **Policy Prohibiting Hedging and Speculative Trading**

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

### **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, 2023, the following Section 16(a) filings were untimely due to administrative error: one Form 4 for each of Mr. Herskowitz (covering a total of one transaction), Dr. Zelefsky (covering a total of one transaction), Mr. Chill (covering a total of one transaction), Mr. Weiss (covering a total of one transaction), and Dr. Rosenwald (covering a total of three transactions); and two Forms 4 for Dr. Litchman (covering a total of four transactions).



**Item 11. Executive Compensation**

**Named Executive Officers**

As determined in accordance with SEC rules, our “named executive officers” (“NEOs”) for the year ended December 31, 2023, are the individuals set forth below:

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

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, 2023, and 2022.

**Summary Compensation Table**

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards <sup>(1)</sup> (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation (\$)	Total (\$)
Manuel Litchman, M.D.	2023	\$ 480,788	\$ — <sup>(2)</sup>	\$ 21,050	\$ —	\$ —	\$ —	\$ 501,838
<i>President and Chief Executive Officer</i>	2022	\$ 448,269	\$ 150,000	\$ 37,820	\$ —	\$ —	\$ —	\$ 636,089
Eliot Lurier <sup>(3)</sup>	2023	—	—	—	—	—	244,283	244,283
<i>Interim Chief Financial Officer</i>	2022	—	—	—	—	—	282,825	282,825

(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 9 to the financial statements included in this Form 10-K.

(2) As of March 11, 2024, Dr. Litchman’s 2023 annual cash incentive has not yet been approved by the Compensation Committee.

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

**Narrative to Summary Compensation Table**

*Employment Agreements*

Dr. Litchman

In April 2017, we entered into an employment agreement with Dr. Litchman, our President and Chief Executive Officer, pursuant to which he received an initial annual base salary of \$395,000. As part of his annual review in January 2023, the Board increased Dr. Litchman’s annual base salary to \$485,500 effective as of April 1, 2023. The employment agreement further provides eligibility for an incentive bonus linked to the realization of certain corporate milestones to be established annually by the Board 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. Dr. Litchman’s annual bonus for 2023 is described under “Annual Incentive Bonus” below. The employment agreement provides that if we terminate Dr. Litchman without cause or if he resigns for good reason, as those terms are defined in the employment agreement, he will be entitled to: (i) severance payments at a rate equal to his base salary then in effect for a period of 12 months following his termination date; (ii) a pro-rata share of the annual incentive bonus for the year in which the termination occurred, to be paid when and if such bonus would have been paid under the employment agreement; (iii) accelerated partial vesting of all unvested time-based equity awards with respect to the same number of shares that would have vested if Dr. Litchman had continued in employment for one year following the termination date; and (iv) if Dr. Litchman timely elects continued health insurance coverage under COBRA, the entire premium necessary to continue such coverage for Dr. Litchman and Dr. Litchman’s eligible dependents until the conclusion of the time when Dr. Litchman is receiving continuation of base salary payments or until Dr. Litchman becomes eligible for group health insurance coverage under another employer’s plan, whichever occurs first, provided however that we have the right to terminate

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such payment of COBRA premiums on behalf of Dr. Litchman and instead pay him a lump sum amount equal to the COBRA premium times the number of months remaining in the specified period if we determine in our discretion that continued payment of COBRA premiums is or may be discriminatory under Section 105(h) of the Internal Revenue Code. In addition, if Dr. Litchman is terminated without cause or resigns for good reason within twelve months following a change in control, he will be entitled to the severance benefits described in (i), (ii) and (iv) of the immediately preceding sentence, as well as 100% accelerated vesting of the options and other equity awards granted to him. In the event Dr. Litchman's employment is terminated due to his death or disability, he or his estate will receive continuing salary payments for ninety days and a pro-rata share of the annual incentive bonus for the year in which the termination occurred, to be paid when and if such bonus would have been paid under the employment agreement. In each case, the severance benefits are conditioned upon Dr. Litchman's execution and non-revocation of a release of claims against us and compliance with certain non-solicitation and non-competition covenants during his employment and for a period of six months thereafter. Also, the severance benefits are subject to reduction to avoid the imposition of excise taxes under Sections 280G and 4999 of the Code, provided that such reduction would result in a better after-tax result for Dr. Litchman.

Mr. Lurier

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

*Annual Cash Incentive Bonus*

In 2023, 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 (weighted at an aggregate of 90% of the target awards) as well as other corporate development goals (weighted at 10% of the target awards), and his individual performance based upon subjective performance reviews. Our corporate goals were achieved at an aggregate level of 96% reflecting the successful achievement of clinical, nonclinical, and corporate development goals. As of March 11, 2024, Dr. Litchman's annual cash incentive bonus has not yet been approved by the Compensation Committee. The actual amounts paid to Dr. Litchman pursuant to his annual cash incentive award is reported in the "Summary Compensation Table" as non-equity incentive plan compensation.

*Equity Awards*

The Compensation Committee has granted Dr. Litchman equity awards under our Mustang Bio, Inc. 2016 Incentive Plan (the "2016 Plan"). In 2017, Dr. Litchman received an option to purchase 69,445 shares, and he received awards of 4,067 restricted stock units in 2022 and 5,000 restricted stock units in 2023, which vest as described in footnotes (2) and (3), respectively, to the Outstanding Equity Awards table below.

***Outstanding Equity Awards at Fiscal Year-Ended December 31, 2023***

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 <sup>(1)</sup> (\$)
Manuel Litchman M.D.	43,403 <sup>(2)</sup>	26,042 <sup>(2)</sup>	\$ 85.95	4/24/2027	11,102 <sup>(3)</sup>	\$ 14,988
Eliot Lurier	—	—	—	—	—	—

(1) Market value is based on \$1.35 per share, the closing price of our common stock on the Nasdaq Capital Market on December 29, 2023, the last trading day of the fiscal year.

(2) The option vests as follows: (i) one half of the option will vest over time, with 25% of such shares vesting after twelve months of employment, and the remaining shares vesting in twelve equal quarterly installments thereafter, subject to Dr. Litchman's "continuous service" (as defined in the 2016 Plan) to the Company on each vesting date; (ii) the remaining one half of the option will vest and become exercisable upon the occurrence of the following milestones being achieved, in each case subject to Dr. Litchman's continuous

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service to the Company on the date of such occurrences: (A) 25% of such shares will vest upon the dosing of the first patient in the first Phase 2 clinical trial of any Company product candidate; (B) 25% of such shares will vest upon the dosing of the first patient in the first Phase 2 clinical trial of a second Company product candidate; (C) 25% of such shares will vest upon our achievement of a fully-diluted market capitalization of \$500,000,000; and (D) 25% of such shares will vest upon our achievement of a fully-diluted market capitalization of \$1 billion. Notwithstanding the foregoing, in the event that a Phase 2 clinical trial for either of the Company product candidates referenced in subsections (i) or (ii) of this paragraph is bypassed, the corresponding percentage of the Performance Option grant that would have otherwise vested pursuant to subsections (i) or (ii) of this paragraph will vest upon the earlier of (x) the dosing of the first patient in the first Phase 3 clinical trial for that Company product candidate, or (y) the filing of a Biologics License Application or New Drug Application with the U.S. Food and Drug Administration, or alternatively the filing of an equivalent regulatory filing with a foreign regulatory agency, with respect to that Company product candidate.

- (3) Subject to Dr. Litchman's continuous service, the restricted stock units vest as follows: (i) 4,301 shares will vest on April 24, 2024; (ii) 3,284 shares will vest on April 24, 2025; (iii) 2,267 shares will vest on April 24, 2026; and (iv) 1,250 shares will vest on April 24, 2027.

### **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"). 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.

### **Director Compensation**

Directors who are also employees are not compensated separately for serving on the Board or any of its committees. Each of our non-employee directors receives cash 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. In addition, to better align the interests of our Board with our stockholders, the Compensation Committee considers and recommends to the Board long-term equity compensation.

### ***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.

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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 (3<sup>rd</sup>) 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 (3<sup>rd</sup>) anniversary of the grant date, subject to the director's continued service on the Board on such date.

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 2023.

Name	Fees Earned or Paid in Cash (\$) <sup>(1)</sup>	Stock Awards (\$) <sup>(2)</sup>	Total (\$)
Neil Herskowitz	\$ 50,000	\$ 50,000	\$ 100,000
Lindsay A. Rosenwald, M.D.	\$ 50,000	\$ 50,000	\$ 100,000
Michael S. Weiss <sup>(3)</sup>	\$ 60,000	\$ 50,000	\$ 110,000
Adam J. Chill	\$ 60,000	\$ 50,000	\$ 110,000
Michael J. Zelefsky, M.D.	\$ 50,000	\$ 50,000	\$ 100,000

- (1) Represents the cash retainer for serving on our Board and committees of the Board.
- (2) As of December 31, 2023, each of Mr. Herskowitz, Dr. Rosenwald, Mr. Weiss, Mr. Chill and Dr. Zelefsky had 13,610 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, 2023.

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 (b)	
<b>Equity compensation plans approved by security holders</b>	76,112	\$ 85.95	282,334
<b>Equity compensation plans not approved by security holders</b>	—	—	—
<b>Total</b>	76,112	\$ 85.95	282,334

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 8, 2024, 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 8, 2024, there were 9,544,747 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 8, 2024. 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 <sup>(1)</sup>	Shares owned	Shares Under Exercisable Options and Unvested Restricted Stock		Total Shares Beneficially Owned	
		Units <sup>(2)</sup>			% of total CS
Michael S. Weiss <sup>(3)</sup>	49,637	—		49,637	* %
Manuel Litchman, M.D.	73,318	54,505		127,823	1.2 %
Lindsay A. Rosenwald, M.D. <sup>(3)</sup>	60,525	—		60,525	* %
Neil Herskowitz	19,703	—		19,703	* %
Adam J. Chill	19,170	—		19,170	* %
Michael J. Zelefsky, M.D.	18,970	—		18,970	* %
James Murphy	—	—		-	* %
All current executive officers and directors as a group (7 persons)	241,323	54,505		295,828	2.8 %
<b>5% or Greater Stockholders:</b>					
Fortress Biotech, Inc <sup>(4)</sup>	1,927,797	—		1,927,797	18.6 %
Armistice Capital, LLC. <sup>(5)</sup>	974,907	—		974,907	9.4 %

\* Less than 1% of our common stock outstanding

- (1) The address of each of the directors and executive officers is c/o Mustang Bio, Inc., 377 Plantation Street, Worcester, Massachusetts 01605, and the address of Fortress Biotech, Inc. is c/o Fortress Biotech, Inc., 1111 Kane Concourse, Suite 301, Bay Harbor Island, FL 33154
- (2) Includes only options exercisable within 60 days of March 8, 2024 and unvested restricted stock units.
- (3) Includes 33,334 warrants issued by Fortress to each of Mr. Weiss and Dr. Rosenwald that cover shares of our common stock that are owned by Fortress. These do not represent equity compensation by us to either Mr. Weiss or Dr. Rosenwald.

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- (4) Includes shares underlying 33,334 warrants issued to each of Mr. Weiss and Dr. Rosenwald, and excludes 250,000 of Class A Preferred Stock, which are convertible into 16,666 shares of Common Stock.
- (5) Based solely on information included in a Schedule 13G/A filed with the SEC on February 14, 2024. The address of Armistice Capital, LLC is 510 Madison Avenue, 7th Floor, New York, New York 10022.

The following table shows information, as of March 8, 2024, concerning the beneficial ownership of our Class A Common Stock:

Name and Address of Beneficial Owner <sup>(1)</sup>	Class A Common Stock Beneficially Owned	
	Number of Shares and Nature of Beneficial Ownership	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.

The following table shows information, as of March 8, 2024, concerning the beneficial ownership of our Class A Preferred Stock:

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

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

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

Since January 1, 2022, 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 466,667 common shares and 250,000 Class A Preferred

shares. Class A Preferred Stock is identical to common stock other than as to voting rights, conversion rights and the Annual Stock Dividend right (as described below). Each share of Class A Preferred Stock is entitled to vote the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of our outstanding common stock and (B) the whole shares of our common stock into which the shares of outstanding Class A common stock and Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Each share of Class A Preferred Stock is convertible, at Fortress' option, into one fully paid and nonassessable share of our common stock, subject to certain adjustments. As holders of Class A Preferred Stock, Fortress will receive on each January 1 (each a "Annual Stock Dividend Payment Date") until the date all outstanding Class A Preferred Stock is converted into common stock, pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock ("Annual Stock Dividends") such that the aggregate number of shares of common stock issued pursuant to such Annual Stock Dividend is equal to two and one-half percent (2.5%) of our fully-diluted outstanding capitalization on the date that is one (1) business day prior to any Annual Stock Dividend Payment Date.

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

Effective as of March 13, 2015, we entered into a Management Services Agreement (the "MSA") with Fortress, pursuant to which Fortress renders advisory and consulting services to us. The MSA has an initial term of five years and is automatically renewed for successive five-year terms unless terminated in accordance with its provisions. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of our operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on our behalf with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). We are obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, we are not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of its actions or inactions based upon their advice. Pursuant to the MSA and our 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, 2023 and 2022, we recorded expense of \$0.5 million and \$1.0 million, respectively, related to this agreement.

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

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

#### ***Payables and Accrued Expenses Related Party***

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

#### ***Director Compensation***

##### **Dr. Rosenwald**

Pursuant to the terms of the Director Compensation Plan, Dr. Rosenwald will receive a cash fee of \$50,000 per year paid quarterly and an annual stock award of the greater of (i) a number of shares of common stock having a fair market value on the grant date of \$50,000 or

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(ii) 10,000 shares of common stock, which shares shall vest and become non-forfeitable on the third anniversary of the grant date, subject to continued service on the Board on such date.

For the year ended December 31, 2023, we recognized \$100,000 in expense in our Statements of Operations related to the director compensation, including approximately \$50,000 in expense related to equity incentive grants. For the year ended December 31, 2022, we recognized \$100,000 in expense in our Statements of Operations related to the director compensation, including approximately \$50,000 in expense related to equity incentive grants. We issued Dr. Rosenwald 7,246 and 4,777 restricted stock awards for the years ended December 31, 2023 and 2022, respectively.

**Mr. Weiss - Advisory Agreement with Caribe BioAdvisors, LLC**

The Board 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, 2023, we recognized \$110,000 in expense in our Statements of Operations related to the advisory agreement, including approximately \$50,000 in expense related to equity incentive grants. For the year ended December 31, 2022, we recognized \$110,000 in expense in our Statements of Operations related to the advisory agreement, including approximately \$50,000 in expense related to equity incentive grants. We issued Mr. Weiss 7,246 and 4,777 shares of restricted stock for the years ended December 31, 2023 and 2022, respectively.

**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, 2023, KPMG LLP billed us an aggregate of approximately \$372,000 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 2023 fiscal year and the review of our financial statements included in our Quarterly Reports on Form 10-Q during that fiscal year.

