Risk Factors Comparison 2025-03-28 to 2024-03-11 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

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~~ **oncolytic virus** product candidates **. ● Our strategic pivot and focus on our lead product candidates, MB- 109 and MB- 106, and our disposal of non- core assets, including our facility, may not result in the cost savings we anticipate and could result in total costs and expenses that are greater than expected** . Risks Inherent in Drug Development and Commercialization ● Preclinical development is highly speculative and carries a high failure risk. ● We may not receive the required regulatory approvals for any of our product candidates on our projected timelines, if at all, which may result in increased costs and delay our ability to generate revenue. ● We may not obtain the desired labeling claims or intended uses for product promotion, or favorable scheduling classifications, to successfully promote our product candidates, if approved. ● If a product candidate demonstrates adverse side effects, we may need to abandon or limit the development of such product candidate. ● Even if a product candidate is approved, it may be subject to various post- marketing requirements, including studies or clinical trials, and increased regulatory scrutiny. ● Our competitors may develop treatments for our products' target indications, which could limit our product candidates' commercial opportunity and profitability. ● If our product candidates, if approved, are not broadly accepted by the healthcare community, the revenues from any such product will likely be limited. ● Any successful products' liability claims related to any of our current or future product candidates may cause us to incur substantial liability and limit the commercialization of any such products ~~. ● 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. **General** Risks ~~Relating to the Sale~~ **and Risks Associated with Ownership** of Our ~~Manufacturing Facility~~ **Common Stock** ● We may ~~be unable to complete the sale of~~ **become involved in securities class action litigation that could divert management' s attention and harm** our ~~manufacturing facility~~ **business. ● The market price for our common stock** ~~as~~ **has** ~~contemplated if~~ **been volatile and may continue to fluctuate or may decline significantly in** the ~~Committee~~ **future. ● The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits, or we could lose key data which could cause us to curtail or cease operations. ● We rely** on ~~Foreign Investment~~ **information technology, and any internet or internal computer system**

failures, inadequacies, interruptions or compromises of our systems or the security of confidential information could damage our reputation and harm our business. ● Our employees, consultants, or third- party partners may engage in **misconduct or** ~~the~~ **other improper activities** ~~United States (" CFIUS ") determines to implement mitigation measures~~ , including ~~the potential divestment of some~~ **but not necessarily limited to noncompliance with regulatory standards and requirements** or **internal procedures** ~~all of the transferred assets by the buyer~~ , **policies or agreements to** which **such employees, consultants** ~~may limit our ability to realize the anticipated cost savings of the sale of the facility~~ and ~~may~~ **partners are subject, any of which could** have a material adverse effect on our **business** ~~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 **not be** ~~incur substantial expenses related to the transaction and the consummation of the sale~~ **able** ~~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 **manage** ~~realize the anticipated benefits of the transaction; unfortunately, key personnel may also depart~~ our **business effectively if** ~~Company in the event that~~ we are unable to ~~complete the transaction~~ **attract and retain key personnel** . ● Our ~~strategic pivot~~ **growth is subject** to **economic** ~~our lead product candidate, MB- 106,~~ and **geopolitical conditions. ● Our business** ~~our disposal of non- core assets, including our facility, may not result in the cost savings we anticipate and~~ could ~~result~~ **be adversely affected by the effects of health pandemics or epidemics, which could cause significant disruptions** in ~~total costs~~ **our operations. ● Our business** and ~~