For the year ended December 31, 2022, KPMG LLP billed us an aggregate of approximately \$330,000 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 2022 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, 2023, and 2022, KPMG LLP billed us an aggregate of approximately \$70,000 and \$95,000, 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, 2023 and 2022 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, 2023 and 2022, 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:

<a href="#">Report of Independent Registered Public Accounting Firm</a> (KPMG LLP, New York, NY; PCAOB ID: 185)	F-2
Financial Statements:	
<a href="#">Balance Sheets as of December 31, 2023 and 2022</a>	F-4
<a href="#">Statements of Operations for the Years Ended December 31, 2023 and 2022</a>	F-5
<a href="#">Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2023 and 2022</a>	F-6
<a href="#">Statements of Cash Flows for the Years Ended December 31, 2023 and 2022</a>	F-7
<a href="#">Notes to Financial Statements</a>	F-8 - F-30

**(b) Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
1.1	<a href="#">At Market Issuance Sales Agreement, dated July 27, 2018, between the Company, B. Riley FBR, Inc., Cantor Fitzgerald &amp; Co., National Securities Corporation, and Oppenheimer &amp; Co. 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 27, 2018).</a>
1.2	<a href="#">Amendment No. 1 to At Market Issuance Sales Agreement, dated July 20, 2020, between the Company, B. Riley FBR, Inc., Cantor Fitzgerald &amp; Co., National Securities Corporation and Oppenheimer &amp; Co. Inc. (incorporated by reference to the Exhibit 1.2 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on July 24, 2020).</a>
1.3	<a href="#">Amendment No. 2 to At Market Issuance Sales Agreement, dated December 31, 2020, between the Company, B. Riley Securities, Inc., Cantor Fitzgerald &amp; Co., National Securities Corporation, Oppenheimer &amp; Co. Inc. and H.C. Wainwright &amp; Co., LLC. (incorporated by reference to the Exhibit 1.1 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on December 31, 2020).</a>

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<b>Exhibit No.</b>	<b>Description</b>
1.4	<a href="#">Amendment No. 3 to At Market Issuance Sales Agreement, dated April 14, 2023, between the Company, B. Riley Securities, Inc., Cantor Fitzgerald &amp; Co. and H.C. Wainwright &amp; 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 April 20, 2023).</a>
2.1	<a href="#">Asset Purchase Agreement, dated May 18, 2023, 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 May 22, 2023). #</a>
2.2	<a href="#">First Amendment to Asset Purchase Agreement, dated June 29, 2023, between the Company and uBriGene (Boston) Biosciences, Inc. (incorporated by reference to the Exhibit 2.2 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on June 30, 2023).</a>
2.3	<a href="#">Second Amendment to Asset Purchase Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc. (incorporated by reference to the Exhibit 2.3 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on July 31, 2023).</a>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
3.3	<a href="#">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).</a>
3.4	<a href="#">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).</a>
3.5	<a href="#">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).</a>
3.6	<a href="#">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).</a>
3.7	<a href="#">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).</a>
3.8	<a href="#">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).</a>
4.1	<a href="#">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).</a>
4.2	<a href="#">Description of Securities of Mustang Bio, Inc. **</a>
4.3	<a href="#">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).</a>

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<b>Exhibit No.</b>	<b>Description</b>
4.4	<a href="#"><u>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).</u></a>
4.5	<a href="#"><u>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).</u></a>
4.6	<a href="#"><u>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).</u></a>
4.7	<a href="#"><u>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).</u></a>
10.1	<a href="#"><u>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).</u></a>
10.2	<a href="#"><u>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).</u></a>
10.3	<a href="#"><u>Future Advance Promissory Note to Fortress Biotech, Inc., dated May 5, 2016 (incorporated by reference to the Exhibit 10.3 of the Registrant's Form 10-12G (file No. 000-55668) filed with the SEC on July 28, 2016).</u></a>
10.4	<a href="#"><u>Promissory Note to NSC Biotech Venture Fund I, LLC, dated July 5, 2016 (incorporated by reference to the Exhibit 10.4 of the Registrant's Form 10-12G (file No. 000-55668) filed with the SEC on July 28, 2016).</u></a>
10.5	<a href="#"><u>License Agreement by and between Mustang Bio, Inc. and City of Hope, dated March 17, 2015 (incorporated by reference to the Exhibit 10.6 of the Registrant's Form 10-12G (file No. 000-55668) filed with the SEC on July 28, 2016).</u> #</a>
10.6	<a href="#"><u>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).</u></a>
10.7	<a href="#"><u>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).</u> †</a>
10.8	<a href="#"><u>Agreement by and between Mustang Bio, Inc. and Chord Advisors, LLC, dated April 8, 2016 (incorporated by reference to the Exhibit 10.10 of the Registrant's Form 10-12G (file No. 000-55668) filed with the SEC on July 28, 2016).</u></a>
10.9	<a href="#"><u>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).</u></a>
10.10	<a href="#"><u>Exclusive License Agreement by and between Mustang Bio, Inc. and The Regents of the University of California, dated March 17, 2017 (incorporated by reference to the Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q (file No. 000-55668) filed with the SEC on August 14, 2017).</u> #</a>
10.11	<a href="#"><u>Exclusive License Agreement (IV/ICV) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017. Filed as Exhibit 10.5 on the Company's Form 10-Q filed on August 14, 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).</u> #</a>
10.12	<a href="#"><u>Amended and Restated Exclusive License Agreement (CD123) by and between Mustang Bio, Inc. and City of Hope, dated February 17, 2017 (incorporated by reference to the Exhibit 10.14 of the Registrant's Annual Report on Form 10-K (file No. 000-55668) filed with the SEC on March 31, 2017).</u> #</a>

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<b>Exhibit No.</b>	<b>Description</b>
10.13	<a href="#">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). #</a>
10.14	<a href="#">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). #</a>
10.15	<a href="#">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). †</a>
10.16	<a href="#">License Agreement (CSI) by and between Mustang Bio, Inc. and City of Hope, dated May 31, 2017 (incorporated by reference to the Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q/A (file No. 001-38191) filed with the SEC on November 14, 2017). #</a>
10.17	<a href="#">License Agreement (PSCA) by and between Mustang Bio, Inc. and City of Hope, dated May 31, 2017 (incorporated by reference to the Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q/A (file No. 001-38191) filed with the SEC on November 14, 2017). #</a>
10.18	<a href="#">License Agreement (HER2) by and between Mustang Bio, Inc. and City of Hope, dated May 31, 2017 (incorporated by reference to the Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q/A (file No. 001-38191) filed with the SEC on November 14, 2017). #</a>
10.19	<a href="#">Lease Agreement by and between Mustang Bio, Inc. and WCS - 377 Plantation Street, Inc., dated October 27, 2017 (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 November 14, 2017).</a>
10.20	<a href="#">Sublease Agreement by and between Mustang Bio, Inc., and The Paul Reverse Life Insurance Company, dated June 14, 2022. (incorporated by reference to Exhibit 10.22 of the Registrant's Annual Report on Form 10-K (file No. 001-38191) filed with the SEC on March 30, 2023).</a>
10.21	<a href="#">First Amendment to Sublease Agreement by and between Mustang Bio, Inc. and The Paul Revere Life Insurance Company, dated October 25, 2022. (incorporated by reference to Exhibit 10.23 of the Registrant's Annual Report on Form 10-K (file No. 001-38191) filed with the SEC on March 30, 2023).</a>
10.22	<a href="#">Second Amendment to Sublease, dated April 27, 2023, between the Company and The Paul Revere Life Insurance Company (incorporated by reference to the Exhibit 10.2 of the Registrant's Current Report on Form 8-K (file No. 000-55668) filed with the SEC on July 20, 2023).</a>
10.23	<a href="#">Third Amendment to Sublease, dated June 15, 2023, between the Company and The Paul Revere Life Insurance Company (incorporated by reference to the Exhibit 10.3 of the Registrant's Current Report on Form 8-K (file No. 000-55668) filed with the SEC on July 20, 2023).</a>
10.24	<a href="#">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).</a>
10.25	<a href="#">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.</a>
10.26	<a href="#">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). †</a>

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<b>Exhibit No.</b>	<b>Description</b>
10.27	<a href="#">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).</a> †
10.28	<a href="#">Form of Option Agreement</a> **
10.29	<a href="#">Form of Restricted Stock Unit Agreement</a> **
10.30	<a href="#">Form of Director Stock Award Agreement</a> **
10.31	<a href="#">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).</a> †
10.32	<a href="#">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).</a> †
10.33	<a href="#">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).</a> †
10.34	<a href="#">Loan and Security Agreement by and between Mustang Bio, Inc., the Borrower, the Lenders and Runway Growth Finance Corp. (as agent), dated March 4, 2022 (incorporated by reference to the Exhibit 99.1 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on March 8, 2022).</a>
10.35	<a href="#">First Amendment to Loan and Security Agreement by and between Mustang Bio, Inc., the Borrower, the Lenders and Runway Growth Finance Corp. (as agent), dated December 7, 2022 (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 13, 2022).</a>
10.36	<a href="#">Consulting Agreement by and between Mustang Bio, Inc. and Danforth Advisors, LLC dated March 17, 2022 (incorporated by reference to the Exhibit 99.1 of the Registrant's Current Report on Form 8-K (file No. 001-38191) filed with the SEC on April 22, 2022).</a>
10.37	<a href="#">Manufacturing Services Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc. (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 July 31, 2023).</a>
10.38	<a href="#">Sub-Contracting Manufacturing Services Agreement, dated July 28, 2023, between the Company and uBriGene (Boston) Biosciences, Inc. (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 July 31, 2023).</a>
10.39	<a href="#">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).</a>
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm, KPMG, LLP, Boston, Massachusetts.</a> **
31.1	<a href="#">Certification of Principal Executive Officer, pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a> **
31.2	<a href="#">Certification of Principal 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.</a> **
32.1	<a href="#">Certification of Principal Executive 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.</a> ***

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<b>Exhibit No.</b>	<b>Description</b>
32.2	<a href="#">Certification of Principal 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.</a> ***
97	<a href="#">Compensation Clawback Policy</a> **
101	The following financial information from Mustang Bio, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2023, 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 granted with respect to omitted portions of this exhibit.

† Indicates management contract or compensatory plan or arrangement.

\*\* Filed herewith.

\*\*\* Furnished herewith.

**Item 16. Form 10-K Summary.**

None.

**INDEX TO FINANCIAL STATEMENTS**

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## **Report of Independent Registered Public Accounting Firm**

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

### *Opinion on the Financial Statements*

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

### *Going Concern*

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

### *Basis for Opinion*

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

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

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

### *Critical Audit Matter*

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

#### *Accounting for the transaction with uBriGene*

As discussed in Note 5 to the financial statements, during 2023, the Company entered into an Asset Purchase Agreement and related amendments with uBriGene Biosciences, Inc. (uBriGene), pursuant to which the Company has agreed to sell its leasehold interest in its cell processing facility and associated assets relating to the production of cell and gene therapies to uBriGene. The Company received proceeds of \$6.0 million, which it allocated to the individual sold assets on a relative fair value basis. The Company recognized a gain of \$1.5 million and recorded \$0.2 million of the consideration as deferred income of in its 2023 financial statement. The transaction requires governmental and lessor approval before the lease interest can be transferred to uBriGene. The Company will recognize the



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deferred income and will receive additional proceeds from uBriGene totaling \$5.0 million, if the Company, within two years from the closing date, (i) completes an issuance of equity securities in an amount equal to or greater than \$10.0 million and (ii) obtains consent of the landlord to the proposed lease transfer.

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

The following are the primary procedures we performed to address this critical audit matter. We inspected the Company's accounting analysis for the transaction. We compared management's assessment of the elements of the transaction delivered and those that were yet to be delivered to supporting documentation. We involved professionals with specialized skills and knowledge, who assisted in:

- inspecting the underlying agreements to understand the relevant terms and conditions and identify the elements of the transaction
- evaluating whether the Company's accounting for the transaction is in accordance with the relevant accounting guidance.

/s/ KPMG LLP

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

Boston, Massachusetts  
March 11, 2024

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

	December 31, 2023	December 31, 2022
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 6,234	\$ 75,656
Other receivables - related party	-	36
Other receivables	3,879	263
Prepaid expenses and other current assets	1,233	2,897
<b>Total current assets</b>	<b>11,346</b>	<b>78,852</b>
Property, plant and equipment, net	3,218	8,440
Fixed assets - construction in process	29	951
Restricted cash	750	1,000
Other assets	833	261
Operating lease right-of-use asset, net	1,566	2,918
<b>Total Assets</b>	<b>\$ 17,742</b>	<b>\$ 92,422</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 14,017	\$ 13,731
Payables and accrued expenses - related party	834	766
Operating lease liabilities - short-term	520	612
<b>Total current liabilities</b>	<b>15,371</b>	<b>15,109</b>
Deferred income	270	270
Note payable, long-term, net	-	27,436
Operating lease liabilities - long-term	1,978	3,334
<b>Total Liabilities</b>	<b>17,619</b>	<b>46,149</b>
<b>Commitments and Contingencies (Note 7)</b>		
<b>Stockholders' Equity</b>		
Preferred stock (\$0.0001 par value), 2,000,000 shares authorized, 250,000 shares of Class A preferred stock issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	—	—
Common stock (\$0.0001 par value), 200,000,000 shares authorized as of December 31, 2023 and December 31, 2022, respectively		
Class A common shares, 845,385 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	—	—
Common shares, 8,374,869 and 7,100,111 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	1	11
Common stock issuable, 419,089 and 187,134 shares as of December 31, 2023 and December 31, 2022, respectively	591	1,109
Additional paid-in capital	380,502	374,522
Accumulated deficit	(380,971)	(329,369)
<b>Total Stockholders' Equity</b>	<b>123</b>	<b>46,273</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 17,742</b>	<b>\$ 92,422</b>

*See accompanying notes to financial statements.*

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

	<b>For the year ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development	\$ 40,513	\$ 62,475
Research and development – licenses acquired	527	1,474
Gain on the sale of property and equipment	(1,466)	—
General and administrative	9,686	12,210
Total operating expenses	<u>49,260</u>	<u>76,159</u>
Loss from operations	<u>(49,260)</u>	<u>(76,159)</u>
Other income (expense)		
Other income	917	1,304
Interest income	850	689
Interest expense	(4,109)	(3,359)
Total other income (expense)	<u>(2,342)</u>	<u>(1,366)</u>
<b>Net Loss</b>	<b><u>\$ (51,602)</u></b>	<b><u>\$ (77,525)</u></b>
Net loss per common share outstanding, basic and diluted	<u>\$ (6.00)</u>	<u>\$ (10.09)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>8,604,104</u>	<u>7,684,508</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				
<b>Balances at December 31, 2021</b>	<b>250,000</b>	<b>\$ —</b>	<b>845,385</b>	<b>\$ —</b>	<b>6,238,866</b>	<b>\$ 9</b>	<b>\$ 4,329</b>	<b>\$ 359,906</b>	<b>\$ (251,844)</b>	<b>\$ 112,400</b>
Common stock issuable - Annual Stock Dividend	—	—	—	—	—	—	1,109	—	—	1,109
Issuance of common shares - Annual Stock Dividend	—	—	—	—	169,107	—	(4,212)	4,212	—	—
Issuance of common shares, net of offering shares -At-the-Market Offering	—	—	—	—	525,206	2	—	6,498	—	6,500
Issuance of common shares - Equity fee on At-the-Market Offering	—	—	—	—	16,550	—	(117)	283	—	166
Issuance of common shares under ESPP	—	—	—	—	22,056	—	—	206	—	206
Stock-based compensation expenses	—	—	—	—	64,664	—	—	2,283	—	2,283
Issuance of common shares - Equity fee on RWG debt	—	—	—	—	63,662	—	—	750	—	750
Issuance of warrants for RWG debt	—	—	—	—	—	—	—	384	—	384
Net loss	—	—	—	—	—	—	—	—	(77,525)	(77,525)
<b>Balances at December 31, 2022</b>	<b>250,000</b>	<b>\$ —</b>	<b>845,385</b>	<b>\$ —</b>	<b>7,100,111</b>	<b>\$ 11</b>	<b>\$ 1,109</b>	<b>\$ 374,522</b>	<b>\$ (329,369)</b>	<b>\$ 46,273</b>
Common stock issuable - Annual Stock Dividend	—	—	—	—	—	—	477	—	—	477
Issuance of common shares - Annual Stock Dividend	—	—	—	—	187,134	—	(1,109)	1,109	—	—
Issuance of common shares, net of offering costs - At-the-Market Offering	—	—	—	—	51,880	—	—	160	—	160
Issuance of common shares, equity fee on At-the-Market Offering	—	—	—	—	—	—	4	—	—	4
Issuance of common shares, net of offering costs - Registered Direct Offering	—	—	—	—	920,000	—	—	3,955	—	3,955
Issuance of common shares, equity fee on Registered Direct Offering	—	—	—	—	—	—	110	—	—	110
Issuance of common shares under ESPP	—	—	—	—	47,511	—	—	178	—	178
Stock-based compensation expenses	—	—	—	—	69,773	—	—	568	—	568
Exercise of warrants	—	—	—	—	93	—	—	—	—	—
Reverse Split (15:1) adjustment	—	—	—	—	(1,633)	(10)	—	10	—	—
Net loss	—	—	—	—	—	—	—	—	(51,602)	(51,602)
<b>Balances at December 31, 2023</b>	<b>250,000</b>	<b>\$ —</b>	<b>845,385</b>	<b>\$ —</b>	<b>8,374,869</b>	<b>\$ 1</b>	<b>\$ 591</b>	<b>\$ 380,502</b>	<b>\$ (380,971)</b>	<b>\$ 123</b>

*See accompanying notes to financial statements.*

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

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

*See accompanying notes to financial statements.*

## Notes to Financial Statements

### Note 1 - Organization and Description of Business

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

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

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

#### *Reverse Stock Split*

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

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

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

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

#### *Liquidity and Capital Resources*

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

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

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

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

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

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

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

In accordance with Accounting Standards Codification (“ASC”) 205-40, Going Concern, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that these

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consolidated financial statements are issued. In performing its evaluation, management excluded elements of its operating plan that cannot be considered probable. Under ASC 205-40, the future receipt of potential funding from future equity or debt issuances, and the potential sale of priority review vouchers cannot be considered probable at this time because these plans are not entirely within the Company's control nor have been approved by the Board of Directors as of the date of these financial statements.

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

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

## **Note 2 - Significant Accounting Policies**

### ***Basis of Presentation***

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

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

### ***Segments***

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating and reporting segment.

### ***Use of Estimates***

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

### ***Cash and Cash Equivalents***

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



***Other Receivables – Related Party***

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

***Restricted Cash***

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

***Property, plant and equipment, net***

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

***Property and equipment - Construction in Process***

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

***Research and Development Costs***

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

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

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

***Annual Stock Dividend***

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

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

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

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

***Fair Value Measurement***

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

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

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

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

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

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

***Leases***

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

### ***Stock-Based Compensation***

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

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

### ***Income Taxes***

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

### ***Net Loss per Share***

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

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

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

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

### ***Comprehensive Loss***

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

**Recent Accounting Pronouncements**

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

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

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

**Note 3 - License, Clinical Trial and Sponsored Research Agreements****Research and Development Expenses – All Licenses**

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

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

**License Agreements**

***City of Hope***

*IV/ICV*

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

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

*HER2 License (MB-103)*

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

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

***CSL Behring (Calimmune) License***

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

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

**Research and Development Expenses - Sponsored Research and Clinical Trial Agreements**

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

(\$ in thousands)	For the year ended December 31,	
	2023	2022
City of Hope National Medical Center		
CD123	\$ 23	\$ 166
IL13R $\alpha$ 2	1,115	1,486
CS1	188	482
HER2	-	784
PSCA	44	103
Fred Hutchinson Cancer Center - CD20	1,254	1,987
St. Jude Children's Research Hospital - XSCID	637	508
Leiden University Medical Center - RAG1 SCID	350	505
Mayo Clinic	551	968
Total	\$ 4,162	\$ 6,989

***City of Hope***

*CD123 (MB-102) Clinical Research Support Agreement*

In February 2017, the Company entered into a Clinical Research Support Agreement for CD123 (the “CD123 CRA”). Pursuant to the terms of the CD123 CRA the Company made an upfront payment of \$19,450 and will contribute an additional \$0.1 million per patient in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately \$0.2 million over three years pertaining to the clinical development of CD123. For the years ended December 31, 2023 and 2022, the Company recorded \$23,000 and \$0.2 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement. In May 2023, the Company terminated the CD123 License and associated Clinical Research Support Agreement.

*IL13R $\alpha$ 2 (MB-101) Clinical Research Support Agreements*

In February 2017, the Company entered into a Clinical Research Support Agreement for IL13R $\alpha$ 2 (the “IL13R $\alpha$ 2 CRA”). Pursuant to the terms of the IL13R $\alpha$ 2 CRA the Company made an upfront payment of approximately \$9,300 and will contribute an additional \$0.1 million related to patient costs in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately \$0.2 million over three years pertaining to the clinical development of IL13R $\alpha$ 2. For the years ended December 31, 2023 and 2022, the Company recorded \$1.1 million and \$1.5 million, respectively, in research and development expenses under the IL13R $\alpha$ 2 CRA in the Statements of Operations pursuant to the terms of this agreement.

In October 2020, the Company entered into a Clinical Research Support Agreement for the IL13R $\alpha$ 2-directed CAR T program for adult patients with leptomeningeal glioblastoma, ependymoma or medulloblastoma (the “IL13R $\alpha$ 2 Leptomeningeal CRA”). Pursuant to the terms of the IL13R $\alpha$ 2 Leptomeningeal CRA, the Company made an upfront payment of approximately \$29,000 and will contribute an additional \$0.1 million per patient in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately \$0.2 million annually pertaining to the clinical development of the IL13R $\alpha$ 2-directed CAR T therapy.

In October 2020, the Company entered into a Sponsored Research Agreement (“SRA”) with COH to conduct combination studies of a potential IL13R $\alpha$ 2 CAR and C134 oncolytic virus therapy. Pursuant to the SRA, the Company funded research in the amount of \$0.3 million for the program. In November 2022, the SRA was amended to include additional funding of \$0.6 million.

In March 2021, the Company entered into a clinical research support agreement for an Institutional Review Board-approved, investigator-initiated protocol entitled: “Single Patient Treatment with Intraventricular Infusions of IL13R $\alpha$ 2-

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targeting and HER2-targeting CAR T cells for a Single Patient (UPN 181) with Recurrent Multifocal Malignant Glioma.” Pursuant to the terms of this agreement, the Company will contribute up to \$0.2 million in connection with the ongoing investigator-initiated study.

*CS1 (MB-104) Clinical Research Support Agreement*

In June 2020, the Company entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: “Phase I Study to Evaluate Cellular Immunotherapy Using Memory-Enriched T Cells Lentivirally Transduced to Express a CS1-Targeting, Hinge-Optimized, 41BB-Costimulatory Chimeric Antigen Receptor and a Truncated EGFR Following Lymphodepleting Chemotherapy in Adult Patients with CS1+ Multiple Myeloma.” The CAR T being studied under this protocol has been designated as MB-104. Under the terms of the agreement the Company will reimburse COH for costs associated with this trial not to exceed \$2.4 million. The agreement will expire upon the delivery of a final study report or earlier. For the years ended December 31, 2023 and 2022, the Company recorded \$0.2 million and \$0.5 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement. In May 2023, the Company terminated the CS1 License and associated Clinical Research Support Agreement.

*HER2 (MB-103) Clinical Research Support Agreement*

In September 2020, the Company entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: “Phase I Study of Cellular Immunotherapy using Memory-Enriched T Cells Lentivirally Transduced to Express a HER2-Specific, Hinge-Optimized, 41BB-Costimulatory Chimeric Receptor and a Truncated CD19 for Patients with Recurrent/Refractory Malignant Glioma.” The CAR T being studied under this protocol has been designated as MB-103. Under the terms of the agreement the Company will pay COH \$29,375 upon execution and will reimburse COH for costs associated with this trial not to exceed \$3.0 million. The agreement will expire upon the delivery of a final study report or earlier. For the year ended December 31, 2023 and 2022, the Company recorded zero and \$0.8 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement. In May 2023, the Company terminated the HER2 License and associated Clinical Research Support Agreement.

*PSCA (MB-105) Clinical Research Support Agreement*

In October 2020, the Company entered into a clinical research support agreement with COH in connection with an Investigator-sponsored study conducted under an Institutional Review Board-approved, investigator-initiated protocol entitled: “A Phase 1b study to evaluate PSCA-specific chimeric antigen receptor (CAR)-T cells for patients with metastatic castration resistant prostate cancer.” The CAR T being studied under this protocol has been designated as MB-105. Under the terms of the agreement the Company will pay COH \$33,000 upon execution and will reimburse COH for costs associated with this trial not to exceed \$2.3 million. The agreement will expire upon the delivery of a final study report or earlier. For the years ended December 31, 2023 and 2022, the Company recorded \$44,000 and \$0.1 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement. In May 2023, the Company terminated the PSCA License and associated Clinical Research Support Agreement.

**Fred Hutch**

*CD20 Clinical Trial Agreement*

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

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For the years ended December 31, 2023 and 2022, the Company recorded \$1.3 million and \$2.0 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

***St. Jude - XSCID (MB-117) Data Transfer Agreement***

In June 2020, the Company entered into a Data Transfer Agreement with St. Jude under which we will reimburse St. Jude for costs associated with St. Jude's clinical trial for the treatment of infants with XSCID. Pursuant to the terms of this agreement the Company paid an upfront fee of \$1.1 million in July 2020, and will continue to reimburse St. Jude for costs incurred in connection with this clinical trial. For the years ended December 31, 2023 and 2022, the Company recorded \$0.6 million and \$0.5 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

***LUMC - RAG1-SCID (MB-110) Sponsored Research Support Agreement***

On September 8, 2021, in connection with the LUMC License, the Company entered into an SRA with LUMC under which the Company will fund research in the amount of approximately \$0.5 million annually over a period of 5 years. The research performed pursuant to this agreement will support technology the Company has licensed from LUMC for the use of a gene therapy under development for the treatment of severe immunodeficiency caused by RAG1. For the year ended December 31, 2023 and 2022, the Company recorded \$0.4 million and \$0.5 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

***Mayo Clinic - Sponsored Research Support Agreement***

In June 2021, the Company entered into an SRA with Mayo Clinic under which the Company will fund research in the amount of \$2.1 million over a period of two years. The research performed pursuant to this agreement will support technology the Company has licensed from Mayo Clinic for a novel technology that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy. In October 2022, the SRA was amended to include additional funding of approximately \$0.1 million. For the year ended December 31, 2023 and 2022, the Company recorded \$0.6 million and \$1.0 million, respectively, in research and development expenses in the Statements of Operations pursuant to the terms of this agreement.

**Note 4 - Related Party Agreements**

***Founders Agreement and Management Services Agreement with Fortress***

Effective March 13, 2015, the Company entered a Founders Agreement with Fortress, which was amended and restated on May 17, 2016, and again on July 26, 2016 (the "Mustang Founders Agreement"). The Mustang Founders Agreement provides that, in exchange for the time and capital expended in the formation of Mustang and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Fortress loaned \$2.0 million, representing the up-front fee required to acquire the Company's license agreement with COH. The Mustang Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Fortress and the Company or a Change in Control (as defined in the Mustang Founders Agreement) occurs. Concurrently with the second amendment on July 26, 2016, to the Mustang Founders Agreement, Fortress entered into an Exchange Agreement whereby Fortress exchanged its 7.25 million Class B Common shares for 7.0 million common shares and 250,000 Class A Preferred shares. Class A Preferred Stock is identical to common stock other than as to voting rights, conversion rights and the Annual Stock Dividend right (as described below). Each share of Class A Preferred Stock is entitled to vote the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding Mustang common stock and (B) the whole shares of Mustang common stock into which the shares of outstanding Class A Common Stock and Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Each share of Class A Preferred Stock is convertible, at Fortress' option, into one fully paid and nonassessable share of Mustang common stock, subject to certain adjustments. As holders of Class A Preferred Stock, Fortress will receive on each January 1 (each a "Annual Stock Dividend Payment Date") until the date all outstanding Class A Preferred Stock is converted into common stock, pro rata per share dividends paid in additional fully



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paid and nonassessable shares of common stock (“Annual Stock Dividends”) such that the aggregate number of shares of common stock issued pursuant to such Annual Stock Dividend is equal to two and one-half percent (2.5%) of Mustang’s fully-diluted outstanding capitalization on the date that is one (1) business day prior to any Annual Stock Dividend Payment Date. The Company records the value of all shares issued for the Annual Stock Dividend as research and development – licenses expense in its Statements of Operations.

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

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

As additional consideration under the Mustang Founders Agreement, Mustang will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Mustang that occurs after the effective date of the Mustang Founders Agreement and ending on the date when Fortress no longer has majority voting control in the Company’s voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of the Company’s annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, the Company will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%) (see Note 9). The Company records the value of all shares issued for the equity fee component of the Mustang Founders Agreement as Stock-based compensation expense in its Statements of Operations.

Effective as of March 13, 2015, the Company entered into a Management Services Agreement (the “MSA”) with Fortress, pursuant to which Fortress renders advisory and consulting services to the Company. The MSA has an initial term of five years and is automatically renewed for successive five-year terms unless terminated in accordance with its provisions. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of the Company’s operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the “Services”). The Company is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of its actions or inactions based upon their advice. Pursuant to the MSA and the Company’s Certificate of Incorporation, Fortress and its affiliates, including all members of the Company’s Board of Directors, will have no fiduciary or other duty to communicate or present any corporate opportunities to the Company or to refrain from engaging in business that is similar to that of the Company. In consideration for the Services, the Company will pay Fortress an annual consulting fee of \$0.5 million (the “Annual Consulting Fee”), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to \$1.0 million for each calendar year in which the Company has net assets in excess of \$100 million at the beginning of the calendar year. The Company records fifty percent of the Annual Consulting Fee in research and development expense and fifty percent in general and administrative expense in the Statement of Operations. For the years ended December 31, 2023 and 2022, the Company recorded expense of \$1.0 million and \$0.5 million, respectively, related to this agreement.

For the year ended December 31, 2023, the Company did not issue any shares of common stock and recorded the value of 66,003 shares issuable to Fortress, which equaled 2.5% of the sum of the gross proceeds of \$0.2 million from the sale of shares of common stock under Mustang’s At-the-Market Offering and \$4.4 million gross proceeds on the Registered Direct Offering. The Company recorded an expense of approximately \$0.1 million in general and administrative expenses related to these shares for the year ended December 31, 2023.

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For the year ended December 31, 2022, the Company issued 13,131 shares of common stock and did not record any shares issuable to Fortress, which equaled 2.5% of the gross proceeds of \$6.6 million from the sale of shares of common stock under Mustang's At-the-Market Offering. The Company recorded an expense of approximately \$0.2 million in general and administrative expenses related to these shares for the year ended December 31, 2022.

***Payables and Accrued Expenses Related Party***

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

***Director Compensation***

***Dr. Rosenwald***

Pursuant to the terms of the Director Compensation Plan, Dr. Rosenwald will receive a cash fee of \$50,000 per year paid quarterly and an annual stock award of the greater of (i) a number of shares of common stock having a fair market value on the grant date of \$50,000 or (ii) 10,000 shares of common stock, which shares shall vest and become non-forfeitable on the third anniversary of the grant date, subject to continued service on the Board on such date.

For the year ended December 31, 2023, the Company recognized \$100,000 in expense in its Statements of Operations related to the director compensation, including approximately \$50,000 in expense related to equity incentive grants. For the year ended December 31, 2022, the Company recognized \$100,000 in expense in its Statements of Operations related to the director compensation, including approximately \$50,000 in expense related to equity incentive grants. The Company issued Dr. Rosenwald 7,246 and 4,777 restricted stock awards for the years ended December 31, 2023 and 2022, respectively.

***Mr. Weiss - Advisory Agreement with Caribe BioAdvisors, LLC***

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

For the year ended December 31, 2023, the Company recognized \$110,000 in expense in its Statements of Operations related to the advisory agreement, including approximately \$50,000 in expense related to equity incentive grants. For the year ended December 31, 2022, the Company recognized \$110,000 in expense in its Statements of Operations related to the advisory agreement, including approximately \$50,000 in expense related to equity incentive grants. The Company issued Mr. Weiss 7,246 and 4,777 shares of restricted stock for the years ended December 31, 2023 and 2022, respectively.

**Note 5 – Property, Plant and Equipment, and Fixed Assets – Construction in Process**

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

In connection with the sale of such assets, the Company received base proceeds of \$6.0 million for the assets and lab supplies on-hand as of the transaction date. Based on the fair value of the consideration received and the relative fair value

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allocation of the consideration, the Company recorded a gain of \$1.5 million in the Statements of Operations, for the year ended December 31, 2023. The Company recorded approximately \$0.2 million of the consideration as deferred income, which will be recognized upon the transfer of the lease. The Company will record adjustments to the fair value of the potential future consideration each reporting period, prospectively.

Mustang's property, plant and equipment consisted of the following:

<i>(\$ in thousands)</i>	<u>Estimated Useful Life (in years)</u>	<u>December 31, 2023</u>	<u>December 31, 2022</u>
Computer equipment	3	\$ —	\$ 145
Furniture and fixtures	5	—	370
Machinery and equipment	5	—	8,632
Leasehold improvements	9	7,694	7,694
Total property, plant and equipment		7,694	16,841
Less: accumulated depreciation		(4,476)	(8,401)
Property, plant and equipment, net		<u>\$ 3,218</u>	<u>\$ 8,440</u>

Depreciation expense for the years ended December 31, 2023 and 2022, was approximately \$1.9 million and \$2.7 million, respectively, and was recorded in research and development expense in the Statements of Operations.

Fixed assets – construction in process primarily reflects buildout costs and equipment that have not yet been placed into service. For the years ended December 31, 2023, and 2022, fixed assets – construction in process was approximately \$29,000 and \$1.0 million, respectively.

**Note 6 - Accounts Payable and Accrued Expenses**

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

<i>(\$ in thousands)</i>	<u>December 31,</u>	
	<u>2023</u>	<u>2022</u>
Accounts payable	\$ 6,322	\$ 6,833
Accrued research and development	4,118	2,782
Accrued compensation	2,838	3,468
Other	739	648
Total accounts payable and accrued expenses	<u>\$ 14,017</u>	<u>\$ 13,731</u>

**Note 7 - Commitments and Contingencies****Leases**

On June 14, 2022, the Company entered into a sublease agreement with The Paul Revere Life Insurance Company. Pursuant to the terms of the sublease agreement, the Company agreed to lease 26,503 square feet, located at 1 Mercantile Street, Worcester, MA (the “Mercantile Street Facility”), through January 2030. The Company recorded a right of use asset and related operating lease liability of \$2.2 million on the Balance Sheet at the lease inception.

On July 18, 2023, the Company executed, with a retroactive Effective Date of June 15, 2023, a Third Amendment to Sublease (the “Third Amendment”), with the Paul Revere Life Insurance Company, pursuant to which the Company relocated from the 26,503 square feet of rentable space on the fourth floor of the Mercantile Center to 11,916 square feet of rentable space on the second floor of the Mercantile Center. As a result of the modification, the Company recorded an adjustment to its right of use asset and related operating lease liability of \$1.0 million and \$1.2 million, respectively, and \$0.2 million gain on the modification of the sublease, which is recorded in Other Income in the Statements of Operations. The Company does not yet occupy the Mercantile Street Facility.

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

The terms of the lease also require that the Company post an initial security deposit of \$0.8 million, in the form of \$0.5 million letter of credit and \$0.3 million in cash, which increased to \$1.3 million (\$1.0 million letter of credit, \$0.3 million in cash) on November 1, 2019. After the fifth lease year, the letter of credit obligation is subject to reduction. In January 2023, the letter of credit was reduced to \$0.8 million.

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

The Company leases office space and copiers under agreements classified as operating leases that expire on various dates through 2030. The Company’s lease liabilities result from the lease of its facilities in Massachusetts, which expire in 2030 and 2026, for the Mercantile Street Facility and Plantation Street Facility, respectively, and its copiers, which expire in 2024. Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Certain of the Company’s leases include renewal options and escalation clauses; renewal options have not been included in the calculation of the lease liabilities and right of use assets as the Company is not reasonably certain to exercise the options. The Company does not act as a lessor or have any leases classified as financing leases. At December 31, 2023, the Company had operating lease liabilities of \$2.5 million and right of use assets of \$1.6 million, which were included in the Balance Sheet. At December 31, 2022, the Company had operating lease liabilities of \$3.9 million and right of use assets of \$2.9 million, which were included in the Balance Sheet.

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

(\$ in thousands)	For the Year Ended	
	December 31, 2023	December 31, 2022
Lease cost		
Operating lease cost	\$ 439	\$ 565
Variable lease cost	467	488
Total	<u>\$ 906</u>	<u>\$ 1,053</u>

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<i>(\$ in thousands)</i>	For the Year Ended	
	December 31, 2023	December 31, 2022
Operating cash flows from operating leases	\$ 529	\$ 485
Gain on lease modification	\$ 220	\$ —
Weighted-average remaining lease term – operating leases	4.5	5.9
Weighted-average discount rate – operating leases	9.1 %	9.1 %

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

<i>(\$ in thousands)</i>	
Year ended December 31, 2024	\$ 723
Year ended December 31, 2025	774
Year ended December 31, 2026	703
Year ended December 31, 2027	269
Year ended December 31, 2028	274
Thereafter	303
Total	3,046
Less present value discount	(548)
Operating lease liabilities	\$ 2,498

**Note 8 – Notes Payable**

On April 11, 2023, the Company’s long-term debt facility with Runway Growth Finance Corp. (the “Term Loan”) was terminated upon receipt by Runway of a payoff amount of \$30.4 million from the Company comprised of principal, interest and the applicable final payment amount. The loss on extinguishment was recorded in interest expense in the Statements of Operations. For the years ended December 31, 2023 and 2022, the Company recorded the following components in interest expense:

<i>(\$ in thousands)</i>	For the year ended December 31,	
	2023	2022
Interest expense	\$ 1,187	\$ 2,899
Amortization of Debt Discount	118	445
Loss on Extinguishment	2,795	—
Other	9	15
Total Interest Expense	\$ 4,109	\$ 3,359

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

The Term Loan accrued interest at a variable annual rate equal to 8.75% plus the greater of (i) 0.50% and (ii) the three month LIBOR Rate for U.S. dollar deposits or the rate otherwise reasonably determined by the Lender to be the rate at which U.S. dollar deposits with a term of three months would be offered by banks in London, England to major banks in the London or other offshore interbank market (the “Applicable Rate”); provided that the Applicable Rate would not be less than 9.25%. On December 7, 2022, the Company entered into the First Amendment (the “First Amendment”) to the Loan Agreement by and between the Company and Runway. The First Amendment amended certain definitions and other provisions of the Loan Agreement to replace LIBOR-based benchmark rates applicable to loans outstanding under the Loan Agreement with SOFR-based rates, subject to adjustments as specified in the First Amendment. The Applicable Rate at December 31, 2022 was 11.69%. For the year ended December 31, 2023, the Company made interest payments of \$1.3

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million, recorded in interest expense in the Statements of Operations. For the year ended December 31, 2022, the Company made interest payments of \$2.7 million, recorded in interest expense in the Statements of Operations.

<i>(\$ in thousands)</i>	December 31, 2023	December 31, 2022
Note payable	\$ —	\$ 31,050
Discount on note payable	—	(3,614)
Long-term note payable	<u>\$ —</u>	<u>\$ 27,436</u>

Amortization of the debt discount associated with the Term Loan was approximately \$0.1 million and \$0.5 million for the year ended December 31, 2023, and 2022, respectively, and was recorded in interest expense in the Statements of Operations.

In addition, the Term Loan was secured by a lien on substantially all of our assets other than certain intellectual property assets and certain other excluded collateral, and it contained a minimum liquidity covenant and other covenants that include among other items: (i) limits on indebtedness, repurchase of stock from employees, officers and directors.

## **Note 9 - Stockholders' Equity**

### ***Common Stock***

The Company, in accordance with its certificate of incorporation, as amended in November 2020 and June 2021, which was retroactively applied, and July 2022, is authorized to issue (i) 200,000,000 common shares with a par value of \$0.0001 per share, of which 1,000,000 shares are designated as Class A Common Stock and the remainder are undesignated Common Stock, and (ii) 2,000,000 shares of Preferred Stock, 250,000 of which are designated as Class A Preferred Stock and the remainder are undesignated Preferred Stock (see below Stock Issuances to Fortress and Note 4).

In connection with the Company's formation, Fortress subscribed for 7,000,000 shares of the Class B Common Stock and 2,000,000 shares of the Company's Common Stock, pursuant to the Founders Agreement. Fortress paid the par value of \$900 in 2016. The fair value of the Company's common shares approximated par value as no licenses had been transferred at that time. In July 2016, the Class B Common Stock held by Fortress was exchanged for Class A Preferred Stock, and the Company amended and restated its Certificate of Incorporation to eliminate the Class B Common Stock and authorized a new series of Class A Preferred Stock. Dividends, if and when declared, are to be distributed pro-rata to the Class A Common Stock, Common Stock and Class A Preferred Common Stock.

The holders of Common Stock are entitled to one vote per share of Common Stock held. The holders of Class A Common Stock are entitled to the number of votes equal to the number of whole shares of Common Stock into which the shares of Class A Common Stock held by such holder are convertible and for a period of ten years from its issuance, the holders of the Class A Common Stock have the right to appoint one member of the board of directors of Mustang; to date, the holders of Class A Common Stock have not yet appointed such director.

### ***At-the-Market Offering of Common Stock***

In July 2018, the Company entered into an At-the-Market Issuance Sales Agreement (the "Mustang ATM") with B. Riley Securities, Inc. (formerly B. Riley FBR, Inc.), Cantor Fitzgerald & Co., National Securities Corporation, (now B. Riley FBR, Inc.), and Oppenheimer & Co. Inc. (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock pursuant to the 2020 S-3. Under the Mustang ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. On December 31, 2020, the Mustang ATM was amended to add H.C. Wainwright & Co., LLC as an Agent. On April 14, 2023, the Mustang ATM was amended to add the limitations imposed by General Instruction I.B.6 to Form S-3 and remove Oppenheimer & Co., Inc. as an Agent.

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During the year ended December 31, 2023, the Company issued approximately 52,000 shares of common stock at an average price of \$3.15 per share for gross proceeds of \$163,000 under the ATM Agreement. In connection with these sales, the Company paid aggregate fees of approximately \$3,000 for net proceeds of approximately \$160,000.

During the year ended December 31, 2022, the Company issued approximately 0.5 million shares of common stock at an average price of \$12.61 per share for gross proceeds of \$6.6 million under the ATM Agreement. In connection with these sales, the Company paid aggregate fees of approximately \$0.1 million for net proceeds of approximately \$6.5 million.

Pursuant to the Founders Agreement, the Company did not issue any shares of its common stock to Fortress for the year ended December 31, 2023, and recorded the value of 1,297 shares issuable to Fortress in connection with the Mustang ATM. Pursuant to the Founders Agreement, Mustang issued 13,131 shares of common stock to Fortress at a weighted average price of \$13.56 per share for the year ended December 31, 2022, in connection with the Mustang ATM.

***Registered Direct Offering***

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

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

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

Pursuant to the Founders Agreement, the Company did not issue any shares of its common stock to Fortress and recorded the value of 64,706 shares issuable to Fortress in connection with the Registered Direct Offering as of December 31, 2023.

***Registration Statements***

On December 12, 2023, we filed registration statement No. 333-275997 on Form S-1, which registered the offer and sale of common stock on behalf of the Selling Stockholders, of up to 2,743,530 shares of our common stock, issuable upon the exercise of certain warrants held by the Selling Stockholders.

On October 23, 2020, the Company filed a shelf registration statement No. 333-249657 on Form S-3 (the “2020 S-3”), which was declared effective on December 4, 2020. Under the 2020 S-3, the Company may sell up to a total of \$100.0 million of its securities. The 2020 S-3 expired on October 23, 2023.

On April 23, 2021, the Company filed a shelf registration statement No. 333-255476 on Form S-3 (the “2021 S-3”), which was declared effective on May 24, 2021. Under the 2021 S-3, the Company may sell up to a total of \$200.0 million of its securities. As of December 31, 2023, approximately \$195.6 million of the 2021 S-3 remains available for sale of securities.

**Stock Issuances to Fortress**

Under the terms of the Second Amended and Restated Founders Agreement, which became effective July 22, 2016, Fortress will receive a grant of shares of our common stock equal to two and one-half percent (2.5%) of the gross amount of any equity or debt financing. Additionally, pursuant to the Amended and Restated Articles of Incorporation, Fortress receives an Annual Stock Dividend on January 1<sup>st</sup>, representing 2.5% of the fully-diluted outstanding equity of Mustang.

For the year ended December 31, 2023, the Company recorded the value of 353,086 shares of common stock to Fortress for the Annual Stock Dividend, as Common stock issuable – Annual Stock Dividend in the Statement of Stockholders' Equity. The Company recorded an expense of approximately \$0.5 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2023.

For the year ended December 31, 2022, the Company recorded the value of 187,134 shares of common stock to Fortress for the Annual Stock Dividend, as Common stock issuable – Annual Stock Dividend in the Statement of Stockholders' Equity. The Company recorded an expense of approximately \$1.1 million in research and development – licenses acquired related to these issuable shares during the year ended December 31, 2022.

For the year ended December 31, 2023, the Company did not issue any shares of common stock and recorded the value of 1,297 shares issuable to Fortress, which equaled 2.5% of the gross proceeds of \$0.2 million from the sale of shares of common stock under Mustang's At-the-Market Offering. In connection with the Registered Direct Offering, the Company recorded 64,706 shares issuable to Fortress, which equaled 2.5% of the gross proceeds of \$4.4 million.

For the year ended December 31, 2022, the Company issued 13,131 shares of common stock to Fortress at a weighted average price of \$13.56 per share, the value of which equaled 2.5% of the gross proceeds of \$6.6 million from the sale of shares of common stock under the Mustang ATM.

**Equity Incentive Plan**

The Company has in effect the 2016 Incentive Plan (the "Incentive Plan"). The Incentive Plan was adopted in 2016 by our stockholders and the compensation committee of the Company's board of directors and is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan initially authorized grants to issue up to 133,333 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

In June 2018, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 333,333 shares. In June 2021, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 533,333 shares. In June 2022, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 200,000 shares, for a total of 733,333 shares.

As of December 31, 2023, 282,334 shares are available for issuance of stock-based awards under the Incentive Plan.

**Stock Options**

The following table summarizes stock option activities for the years ended December 31, 2023 and 2022:

	<b>Stock Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (in years)</b>
Outstanding at December 31, 2021	76,112	\$ 85.95	5.31
Outstanding at December 31, 2022	76,112	\$ 85.95	4.31
Outstanding at December 31, 2023	76,112	\$ 85.95	3.31
Options vested and exercisable at December 31, 2023	47,570	\$ 85.95	3.31



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As of December 31, 2023, the Company had no unrecognized stock-based compensation expense related to options. The Company accounts for forfeited awards as they occur as permitted.

**Restricted Stock Awards**

Certain employees and directors have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted stock award activities for the years ended December 31, 2023 and 2022:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2021	18,732	\$ 60.75
Granted	23,888	10.50
Vested	(8,604)	73.35
Nonvested at December 31, 2022	34,016	\$ 22.20
Granted	36,230	6.90
Vested	(5,540)	46.20
Nonvested at December 31, 2023	<u>64,706</u>	<u>\$ 11.59</u>

As of December 31, 2023, the Company had unrecognized stock-based compensation expense related to restricted stock of \$0.4 million, which is expected to be recognized over a weighted average period of approximately 2.1 years.

**Restricted Stock Units**

The following table summarizes restricted stock units' activities for the year ended December 31, 2023 and 2022:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2021	155,704	\$ 49.05
Granted	98,976	11.40
Forfeited	(34,333)	37.95
Vested	(54,435)	44.70
Nonvested at December 31, 2022	165,912	\$ 27.60
Granted	29,732	5.13
Forfeited	(51,366)	27.22
Vested	(49,081)	31.53
Nonvested at December 31, 2023	<u>95,197</u>	<u>\$ 18.78</u>

As of December 31, 2023, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately \$0.5 million, which is expected to be recognized over a weighted average period of approximately 2.1 years.

The following table summarizes stock-based compensation expense for the years ended December 31, 2023 and 2022 (in thousands).

	For the year ended December 31,	
	2023	2022
General and administrative	\$ 436	\$ 700
Research and development	132	1,583
Total stock-based compensation expense	<u>\$ 568</u>	<u>\$ 2,283</u>

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**Stock Warrants**

In connection with the Company's Registered Direct Offering on October 26, 2023, the Company issued pre-funded warrants to purchase up to 1,668,236 shares of common stock, and in a concurrent private placement, the Company issued unregistered warrants to purchase up to 2,588,236 shares of common stock. In connection with these offerings, H.C. Wainwright received Placement Agent Warrants to purchase up to 155,294 shares of common stock.

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

A summary of warrant activities for years ended December 31, 2023 and 2022, is presented below:

	<b>Warrants</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (in years)</b>
Outstanding as of December 31, 2021	220,577	\$ 120.30	0.73
Expired	(200,251)	127.49	—
Granted	49,869	12.03	9.18
Outstanding as of December 31, 2022	70,195	\$ 22.80	8.29
Exercised	(93)	—	—
Granted	4,411,766	1.00	5.29
Outstanding as of December 31, 2023	4,481,868	\$ 1.34	5.34

Upon the exercise of warrants, the Company will issue new shares of Common Stock.

**Employee Stock Purchase Plan**

In connection with our Employee Stock Purchase Plan ("ESPP"), eligible employees of Mustang and Fortress can purchase the Company's Common Stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period.

As of December 31, 2023, 86,578 shares have been purchased and 380,089 shares are available for future sale under the Company's ESPP.

**Note 10 - Income Taxes**

The Company has accumulated net losses since inception and has not recorded an income tax provision or benefit during the years ended December 31, 2023 and 2022.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	<u>For the year ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
Statutory federal income tax rate	21 %	21 %
State taxes, net of federal tax benefit	16 %	16 %
Non-deductible items	— %	(1)%
Tax credits	4 %	5 %
Other	(3)%	1 %
Change in valuation allowance	(38)%	(42)%
Income taxes provision (benefit)	<u>—</u>	<u>—</u>

The components of the net deferred tax asset as of December 31, 2023 and 2022 are the following:

<i>(\$ in thousands)</i>	<u>For the year ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
<b>Deferred tax assets:</b>		
Net operating loss carryovers	\$ 84,651	\$ 75,011
Stock compensation and other	1,946	2,399
Change in fair value of warrant liabilities	59	59
Amortization of license	11,856	13,375
Lease liability	929	1,466
Accruals and reserves	1,841	1,434
Startup costs	5	6
Tax credits	18,189	15,649
174 Capitalization	28,800	19,787
<b>Total deferred tax assets</b>	<u>148,276</u>	<u>129,186</u>
Less: valuation allowance	(147,694)	(128,101)
<b>Net deferred tax assets</b>	<u>\$ 582</u>	<u>\$ 1,085</u>
<b>Deferred tax liabilities:</b>		
Right of use asset	(582)	(1,085)
<b>Total deferred tax assets, net</b>	<u>\$ —</u>	<u>\$ —</u>

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax assets as of December 31, 2023 and 2022. A valuation allowance of approximately \$147.7 million and \$128.1 million, respectively, was recorded for the years ended December 31, 2023 and 2022.

As of December 31, 2023, the Company had federal and state net operating loss carryforwards of approximately \$244.1 million and \$514.9 million, respectively. Approximately \$220.4 million and \$0.4 million of the federal and state net operating loss carryforwards, respectively, can be carried forward indefinitely. As of December 31, 2023, the Company had federal and state income tax credits of approximately \$14.1 million and \$5.2 million, respectively, which will begin to expire in 2034. Under the provisions of Section 382 of the Internal Revenue Code, a corporation that undergoes an "ownership change", as defined therein, is subject to limitations on its use of pre-change NOLs and income tax credits carryforwards to offset future tax liabilities. Certain tax attributes may be subject to an annual limitation as a result of the Company's January 2017 capital raise, as it appears to constitute an ownership change under Section 382. Additionally, under Section 382, annual use of the Company's net operating loss carryforwards to offset taxable income may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such

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limitations have been triggered as of December 31, 2023. The Company has no income tax effect due to the recognition of a full valuation allowance on all of its deferred tax assets as it believes that it is more likely than not that the deferred tax assets will not be realized regardless of whether an “ownership change” has occurred.

There are no significant items determined to be unrecognized tax benefits taken or expected to be taken in a tax return, in accordance with ASC 740 “Income Taxes” (“ASC 740”), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements, that have been recorded on the Company’s financial statements for the periods ended December 31, 2023 and 2022. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

Additionally, ASC 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for the periods ended December 31, 2023 and 2022.

The Company is subject to U.S. federal and various state taxes. As of December 31, 2023, the earliest federal tax year open for the assessment of income taxes under the applicable statutes of limitations is its 2020 tax year.

Beginning with the 2022 tax year, the Company is required to capitalize research and development expenses for tax purposes as defined under Internal Revenue Code Section 174. For expenses that are incurred for research and development in the U.S., the amounts will be amortized over 5 years, and for expenses that are incurred for research and development outside the U.S., the amounts will be amortized over 15 years. As a result of Section 174 capitalization, the Company recognized a deferred tax asset of \$28.8 million.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer’s social security payments, net operating loss utilization and carryback periods and modifications to the net interest deduction limitations. The CARES Act did not have a material impact on the Company’s income tax provision for 2023 and 2022. The Company will continue to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows.

On December 27, 2020, the Consolidated Appropriations Act, 2021 (“Consolidated Appropriations Act”) was signed into law. The Consolidated Appropriations Act is intended to enhance and expand certain provisions of the CARES Act, allows for the deductions of expenses related to the Payroll Protection Program funds received by companies, and provides an update to meals and entertainment expensing for 2021. The Consolidated Appropriations Act did not have a material impact to the Company’s income tax provision for 2023 and 2022.

**Note 11 – Subsequent Events**

In connection with the sale of the Company’s leasehold interest in its cell processing facility located in Worcester, Massachusetts and associated assets relating to the manufacturing and production of cell and gene therapies at the Facility (the “Transaction”) to uBriGene (Boston) Biosciences, Inc., a Delaware corporation (“uBriGene”) and an indirect, wholly owned subsidiary of UBrigene (Jiangsu) Biosciences Co., Ltd., a Chinese contract development and manufacturing organization, the Company and uBriGene previously submitted a voluntary notice with the U.S. Committee on Foreign Investment in the United States (“CFIUS”) on August 10, 2023 to obtain clearance for the Transaction, although obtaining such clearance was not a condition to closing the Transaction.

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

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Following the 45-day review period and subsequent 45-day investigation period described above, on February 12, 2024, the Company and uBriGene requested permission to withdraw and re-file their joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon the Company's and uBriGene's request to withdraw and re-file their joint voluntary notice to CFIUS, on February 12, 2024, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period on February 13, 2024. The new 45-day review period will conclude no later than March 28, 2024. If CFIUS does not conclude its review by March 28, 2024, the proceeding will transition to a second 45-day phase as CFIUS further investigates the Transaction.

**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 and Chief Executive Officer

March 11, 2024

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 and Chief Executive Officer (Principal Executive Officer)	March 11, 2024
<u>/s/ James Murphy</u> James Murphy	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2024
<u>/s/ Michael S. Weiss</u> Michael S. Weiss	Chairman of the Board of Directors and Executive Chairman	March 11, 2024
<u>/s/ Adam Chill</u> Adam Chill	Director	March 11, 2024
<u>/s/ Neil Herskowitz</u> Neil Herskowitz	Director	March 11, 2024
<u>/s/ Lindsay A. Rosenwald</u> Lindsay A. Rosenwald, M.D.	Director	March 11, 2024
<u>/s/ Michael Zelefsky</u> Michael Zelefsky, M.D.	Director	March 11, 2024

**DESCRIPTION OF THE REGISTRANT'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE  
SECURITIES EXCHANGE ACT OF 1934**

The following descriptions of our capital stock and of certain provisions of our Amended and Restated Certificate of Incorporation (“**Certificate of Incorporation**”), as amended, our Amended and Restated Bylaws (“**Bylaws**”), and of certain provisions of Delaware law do not purport to be complete and are subject to and qualified in their entirety by reference to the full text of our Certificate of Incorporation, our Bylaws, and the General Corporation Law of the State of Delaware (the “**DGCL**”).

When used herein, the terms “**Company**,” “**we**,” “**our**,” and “**us**” refer to Mustang Bio, Inc.

**Authorized Capital Stock**

The Company is authorized to issue (i) 200,000,000 shares of common stock, par value \$0.0001 per share (“**Common Stock**”), 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, par value \$0.0001 per share (“**Preferred Stock**”), of which 250,000 are designated as Class A Preferred Stock and the remainder are undesignated Preferred Stock.

**Common Stock**

*Voting Rights*

The holders of our Common Stock are entitled to one vote per share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings). Holders of our Common Stock do not have cumulative voting rights. The number of authorized shares of Common Stock and Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of shares of capital stock of the Company representing a majority of the votes represented by all outstanding shares of capital stock of the Company entitled to vote, irrespective of the provisions of Section 242(b)(2) of the DGCL.

*Liquidation Rights*

Upon our liquidation, dissolution, or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our Common Stock, including Class A Common Stock, outstanding at that time after payment of other claims of creditors, if any.

*Preemptive, Conversion, or Similar Rights*

The holders of our Common Stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking fund provisions applicable to our Common Stock.

*Dividends*

The holders of outstanding shares of Common Stock, including Class A Common Stock, are entitled to receive dividends out of funds legally available at the times and in the amount that our Board of Directors may determine. All dividends are non-cumulative. No dividend or other distribution shall be paid or declared and set apart for payment (other than dividends payable solely in capital stock on the capital stock of the Company) on the shares of Common Stock of the Company until all dividends on the Class A Preferred Stock shall have been paid or declared and set apart for payment.

**Class A Common Stock**

*Voting Rights*

The holders of our Class A Common Stock are entitled to cast 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. For a period of ten (10) years from issuance, the holders of the Class A Common Stock have the right to appoint one member of the Board of Directors of the Company. To date, the holders of Class A Common Stock have not yet appointed such director.

*Preemptive, Conversion, or Similar Rights*

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

**Preferred Stock**

**Class A Preferred Stock**

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

*Voting Rights*

On any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Class A Preferred Stock will be entitled to cast for each share of Class A Preferred Stock held by such holder as of the record date for determining stockholders entitled to vote on such matter, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the number of shares of outstanding Common Stock and (B) the whole shares of Common Stock in to which the shares of outstanding Class A Common Stock and the Class A Preferred Stock are convertible, and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Except as provided by law or by the provisions of our Certificate of Incorporation, the holders of Class A Common Stock and Class A Preferred Stock will vote together with the holders of Common Stock as a single class.

*Preemptive, Conversion, or Similar Rights*

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

*Dividends*

The holders of the outstanding shares of Class A Preferred Stock receive on each January 1 (each a “**PIK Dividend Payment Date**”) after the original issuance date of the Class A Preferred Stock until the date all outstanding Class A Preferred Stock is converted into Common Stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and non-assessable shares of Common Stock such that the aggregate number of shares of Common Stock issued pursuant to such PIK dividend is equal to 2.5% of the Company’s fully-diluted outstanding capitalization on the date that is one business day prior to any PIK Dividend Payment Date (“**PIK Record Date**”). In the event the Class A Preferred Stock converts into Common Stock, the holders shall receive all PIK dividends accrued through the date of such conversion. No dividend or other distribution shall be paid, or declared and



set apart for payment (other than dividends payable solely in capital stock on the capital stock) on the shares of Common Stock until all PIK dividends on the Class A Preferred Stock shall have been paid or declared and set apart for payment. All dividends are non-cumulative.

### **Undesignated Preferred Stock**

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

### **Certain Certificate of Incorporation, Bylaws, and Statutory Provisions**

Certain of the provisions of our Certificate of Incorporation and Bylaws and of the DGCL summarized below may have an anti-takeover effect and may delay, defer, or prevent a tender offer or takeover attempt that a holder of shares of our Common Stock might consider in its interest, including an attempt that might result in a receipt of a premium over the market price for such shares.

#### *Directors' Liability; Indemnification of Directors and Officers*

Our Certificate of Incorporation provides that to the fullest extent permitted by the DGCL, as the same exists or as may hereafter be amended, no present or former director of the Company shall be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director. In addition, our Certificate of Incorporation and Bylaws provide that we will indemnify each director and the officers, employees, and agents determined by our Board of Directors to the fullest extent provided by the laws of the State of Delaware.

#### *Special Meetings of Stockholders*

Our Bylaws provide that special meetings of the stockholders may be called, at any time for any purpose or purposes, by the Board of Directors or by such person or persons as may be authorized by the Certificate of Incorporation or the Bylaws, or by such person or persons duly designated by the Board of Directors whose powers and authority, as expressly provided in a resolution of the Board of Directors, include the power to call such meetings, but such special meetings may not be called by any other person or persons.

#### *Stockholder Action by Written Consent Without a Meeting*

Our Bylaws provide that any action required by the DGCL to be taken at any annual or special meeting of stockholders of a corporation, or any action that may be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice, and without a vote, if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. provided that such copy, facsimile, or other reproduction shall be a complete reproduction of the entire original writing.

#### *Election and Removal of Directors*

Our Certificate of Incorporation provides that for a period of ten (10) years from the date of the first issuance of shares of Class A Common Stock, the holders of record of the shares of Class A Common Stock (or other capital stock or securities that are issued upon conversion of or in exchange for the Class A Common Stock and whether or not the Class A Special Conversion Termination Date (as defined in the Certificate of Incorporation) has occurred), exclusively and as a separate class, shall be entitled to appoint or elect one (1) director of the Company. The holders of record of the shares of Common Stock and Preferred Stock (including Class A Common Stock and Class A Preferred Stock) and of any other class or series of voting stock, exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Company, if any.

Any director may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class(es) of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. At any meeting held for the purpose of electing a director, the presence in

person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. A vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to our Certificate of Incorporation.

Our Bylaws provide that directors shall be elected at each annual meeting of stockholders to hold office until the next annual meeting. Directors need not be stockholders unless so required by our Certificate of Incorporation or Bylaws, wherein other qualifications for directors may be prescribed. Each director, including a director elected to fill a vacancy, shall hold office until his or her successor is elected and qualified or until his or her earlier resignation or removal. Each director shall be a natural person. Elections of directors need not be by written ballot.

Any director may resign at any time upon notice given in writing or electronic transmission to the Company. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have the power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in our Bylaws in the filling of other vacancies.

Unless otherwise provided in our Certificate of Incorporation or Bylaws: (a) vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director; and (b) whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the Certificate of Incorporation, vacancies and newly created directorships of such class or classes or series may be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected.

#### *Amendment of the Certificate of Incorporation and Bylaws*

Our Certificate of Incorporation provides that the Company reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in our Certificate of Incorporation, and other provisions authorized by the DGCL and the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to our Certificate of Incorporation in its present form or as hereafter amended, are granted subject to the rights reserved in our Certificate of Incorporation.

In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors of the Company is expressly authorized to make, alter, and repeal the Bylaws of the Company, subject to the power of the stockholders of the Company to alter or repeal any bylaw whether adopted by them or otherwise.

Our Bylaws provide that the original or other bylaws of the Company may be adopted, amended, or repealed by the stockholders entitled to vote; provided, however, that the Company may, in our Certificate of Incorporation, confer the power to adopt, amend or repeal bylaws upon the directors. The fact that such power has been so conferred upon the directors shall not divest the stockholders of the power, nor limit their power to adopt, amend or repeal bylaws.

#### *Anti-Takeover Provisions of Delaware Law*

Our Certificate of Incorporation provides that the Company elects not to be governed by Section 203 of the DGCL. To the fullest extent permitted by section 122(17) of the DGCL, the Company, on behalf of itself and its subsidiaries, renounces any interest or expectancy of the Company and its subsidiaries in any Excluded Opportunity (as defined in the Certificate of Incorporation) or in being offered an opportunity to receive notice of or participate in any Excluded Opportunity, even if the opportunity is one that the Company or its subsidiaries might reasonably be deemed to have pursued or had the ability or desire to pursue if granted the opportunity to do so and no such individual, corporation, limited liability company, partnership, firm, joint venture, association, joint-stock company, trust, estate, unincorporated organization, governmental or regulatory body or other entity (“**Person**”) shall be liable to the Company or any of its subsidiaries for breach of any fiduciary or other duty, as a director or officer or otherwise, by reason of the fact that such Person pursues or acquires such Excluded Opportunity, directs such Excluded Opportunity to another Person or fails to present such Excluded Opportunity, or information regarding such Excluded Opportunity, to the Company or its subsidiaries. Any Person purchasing or otherwise acquiring any interest in any shares of stock of the Company shall be deemed to have notice of and consented to the provisions of our Certificate of Incorporation. Neither the alteration, amendment or repeal of our Certificate of Incorporation nor the adoption of any provision of our Certificate of Incorporation inconsistent with the above shall eliminate or reduce the effect of the above in respect of any business opportunity first identified or any other matter occurring, or any cause of action, suit or claim that, but for the above, would accrue or arise, prior to such alteration, amendment, repeal or adoption.

**Stock Exchange Listing**

Our Common Stock is listed on the Nasdaq Capital Market under the symbol “MBIO”.

**Transfer Agent and Registrar**

The Transfer Agent for our Common Stock is VStock Transfer, LLC.

MUSTANG BIO, INC.  
2016 INCENTIVE PLAN

STOCK OPTION AGREEMENT

Unless otherwise defined herein, the terms defined in the 2016 Incentive Plan (the “Plan”) shall have the same defined meanings in this Stock Option Agreement.

I. NOTICE OF STOCK OPTION GRANT

Name:

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

The undersigned Optionee has been granted an Option to purchase shares of Common Stock of the Company (“Common Stock”), subject to the terms and conditions of the Plan and this Option Agreement, as follows:

Date of Grant:

Vesting Commencement Date:

Exercise Price per Share:

Total Number of Shares Granted:

Total Exercise Price:

Type of Option: \_\_\_\_\_ Incentive Stock Option  
\_\_\_\_\_ Nonstatutory Stock Option

Term/Expiration Date:

Vesting Schedule:

This Option shall be exercisable, in whole or in part, according to the following vesting schedule:

[Vesting Schedule]

Vesting will cease upon the termination of the Optionee’s Continuous Service, and any unvested portion of the Option will be forfeited upon such termination, except as and to the extent provided in Optionee’s Executive Employment Agreement with the Company. In addition, the Option will automatically vest in its entirety upon a Change in Control provided that Optionee provides Continuous Service to the Company through such date.



Post-Termination Exercise Period:

The vested portion of this Option shall be exercisable for three (3) months after Optionee's Continuous Service ends (other than on account of death or Disability), provided, however, that if Optionee's Continuous Service is terminated for Cause, then the Option will immediately be terminated and no portion will thereafter be exercisable. Upon a termination of Optionee's Continuous Service due to death or Disability, this Option may be exercised for one (1) year after such Termination. In no event may Optionee exercise this Option after the Expiration Date as provided above.

**II. AGREEMENT**

1. Grant of Option. The Plan Administrator of the Company hereby grants to the Optionee named in the Notice of Grant (the "**Optionee**"), an option (the "**Option**") to purchase the number of Shares set forth in the Notice of Grant, at the exercise price per Share set forth in the Notice of Grant (the "**Exercise Price**"), and subject to the terms and conditions of the Plan, which is incorporated herein by reference. Subject to Section 13 of the Plan, in the event of a conflict between the terms and conditions of the Plan and this Option Agreement, the terms and conditions of the Plan shall prevail.

If designated in the Notice of Grant as an Incentive Stock Option ("**ISO**"), this Option is intended to qualify as an Incentive Stock Option as defined in Section 422 of the Code. Nevertheless, to the extent that it exceeds the \$100,000 rule of Code Section 422(d), this Option shall be treated as a Nonstatutory Stock Option ("**NSO**"). To the extent this Option is not designated as an ISO in the Notice of Stock Option Grant, the Option is an NSO.

2. Exercise of Option.

(a) Right to Exercise. This Option shall be exercisable during its term in accordance with the Vesting Schedule and Post-Termination Exercise Period set out in the Notice of Grant and with the applicable provisions of the Plan and this Option Agreement.

(b) Method of Exercise. This Option shall be exercisable by delivery of an exercise notice in the form attached as Exhibit A (the "**Exercise Notice**") which shall state the election to exercise the Option, the number of Shares with respect to which the Option is being exercised, and such other representations and agreements as may be required by the Company. The Exercise Notice shall be accompanied by payment of the aggregate Exercise Price as to all Exercised Shares. This Option shall be deemed to be exercised upon receipt by the Company of such fully executed Exercise Notice accompanied by the aggregate Exercise Price. Optionee may exercise the Option only for whole Shares.

No Shares shall be issued pursuant to the exercise of an Option unless such issuance and such exercise complies with Applicable Laws. Assuming such compliance, for income tax purposes the Shares shall be considered transferred to the Optionee on the date on which the Option is exercised with respect to such Shares.

3. Optionee's Representations. In the event the Shares have not been registered under the Securities Act of 1933, as amended (the "**Securities Act**"), at the time this Option is exercised, the Optionee shall, if required by the Company, concurrently with the exercise of all or any portion of this Option, deliver to the Company his or her Investment Representation Statement in the form attached hereto as Exhibit B.

4. Lock-Up Period. Optionee hereby agrees that, if so requested by the Company or any representative of the underwriters (the "**Managing Underwriter**") in connection with any registration of the offering of any securities of the Company under the Securities Act, Optionee shall not sell or otherwise transfer any Shares or other securities of the Company during the 180-day period (or such other period as may be requested in writing by the Managing Underwriter and agreed to in writing by the Company) (the "**Market Standoff Period**") following the effective date of a registration statement of the Company filed under the Securities Act. Such restriction shall apply only to the first registration statement of the Company to become effective under the Securities Act that includes securities to be sold on behalf of the Company to the public in an underwritten public offering under the Securities Act. The Company may impose stop-transfer instructions with respect to securities subject to the foregoing restrictions until the end of such Market Standoff Period.

5. Method of Payment. Payment of the aggregate Exercise Price shall be by any of the following, or a combination thereof, at the election of the Optionee:

(a) cash or check;

(b) if the fair market value of one Share is greater than the Exercise Price (at the date of calculation as set forth below), the Optionee may elect to receive Shares equal to the value (as determined below) of this Option (or the portion thereof being exercised) via a cashless exercise, in which event the Company shall issue to the Optionee a number of Shares computed using the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where: X = the number of Shares to be issued to the Optionee

Y = the number of Shares purchasable under the Option or, if only a portion of the Option is being exercised, that portion of the Option being exercised (at the date of such calculation)

A = the fair market value of one Share (at the date of such calculation)

B = Exercise Price (as adjusted to the date of such calculation)

For purposes of the above calculation, the "fair market value" of one Share shall be that price determined by the Company's Board of Directors in good faith; provided, however, if the Company is trading in the over the counter market or on a recognized exchange, fair market value shall be the last sales price on the day prior to exercise.; or

(c) surrender of other Shares which, (i) in the case of Shares acquired upon exercise of an option, have been owned by the Optionee for more than six (6) months on the date of surrender, and (ii) have a Fair Market Value on the date of surrender equal to the aggregate Exercise Price of the exercised Shares.

6. Restrictions on Exercise. This Option may not be exercised until such time as the Plan has been approved by the stockholders of the Company, or if the issuance of such Shares upon such exercise or the method of payment of consideration for such shares would constitute a violation of any Applicable Law.

7. Non-Transferability of Option. This Option may not be transferred in any manner otherwise than by will or by the laws of descent or distribution and may be exercised during the lifetime of Optionee only by Optionee. The terms of the Plan and this Option Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of the Optionee.

8. Term of Option. This Option may be exercised only within the term set out in the Notice of Grant, and may be exercised during such term only in accordance with the Plan and the terms of this Option.

9. Tax Consequences. Set forth below is a brief summary as of the date of this Option of some of the federal tax consequences of exercise of this Option and disposition of the Shares. THIS SUMMARY IS NECESSARILY INCOMPLETE, AND THE TAX LAWS AND REGULATIONS ARE SUBJECT TO CHANGE. THIS SUMMARY DOES NOT INCLUDE ANY DISCUSSION OF STATE OR LOCAL TAX CONSEQUENCES. OPTIONEE SHOULD CONSULT A TAX ADVISER BEFORE EXERCISING THIS OPTION OR DISPOSING OF THE SHARES.

(a) Exercise of ISO. If this Option qualifies as an ISO, there will be no regular federal income tax liability upon the exercise of the Option, although the excess, if any, of the fair market value of the Shares on the date of exercise over the Exercise Price will be treated as an item of adjustment to the alternative minimum tax for federal tax purposes in the year of exercise and may subject the Optionee to the alternative minimum tax. If the Option qualifies as an ISO and is exercised through a cashless exercise process as described in Section 5(b) above, the exercise may be treated as a Disqualifying Disposition as to the Shares surrendered such that the difference between the fair market value of the Shares surrendered over the Exercise Price for those Shares will be treated as compensation income (taxable at ordinary income rates).

(b) Exercise of Nonstatutory Stock Option. If this Option does not qualify as an ISO, there may be a regular federal income tax liability upon the exercise of the Option. The Optionee will be treated as having received compensation income (taxable at ordinary income tax rates) equal to the excess, if any, of the fair market value of the Shares on the date of exercise over the Exercise Price and the Company will qualify for a deduction in the same amount, subject to the requirement that the compensation be reasonable. If Optionee is an employee, the Company will be required to withhold from Optionee's compensation or collect from Optionee and pay to the applicable taxing authorities an amount equal to a percentage of this compensation income at the time of exercise.

(c) Disposition of Shares. In the case of an NSO, if Shares are held for at least one year, any gain realized on disposition of the Shares will be treated as long-term capital gain for federal income tax purposes. In the case of an ISO, if Shares transferred pursuant to the Option are held for at least one year after exercise and are disposed of at least two years after the Date of Grant, any gain realized on disposition of the Shares will also be treated as long-term capital gain for federal income tax purposes. If Shares purchased under an ISO are disposed of before the later of (1) the date two years after the Date of Grant, or (2) the date one year after the date of exercise (such disposition a “**Disqualifying Disposition**”), any gain realized on such disposition will be treated as compensation income (taxable at ordinary income rates) in an amount equal to the excess of the lesser of (1) the fair market value of the Shares on the date of exercise, or (2) the sale price of the Shares over the Exercise Price paid for those Shares. The Company will also be allowed a deduction equal to any such amount recognized, subject to the requirement that the compensation be reasonable.

(d) Notice of Disqualifying Disposition of ISO Shares. If the Option is designated as an ISO, then in the event of a Disqualifying Disposition, the Optionee shall immediately, and in any event not later than fifteen (15) days after such disposition, notify the Company in writing of such disposition.

10. Withholding Obligations. At the time Optionee exercises the Option (in whole or in part), or at the time of a Disqualifying Disposition in the case of an ISO, Optionee may incur tax obligations under federal, state, local, and/or foreign law, which the Company may be required to withhold from Optionee’s compensation or otherwise collect from Optionee. Optionee agrees that the Company may satisfy such withholding by any of the following means or by a combination of such means, in the Company’s discretion: (i) withholding from any compensation otherwise payable to the Optionee by the Company; (ii) causing the Optionee to tender a cash payment; or (iii) withholding from the Shares otherwise issuable to Optionee upon exercise of the Option the number of Shares with a Fair Market Value (measured as of the date the tax withholding obligations are to be determined) equal to the amount of such tax withholding; provided, however, that the number of such Shares so withheld will not exceed the amount necessary to satisfy the Company’s required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income (or such lesser amount as may be necessary to avoid classification of the Shares as a liability for financial accounting purposes). Optionee understands that all matters with respect to the total amount of taxes to be withheld in respect of such compensation income will be determined by the Company in its reasonable discretion. Optionee further understands that, although the Company will pay withheld amounts to the applicable taxing authorities, the Optionee remains responsible for payment of all taxes due as a result of income arising under the Agreement.

11. Entire Agreement; Governing Law. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute one agreement. The Plan is incorporated herein by reference. The Plan and this Option Agreement constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and Optionee with respect to the subject matter hereof, and may not be modified adversely to the Optionee’s interest except by means of a



writing signed by the Company and Optionee. This Agreement will be governed by the laws of the state of Delaware (with the exception of its conflict of law provisions).

12. No Guarantee of Continued Service. OPTIONEE ACKNOWLEDGES AND AGREES THAT THE VESTING OF SHARES PURSUANT TO THE VESTING SCHEDULE HEREOF IS EARNED ONLY BY CONTINUING AS AN EMPLOYEE OR OTHER SERVICE PROVIDER AT THE WILL OF THE COMPANY (NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THIS OPTION OR ACQUIRING SHARES HEREUNDER). OPTIONEE FURTHER ACKNOWLEDGES AND AGREES THAT THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED EMPLOYMENT FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND SHALL NOT INTERFERE IN ANY WAY WITH OPTIONEE'S RIGHT OR THE COMPANY'S RIGHT TO TERMINATE OPTIONEE'S RELATIONSHIP WITH THE COMPANY AT ANY TIME, WITH OR WITHOUT CAUSE.

[Signature Page Follows]

Optionee acknowledges receipt of a copy of the Plan and represents that he or she is familiar with the terms and provisions thereof, and hereby accepts this Option subject to all of the terms and provisions thereof. Optionee has reviewed the Plan and this Option in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Option and fully understands all provisions of the Option. Optionee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan or this Option. Optionee further agrees to notify the Company upon any change in the residence address indicated below.

**OPTIONEE**

**MUSTANG BIO, INC.**

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Print Name*

\_\_\_\_\_  
*Print Name*

\_\_\_\_\_  
*Residence Address*

\_\_\_\_\_  
*Title*

**EXHIBIT A**  
**2016 INCENTIVE PLAN**  
**EXERCISE NOTICE**

Mustang Bio, Inc.

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Attention: Corporate Secretary

1. Exercise of Option. Effective as of today, \_\_\_\_\_, \_\_\_\_\_, the undersigned (“**Optionee**”) hereby elects to exercise Optionee’s option to purchase \_\_\_\_\_ shares of the Common Stock (the “**Shares**”) of Mustang Bio, Inc. (the “**Company**”) under and pursuant to the 2016 Incentive Plan (the “**Plan**”) and the Stock Option Agreement dated \_\_\_\_\_, \_\_\_\_\_ (the “**Option Agreement**”).

2. Delivery of Payment (check one).

\_\_\_ Optionee herewith delivers to the Company the full purchase price of the Shares, as set forth in the Option Agreement, and any and all withholding taxes due in connection with the exercise of the Option; or

\_\_\_ Optionee hereby elects the cashless exercise provision of Section 5(b) of the Option Agreement.

3. Representations of Optionee. Optionee acknowledges that Optionee has received, read and understood the Plan and the Option Agreement and agrees to abide by and be bound by their terms and conditions.

4. Rights as Stockholder. Until the issuance of the Shares (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder shall exist with respect to the Shares, notwithstanding the exercise of the Option. The Shares shall be issued to the Optionee as soon as practicable after the Option is exercised in accordance with the Option Agreement. No adjustment shall be made for a dividend or other right for which the record date is prior to the date of issuance except as provided in Section 13 of the Plan.

5. Company’s Right of First Refusal. Before any Shares held by Optionee or any transferee (either being sometimes referred to herein as the “**Holder**”) may be sold or otherwise transferred (including transfer by gift or operation of law), the Company or its assignee(s) shall have a right of first refusal to purchase the Shares on the terms and conditions set forth in this Section 5 (the “**Right of First Refusal**”).

(a) Notice of Proposed Transfer. The Holder of the Shares shall deliver to the Company a written notice (the “**Notice**”) stating: (i) the Holder’s bona fide intention to sell or otherwise transfer such Shares; (ii) the name of each proposed purchaser or other transferee

(“**Proposed Transferee**”); (iii) the number of Shares to be transferred to each Proposed Transferee; and (iv) the bona fide cash price or other consideration for which the Holder proposes to transfer the Shares (the “**Offered Price**”), and the Holder shall offer the Shares at the Offered Price to the Company or its assignee(s).

(b) Exercise of Right of First Refusal. At any time within thirty (30) days after receipt of the Notice, the Company and/or its assignee(s) may, by giving written notice to the Holder, elect to purchase all, but not less than all, of the Shares proposed to be transferred to any one or more of the Proposed Transferees, at the purchase price determined in accordance with subsection (c) below.

(c) Purchase Price. The purchase price (“**Purchase Price**”) for the Shares purchased by the Company or its assignee(s) under this Section 5 shall be the Offered Price. If the Offered Price includes consideration other than cash, the cash equivalent value of the non-cash consideration shall be determined by the Board of Directors of the Company in good faith.

(d) Payment. Payment of the Purchase Price shall be made, at the option of the Company or its assignee(s), in cash (by check), by cancellation of all or a portion of any outstanding indebtedness of the Holder to the Company (or, in the case of repurchase by an assignee, to the assignee), or by any combination thereof within thirty (30) days after receipt of the Notice or in the manner and at the times set forth in the Notice.

(e) Holder’s Right to Transfer. If all of the Shares proposed in the Notice to be transferred to a given Proposed Transferee are not purchased by the Company and/or its assignee(s) as provided in this Section 5, then the Holder may sell or otherwise transfer such Shares to that Proposed Transferee at the Offered Price or at a higher price; *provided* that such sale or other transfer is consummated within 120 days after the date of the Notice, that any such sale or other transfer is effected in accordance with any applicable securities laws and that the Proposed Transferee agrees in writing that the provisions of this Section 5 shall continue to apply to the Shares in the hands of such Proposed Transferee. If the Shares described in the Notice are not transferred to the Proposed Transferee within such period, a new Notice shall be given to the Company, and the Company and/or its assignees shall again be offered the Right of First Refusal before any Shares held by the Holder may be sold or otherwise transferred.

(f) Exception for Certain Family Transfers. Anything to the contrary contained in this Section 5 notwithstanding, the transfer of any or all of the Shares during the Optionee’s lifetime or on the Optionee’s death by will or intestacy to the Optionee’s immediate family or a trust for the benefit of the Optionee’s immediate family shall be exempt from the provisions of this Section 5. “**Immediate Family**” as used herein shall mean spouse, lineal descendant or antecedent, father, mother, brother or sister. In such case, the transferee or other recipient shall receive and hold the Shares so transferred subject to the provisions of this Section 5, and there shall be no further transfer of such Shares except in accordance with the terms of this Section 5.

(g) Termination of Right of First Refusal. The Right of First Refusal shall terminate as to any Shares upon the earlier of (i) the first sale of Common Stock of the Company

to the general public, or (ii) a Change in Control (as defined in the Plan) in which the successor corporation has equity securities that are publicly traded.

6. Tax Consultation. Optionee understands that Optionee may suffer adverse tax consequences as a result of Optionee's purchase or disposition of the Shares. Optionee represents that Optionee has consulted with any tax consultants Optionee deems advisable in connection with the purchase or disposition of the Shares and that Optionee is not relying on the Company for any tax advice.

7. Restrictive Legends and Stop-Transfer Orders.

(a) Legends. Optionee understands and agrees that the Company shall cause the legends set forth below or legends substantially equivalent thereto, to be placed upon any certificate(s) evidencing ownership of the Shares together with any other legends that may be required by the Company or by state or federal securities laws:

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "ACT") AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT OR, IN THE OPINION OF COMPANY COUNSEL SATISFACTORY TO THE ISSUER OF THESE SECURITIES, SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION IS IN COMPLIANCE THEREWITH.

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFER AND A RIGHT OF FIRST REFUSAL HELD BY THE ISSUER OR ITS ASSIGNEE(S) AS SET FORTH IN THE EXERCISE NOTICE BETWEEN THE ISSUER AND THE ORIGINAL HOLDER OF THESE SHARES, A COPY OF WHICH MAY BE OBTAINED AT THE PRINCIPAL OFFICE OF THE ISSUER. SUCH TRANSFER RESTRICTIONS AND RIGHT OF FIRST REFUSAL ARE BINDING ON TRANSFEREES OF THESE SHARES.

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS ON TRANSFER FOLLOWING THE EFFECTIVE DATE OF THE UNDERWRITTEN PUBLIC OFFERING OF THE COMPANY'S SECURITIES AND MAY NOT BE SOLD OR OTHERWISE DISPOSED OF BY THE HOLDER WITHOUT THE CONSENT OF THE COMPANY OR THE MANAGING UNDERWRITER.

(b) Stop-Transfer Notices. Optionee agrees that, in order to ensure compliance with the restrictions referred to herein, the Company may issue appropriate "stop transfer" instructions to its transfer agent, if any, and that, if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.

(c) Refusal to Transfer. The Company shall not be required (i) to transfer on its books any Shares that have been sold or otherwise transferred in violation of any of the provisions of this Exercise Notice or (ii) to treat as owner of such Shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such Shares shall have been so transferred.

8. Successors and Assigns. The Company may assign any of its rights under this Exercise Notice to single or multiple assignees, and this Exercise Notice shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth, this Exercise Notice shall be binding upon Optionee and his or her heirs, executors, administrators, successors and assigns.

9. Interpretation. Any dispute regarding the interpretation of this Exercise Notice shall be submitted by Optionee or by the Company forthwith to the administrator of the Plan which shall review such dispute at its next regular meeting. The resolution of such a dispute by the administrator of the Plan shall be final and binding on all parties.

10. Governing Law; Severability. This Exercise Notice is governed by the internal substantive laws but not the choice of law rules, of the State of Delaware. In the event that any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Exercise Notice will continue in full force and effect.

11. Entire Agreement. The Plan and Option Agreement are incorporated herein by reference. This Exercise Notice, the Plan, the Option Agreement and the Investment Representation Statement constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and Optionee with respect to the subject matter hereof, and may not be modified adversely to the Optionee's interest except by means of a writing signed by the Company and Optionee.

Submitted by:

Accepted by:

**OPTIONEE**

**MUSTANG BIO, INC.**

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Print Name*

\_\_\_\_\_  
*Print Name*

\_\_\_\_\_  
*Title*

*Address:*

*Address:*

\_\_\_\_\_  
*Date Received*

## EXHIBIT B

### INVESTMENT REPRESENTATION STATEMENT

OPTIONEE: \_\_\_\_\_  
COMPANY: MUSTANG BIO, INC.  
SECURITY: COMMON STOCK  
AMOUNT: \_\_\_\_\_  
DATE: \_\_\_\_\_

In connection with the purchase of the above-listed securities, I, the Optionee, represent to the Company the following.

1. Optionee is aware of the Company's business affairs and financial condition and has acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the securities. Optionee is purchasing the securities for investment for Optionee's own account only, and not with a view to, or for resale in connection with, any "distribution" thereof within the meaning of the Securities Act of 1933, as amended (the "Securities Act").

2. Optionee understands that the securities have not been registered under the Securities Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of Optionee's investment intent as expressed herein.

3. Optionee further understands that the securities must be held indefinitely unless subsequently registered under the Securities Act or unless an exemption from registration is available. Moreover, Optionee understands that the Company is under no obligation to register the securities. In addition, Optionee understands that the certificate evidencing the securities will be imprinted with a legend that prohibits the transfer of the securities unless they are registered or such registration is not required in the opinion of counsel for the Company.

4. Optionee is familiar with the provisions of Rules 144 and 701, promulgated under the Securities Act, that permit limited public resale of "restricted securities" acquired, directly or indirectly, from the issuer thereof (or from an affiliate of such issuer) in a nonpublic offering, subject to the satisfaction of certain conditions.

In the event the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the securities exempt under Rule 701 may be resold by the Optionee 90 days thereafter, subject to the satisfaction of certain of the conditions specified by Rule 144, including the sale being made through a broker in an unsolicited "broker's transaction" or in transactions directly with a market maker (as that term is defined under the Exchange Act) and, in the case of an affiliate, the availability of certain public information about the Company, and the amount of securities being sold during any three month period not exceeding the limitations specified in Rule 144(e), if applicable.

If the purchase of the securities does not qualify under Rule 701 at the time of purchase, then the securities may be resold by the Optionee in certain limited circumstances subject to the provisions of Rule 144, which require: (a) the availability of certain public information about the Company; (b) the resale occurring not less than six months after the party has purchased, and made full payment (within the meaning of Rule 144) for, the securities to be sold; and (c) in the case of an affiliate, the sale being made through a broker in an unsolicited “broker’s transaction” or in transactions directly with a market maker (as that term is defined under the Exchange Act) and the amount of securities being sold during any three-month period not exceeding the specified limitations. If all of the requirements of Rule 144 are not satisfied, Optionee may be able to sell the securities without registration pursuant to the exemption contained in Rule 144, provided that the resale occurs not less than one year after the party has purchased, and made full payment (within the meaning of Rule 144) for, the securities.

5. Optionee further understands that at the time Optionee wishes to sell the securities there may be no public market upon which to make such a sale, and that, even if such a public market then exists, the Company may not be satisfying the current public information requirements of Rules 144 or 701, and that, in such event, Optionee may be precluded from selling the securities under Rules 144 or 701 even if the relevant holding periods have been satisfied.

6. Optionee further understands that in the event all of the applicable requirements of Rules 144 or 701 are not satisfied, registration under the Securities Act or some registration exemption will be required; and that, notwithstanding the fact that Rules 144 and 701 are not exclusive, the Staff of the Securities and Exchange Commission has expressed its opinion that persons proposing to sell private placement securities other than in a registered offering and otherwise than pursuant to Rules 144 or 701 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales, and that such persons and their brokers who participate in such transactions do so at their own risk.

**OPTIONEE**

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*Signature*

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*Print Name*

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*Date*

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MUSTANG BIO, INC.  
2016 STOCK INCENTIVE PLAN

RESTRICTED STOCK UNIT AWARD AGREEMENT

This Restricted Stock Unit Award Agreement (this “*Agreement*”) is made and entered into between Mustang Bio, Inc. (the “*Company*”) and [ ] (“*Grantee*”), effective as of [ ] (such date the “*Date of Grant*”). This Agreement sets forth the terms and conditions associated with the Company’s award to Grantee of Restricted Stock Units payable as described below in shares of Common Stock from the Company pursuant to the Company’s 2016 Stock Incentive Plan (the “*Plan*”) for the number of Units set forth below (collectively, the “*Award*”). Capitalized terms used herein which are not otherwise defined herein will have the meanings ascribed to them under the Plan.

NOW, THEREFORE, in consideration of the foregoing and Grantee’s continued provision of valuable services as an employee or consultant of the Company, it is agreed by and between the parties as follows:

**1. Grant of Units.** Effective as of the Date of Grant, the Company hereby grants the Grantee [ ] Restricted Stock Units (the “*Units*”). The Units are subject to the vesting, payment, and other provisions of this Agreement and the Plan. Each Unit represents the value of one (1) share of Common Stock of the Company (a “*Share*”). The Company will account for the Units in a bookkeeping account on the Grantee’s behalf until they become payable or are forfeited.

**2. Vesting.** The Units are unvested when granted, and will vest as described below, provided that vesting may accelerate or cease as provided for in this Agreement or in the Plan.

[Vesting Schedule]

**3. Effect of Termination of Continuous Service.** In the event of the termination of Grantee’s Continuous Service, all Units that are not vested will be forfeited.

**4. Delivery of Shares to Settle Vested Units.** Units vested as provided in Section 2 will be settled by delivering to Grantee a number of Shares equal to the number of vested Units as soon as practicable after the vesting date, provided that the Company may provide a reasonable delay in the issuance or delivery of the Shares to address tax withholding and other administrative matters and provided further that delivery of the Shares will occur no later than two and one-half months following the conclusion of the year in which the vesting occurs.

On such date, the Company will, at its election, either: (a) issue a certificate representing the Shares payable pursuant to this Agreement; or (b) not issue any certificate representing the Shares payable pursuant to this Agreement and instead document the Grantee’s interest in the Shares by registering such Shares with the Company’s transfer agent (or another custodian selected by the Company) in bookentry form in the Grantee’s name.

**5. Capitalization Changes.** The number of Units convertible to Shares subject to this Award may be adjusted from time to time by the Administrator to account for changes in capitalization as described in Section 12 of the Plan.

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**6. Rights as a Stockholder.** The Units represent a right to payment from the Company if the conditions of the Agreement are met and do not give the Grantee ownership of any Common Stock prior to delivery as provided in Section 4. Grantee shall not have any rights and/or privileges of a stockholder of the Company with respect to the Units prior to such delivery. If Grantee becomes vested in Units as provided in Section 2, any Shares to which Grantee becomes entitled shall be delivered to Grantee as provided in Section 4, and Grantee shall have full ownership of the Shares upon such delivery.

**7. Non-Transferability of the Award.** The Units and the right to payment under this Agreement are not transferable, may not be sold, exchanged, transferred, pledged, hypothecated, encumbered or otherwise disposed of except as provided in the Plan. Any purported transfer of the Units or the right to payment under this Agreement is null and void and will not be given effect.

**8. Award Not An Employment Agreement.** The Award is not an employment or service contract, and nothing this Agreement confers or will be construed as conferring upon the Grantee any right to continue in the employment or service of the Company, or as interfering with or restricting in any way the right of either party to terminate such employment or service at any time.

**9. Tax Consequences.** Grantee acknowledges that he/she understands the federal, state, and local tax consequences of the Award and the issuance, vesting, forfeiture, and delivery provisions hereof relating to the Units. Grantee will rely solely on the advice of his/her own tax advisors and not on any statements or representations of the Company or any of its agents. Grantee understands that Grantee (and not the Company) shall be responsible for his/her own tax liability that may arise as a result of the Award or the transactions contemplated by this Agreement.

**10. Withholding Obligations.** Grantee understands that, at the time that Grantee becomes vested and/or receives payment for any Units (including through the delivery of Shares), the Company may be required to withhold federal, state and local income and employment taxes. At the time of vesting, or at or before the time Grantee receives a distribution of the Shares underlying the Units or other consideration, or at any time thereafter as requested by the Company, Grantee hereby authorizes the Company to satisfy any required withholding to satisfy federal, state, local, payroll, and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with the Units (the "**Withholding Taxes**"). Notwithstanding any other provision of this Section, the Company may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to the Units by any of the following means or by a combination of such means: (a) withholding from any compensation otherwise payable to the Grantee by the Company; (b) causing the Grantee to tender a cash payment; or (c) withholding Shares from the Shares issued or otherwise issuable to Grantee in connection with the Units with a Fair Market Value (measured as of the date the Withholding Taxes are to be determined) equal to the amount of such Withholding Taxes; *provided, however*, that the number of such Shares so withheld shall not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income (or such lesser amount as may be necessary to avoid classification of the Units as a liability for financial accounting purposes). Grantee understands that all matters with respect to the total amount of taxes to be withheld in respect of such compensation income will be determined by the Administrator in its reasonable discretion. Grantee further understands that, although the Company may pay withheld amounts to the applicable taxing authorities, the Grantee is responsible for payment of all taxes due as a result of compensation arising under the Agreement.

**11. Data Privacy.** Grantee acknowledges that the Company holds certain personal information about Grantee, including, but not limited to: name, home address and telephone number, date of birth, social security number or other identification number, compensation, nationality, job title, details of the Award, and any other entitlement to shares of stock awarded, cancelled, exercised, vested or unvested. Grantee consents to the collection, use and transfer, in electronic or other form, of such personal data for the purpose of implementing, administering, and managing this Award.

**12. Notices.** Any notice or request required or permitted hereunder shall be given in writing to each of the other parties hereto and shall be deemed effectively given on the earlier of (a) the date of personal delivery, or (b) three days after the date of deposit in the United States Mail by registered or certified mail, postage prepaid, return receipt requested, addressed in the case of the Company to the Company's Chief Executive Officer at the Company's primary business address and in the case of the Grantee to the most recent address shown in the Company's records.

**13. Incorporation of the Plan; Entire Agreement; Modification.** The Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of this Agreement, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of this Agreement and those of the Plan, the provisions of the Plan shall control. This Agreement (including the Plan) sets forth all of the promises, agreements, conditions and understandings between the parties hereto with respect to the Award, and there are no promises, agreements, conditions, understandings, warranties or representations, oral or written, express or implied, between them with respect to the Award other than as set forth therein or herein. This Agreement supersedes and replaces any and all prior agreements between the parties hereto with respect to Restricted Stock Units granted under this Award. Except as provided by the Plan, no modification, amendment or waiver of any of the provisions of this Agreement will be effective unless approved in writing by both parties.

**14. Choice of Law.** The interpretation, performance and enforcement of this Agreement shall be governed by the law of the state of New York without regard to the conflicts of laws rules of any jurisdiction.

**15. Miscellaneous.**

(a) The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

(b) If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

(c) This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, successors and assigns. The rights and obligations of the Company under this Agreement shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(d) The waiver by either party of compliance with any provision of this Agreement by the other party will not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by such party of a provision of this Agreement.

(e) Grantee agrees upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of the Award.

(f) Grantee acknowledges and agrees that he/she (i) has reviewed this Agreement and the Plan in their entirety; (ii) fully understands the provisions of each such document; and (iii) has had an opportunity to obtain the advice of counsel prior to executing and accepting the Award. Grantee further

acknowledges receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act.

(g) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(h) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

(i) This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same agreement. Facsimile or PDF reproductions of original signatures will be deemed binding for the purpose of the execution of this Agreement.

**16. Application of Section 409A of the Code.**

(a) The parties intend that the delivery of Shares or other consideration in respect of the Units provided under this Agreement satisfies, to the greatest extent possible, the exemption from the application of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively, "**Section 409A**") provided under Treasury Regulations Section 1.409A-1(b)(4) (or any other applicable exemption), and this Agreement will be construed to the greatest extent possible as consistent with those provisions. To the extent not so exempt, the delivery of Shares or other consideration in respect of the Units provided under this Agreement will be conducted, and this Agreement will be construed, in a manner that complies with Section 409A and is consistent with the requirements for avoiding taxes or penalties under Section 409A.

(b) The parties further intend that each installment of any payments provided for in this Agreement is a separate "payment" for purposes of Section 409A.

(c) To the extent any payment hereunder due upon the occurrence of a Corporate Transaction is deferred compensation that is subject to Section 409A, and is not otherwise exempt from complying with the provisions of Section 409A, then a Corporate Transaction shall only be deemed to occur if the Corporate Transaction also qualifies as a "change in control event" with respect to the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5).

(d) The Company makes no representations to Grantee regarding the compliance of this Agreement or the Units with Section 409A, and Grantee is solely responsible for the payment of any taxes or penalties arising under Section 409A(a)(1), or any state law of similar effect, with respect to the grant or vesting of the Units or the delivery of the Shares subject to this Award.

[SIGNATURE PAGE FOLLOWS]

Mustang Bio, Inc. · 377 Plantation Street · Worcester, MA · 01605

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**IN WITNESS WHEREOF**, the Company has caused this Agreement to be signed by its duly authorized officer, and Grantee has hereunto set his/her hand and seal.

**GRANTEE:**

**COMPANY:**

MUSTANG BIO, INC.

\_\_\_\_\_  
Signature

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Mustang Bio, Inc. · 377 Plantation Street · Worcester, MA · 01605

---

**RESTRICTED STOCK AWARD CERTIFICATE**

*Non-transferable*  
GRANT TO

(“Grantee”)

by Mustang Bio, Inc. (the “Company”) of  
shares of its common stock, \$0.0001 par value (the “Shares”)

pursuant to and subject to the provisions of the Mustang Bio, Inc. 2016 Incentive Plan (the “Plan”) and the Amended and Restated Non-Employee Directors Compensation Plan (the “Director Plan”) and to the terms and conditions set forth on the following pages of this award certificate (this “Certificate”). Capitalized terms used herein and not otherwise defined shall have the meanings assigned to such terms in the Plan.

Unless vesting is accelerated in accordance with the Plan, the Shares shall vest and become nonforfeitable in accordance with the following schedule, provided that Grantee remains in Continuous Service on each applicable vesting date:

<u>Continuous Service</u> <u>after Grant Date</u>	<u>Number of</u> <u>Shares Vested</u>
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By accepting the Shares, Grantee shall be deemed to have agreed to the terms and conditions set forth in this Certificate, the Plan and the Director Plan.

IN WITNESS WHEREOF, Mustang Bio, Inc., acting by and through its duly authorized officers, has caused this Certificate to be duly executed.

MUSTANG BIO, INC.

By: \_\_\_\_\_

Grant Date:



## TERMS AND CONDITIONS

1. Restrictions. The Shares are subject to each of the following restrictions. “Restricted Shares” mean those Shares that are subject to the restrictions imposed hereunder which restrictions have not then expired or terminated. Restricted Shares may not be sold, transferred, exchanged, assigned, pledged, hypothecated or otherwise encumbered to or in favor of any party, or be subjected to any lien, obligation or liability of Grantee to any other party. If Grantee’s Continuous Service terminates for any reason, then Grantee shall forfeit all of Grantee’s right, title and interest in and to the Restricted Shares as of the date of termination, and such Restricted Shares shall revert to the Company immediately following the event of forfeiture. The restrictions imposed under this Section 1 shall apply to all shares of Stock or other securities issued with respect to Restricted Shares hereunder in connection with any merger, reorganization, consolidation, recapitalization, stock dividend or other change in corporate structure affecting the Stock.

2. Expiration and Termination of Restrictions. The restrictions imposed under Section 1 will expire on the earliest to occur of the following (the period prior to such expiration being referred to herein as the “Restricted Period”):

(a) as to the number of the Restricted Shares specified on the cover page hereof, on the respective dates specified on such cover page, provided that Grantee is in Continuous Service on each such date; or

(b) as to all of the Restricted Shares, upon the occurrence of a Change in Control, provided that Grantee is in Continuous Service on the date of such Change in Control.

3. Delivery of Shares. The Shares will be registered in the name of Grantee as of the Grant Date and may be held by the Company during the Restricted Period in certificated or uncertificated form. Any certificate for the Restricted Shares issued during the Restricted Period shall bear a legend in substantially the following form (in addition to any legend required under applicable state securities laws): “This certificate and the shares of stock represented hereby are subject to the terms and conditions (including forfeiture and restrictions against transfer) contained in a Restricted Stock Certificate between the registered owner of the shares represented hereby and Mustang Bio, Inc.

Release from such terms and conditions shall be made only in accordance with the provisions of such Certificate, copies of which are on file in the offices of Mustang Bio, Inc.” Stock certificates for the Shares, without the first above legend, shall be delivered to Grantee or Grantee’s designee upon request of Grantee after the expiration of the Restricted Period, but delivery may be postponed for such period as may be required for the Company with reasonable diligence to comply, if deemed advisable by the Company, with registration requirements under the 1933 Act, listing requirements of any Exchange, and requirements under any other law or regulation applicable to the issuance or transfer of the Shares.

4. Voting and Dividend Rights. Grantee, as beneficial owner of the Shares, shall have full voting and dividend rights with respect to the Shares during and after the Restricted Period, or until the Shares are forfeited. If Grantee forfeits any rights he or she may have under this Certificate, Grantee shall no longer have any rights as a stockholder with respect to the Restricted Shares or any interest therein and Grantee shall no longer be entitled to vote or receive dividends on such Restricted Shares. In the event that for any reason Grantee shall have received dividends upon such Shares after such forfeiture, Grantee shall repay to the Company any amount equal to such dividends.

5. No Right of Continued Service. Nothing in this Certificate shall interfere with or limit in any way the right of the Company or any Affiliate to terminate Grantee’s Continuous Service at any time, nor confer upon Grantee any right to continue providing services to the Company or any Affiliate.

6. Payment of Taxes. Upon issuance of the Shares hereunder, Grantee may make an election to be taxed upon such award under Section 83(b) of the Code (an “(83(b) Election)”). To effect such 83(b) Election, Grantee may file an appropriate election with Internal Revenue Service within 30 days after the Grant Date and otherwise in accordance with applicable Treasury Regulations.

7. Clawback. The Shares shall be subject to any compensation recoupment policy of the Company that is applicable by its terms to Grantee and to awards of this type.

8. Plan Controls. The terms contained in the Plan and the Director Plan are incorporated into and made a part of this Certificate, and this Certificate shall be governed by and construed in accordance with the Plan and the Director Plan. In the event of any actual or alleged conflict between the provisions of the Plan or the Director Plan and the provisions of this Certificate, the provisions of the Plan or the Director Plan shall be controlling and determinative.

9. Successors. This Certificate shall be binding upon any successor of the Company, in accordance with the terms of this Certificate, the Plan and the Director Plan.

10. Notice. Notices and communications under this Certificate must be in writing and either personally delivered or sent by registered or certified United States mail, return receipt requested, postage prepaid. Notices to the Company must be addressed to Mustang Bio, Inc., 2 Gansevoort St, 9<sup>th</sup> Floor, New York, NY 10014: Attn: Secretary, or any other address designated by the Company in a written notice to Grantee. Notices to Grantee will be directed to the address of Grantee then currently on file with the Company, or at any other address given by Grantee in a written notice to the Company.

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statement (No. 333-255476) 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 11, 2024, with respect to the financial statements of Mustang Bio, Inc.

/s/ KPMG LLP  
Boston, Massachusetts  
March 11, 2024

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

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

- (1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 of Mustang Bio, Inc. (the registrant);
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in 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) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 11, 2024

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

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

I, James Murphy, Interim Chief Financial Officer (Principal Financial Officer), certify that:

- (1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2023 of Mustang Bio, Inc. (the registrant);
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in 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) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 11, 2024

By: /s/ James Murphy  
James Murphy  
Interim Chief Financial Officer  
(Principal Financial Officer)

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**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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Manuel Litchman, M.D., President and Chief Executive Officer, 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 11, 2024

By: /s/ Manuel Litchman

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

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**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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Murphy, Interim Chief 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 11, 2024

By: /s/ James Murphy  
James Murphy  
Interim Chief Financial Officer  
(Principal Financial Officer)

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## MUSTANG BIO, INC.

**Clawback Policy  
October 2, 2023**

The Board of Directors (“Board”) of Mustang Bio, Inc. (“Company”) believes that it is in the best interests of the Company and its shareholders to adopt this Clawback Policy (“Policy”) which provides for the recoupment of certain executive compensation in the event of an Accounting Restatement (as defined below).

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Securities Exchange Act of 1934, as amended (“Exchange Act”), and final rules and amendments adopted by the Securities and Exchange Commission (“SEC”) to implement the aforementioned legislation, and Rule 5608 of the Nasdaq Stock Exchange’s listing standards.

This policy shall be effective as of October 2, 2023, the Effective Date of Rule 5608 of the Nasdaq Stock Exchange’s listing standards (the “Effective Date”) and applies to all Covered Officers (as defined below) of Mustang Bio, Inc.

**Administration**

This Policy shall be administered by the Compensation Committee of the Board (if composed entirely of independent directors) or if so designated by the Board, a separate committee of the Board, consisting of a majority of the independent directors serving on the board (as applicable, the “Administrator”). The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy. Any determinations made by the Administrator shall be final and binding on all affected individuals and need not be uniform with respect to each individual covered by the Policy. In the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board, such as the Audit Committee or the Compensation Committee, as may be necessary or appropriate as to matters within the scope of such other committee’s responsibility and authority.

Subject to any limitation under applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

**Definitions**

For purposes of this Policy, the following definitions will apply:

“**Accounting Restatement**” means an accounting restatement of the Company’s financial statements due to the Company’s material noncompliance with any financial reporting requirement under the securities laws, including those that either (a) correct an error in a previously issued financial statement that is material to such previously issued financial statement or (b) correct an error that is not material to a previously issued financial statement but would result in a material misstatement if left uncorrected in a current report or the error correction was not recognized in the current period.

“**Administrator**” has the meaning set forth in the “Administration” section above.

“**Board**” means the Company’s Board of Directors.

“**Clawback Exception**” has the meaning ascribed to such term in the “Clawback Exceptions” section below.

“**Covered Officer**” means the Company’s officers for purposes of Section 16 under the Exchange Act during any portion of the performance period of the Incentive-Based Compensation.

“**Excess Compensation**” means any amount of Incentive-Based Compensation Received by a Covered Officer that exceeds the amount of Incentive-Based Compensation that otherwise would have been received had it been determined

based on the restated financial information or properly calculated financial measure. Excess Compensation shall be calculated on a pre-tax basis.

**“Incentive-Based Compensation”** means any non-equity incentive plan awards, bonuses paid from a bonus pool, cash awards, equity or equity-based awards, or proceeds received upon sale of shares acquired through an incentive plan; provided that such compensation is granted, earned, and/or vested based wholly or in part on the attainment of a financial performance measure, as determined in accordance with Section 10D of the Exchange Act and the Nasdaq Stock Exchange listing standards (the **“Clawback Rules”**). Incentive-Based Compensation does not include any salaries, discretionary bonuses, non-equity incentive plan awards earned upon satisfying a strategic measure or operational measure (e.g., completion of a project), or equity-based awards that are not contingent on achieving any financial reporting measure (e.g., time vested stock options, restricted stock or restricted stock units).

**“Look-Back Period”** means the three (3) completed fiscal years immediately preceding the earlier of the date on which (a) the Board or appropriate committee concludes, or reasonably should have concluded, that an Accounting Restatement is required or (b) a regulator directs an Accounting Restatement.

**“Received”** means any Incentive-Based Compensation that is received during the fiscal year in which the applicable financial reporting measure upon which the payment is based is achieved, even if payment or grant of the Incentive-Based Compensation occurs after the end of such period.

#### **Clawback Due to Accounting Restatement**

In the event the Company is required to prepare an Accounting Restatement, the Administrator shall require reimbursement or forfeiture (**“clawback”**) of any Excess Compensation Received by any Covered Officer (current or former) during the applicable Look-Back Period, regardless of whether the Covered Officer engaged in misconduct or was otherwise directly or indirectly responsible, in whole or in part, for the Accounting Restatement.

In the event the Administrator cannot determine the Excess Compensation from the information in the Accounting Restatement or from the recalculated financial measure, then it will make its determination based on a reasonable estimate of the effect of the Accounting Restatement or recalculation. Such determination will be final and binding.

If a Clawback Exception applies with respect to a Covered Officer, the Company may forgo the recovery described in this Section from such Covered Officer.

#### **Clawback Method**

The Administrator may determine, in its sole discretion, the method for the clawback of any amounts due under this Policy, which may include without limitation direct payment from the Covered Officer, recovery over time, the forfeiture or reduction of future pay or awards, or any other method that will provide for recovery within a reasonable manner and without undue delay. The Company may enter into deferred payment plans with Covered Officers to effectuate clawback to avoid unreasonable economic hardship. Any amounts due under this Policy may be deducted as an offset from amounts due to the Covered Officer from the Company, except to the extent such set-off is prohibited by law or would violate Section 409A of the Internal Revenue Code of 1986, as amended and the regulations thereunder.

#### **Clawback Exceptions**

The Company will be required, in the event of an Accounting Restatement, to recover all Excess Compensation received by a Covered Officer during the Look-Back Period unless: (i) one of the following conditions is met; and (ii) the Committee has made a determination that recovery would be impracticable in accordance with Rule 10D-1 of the Exchange Act:

- (i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered (and the Company has already made a reasonable attempt to recover such erroneously awarded Excess Compensation from such Covered Officer, has documented such

- reasonable attempt(s) to recover, and has provided such documentation to the Nasdaq Stock Exchange);
- (ii) recovery would violate home country laws that existed at the time of adoption of the rule and the Company receives an opinion of counsel to that effect; or
  - (iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code and regulations thereunder. For purposes of clarity, this Clawback Exception only applies to tax-qualified retirement plans and does not apply to other plans, including long term disability, life insurance, and supplemental executive retirement plans, or any other compensation that is based on Incentive-Based Compensation in such plans, such as earnings accrued on notional amounts of Incentive-Based Compensation contributed to such plans.

### **General**

The Company shall not indemnify any Covered Officer against the loss of any covered compensation as a result of the application of this Policy.

This Policy is in addition to (and not in lieu of) any right of repayment, forfeiture or right of offset against any employees that is required pursuant to any statutory repayment requirement (regardless of whether implemented at any time prior to or following the adoption or amendment of this Policy), including Section 304 of the Sarbanes-Oxley Act of 2002. Any amounts paid to the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 shall be considered in determining any amounts recovered under this Policy.

The terms of this Policy shall be binding and enforceable against all Covered Officers subject to this Policy and their beneficiaries, heirs, executors, or other legal representatives. If any provision of this Policy or the application of such provision to any Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision (or the application of such provision) valid, legal or enforceable.

Each Covered Officer shall sign and return to the Company, within the later of: (i) 60 calendar days following the Effective Date or (ii) 30 calendar days following the date the individual becomes a Covered Officer, the Acknowledgement and Agreement Form attached hereto as Exhibit A, pursuant to which the Covered Officer agrees to be bound by, and to comply with, the terms and conditions of this Policy.

To the extent the Clawback Rules require recovery of Incentive-Based Compensation in additional circumstances beyond those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Clawback Rules.

The Board may amend this Policy from time-to-time in its discretion and as necessary to comply with any rules or standards adopted by the SEC and the listings standards of any national securities exchange on which the Company's securities are listed.

Exhibit A

**Mustang Bio, Inc. (the "Company")  
Clawback Policy**

**Acknowledgement and Agreement Form**

I, the undersigned, acknowledge and agree that I have received and reviewed the Clawback Policy of Mustang Bio, Inc. (the "**Policy**"), effective as of October 2, 2023, as adopted by the Company's Board of Directors.

Furthermore, I acknowledge and agree:

- that I am fully bound by, and subject to, all of the terms and conditions of the Policy, as may be amended, restated, supplemented or otherwise modified from time to time.
- that I have been designated as a "Covered Officer" as defined in the policy.
- that my execution of this Acknowledgement and Agreement Form is in consideration of, and is a condition to, my continued employment (if currently an employee) and my receipt of future awards from the Company, though nothing in this Acknowledgement and Agreement Form shall obligate the Company to make any particular award.

In the event of any inconsistency between the Policy and the terms of any employment agreement to which I am a party, or to the terms of any compensation plan, program, agreement or arrangement under which any incentive-based compensation covered by the Policy is payable, the terms of this Policy shall govern and shall be deemed incorporated into all such plans, programs, agreements (including any employment agreements) or arrangements, including and without limitation, those granted or awarded prior to the date hereof and those granted or awarded in the future.

In the event any Incentive-Based Compensation (as defined in the Policy) is subject to recoupment or recovery under the terms of the Policy, I will promptly take any action necessary to effectuate the recoupment or recovery of such compensation by the Company.

**COVERED OFFICER**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date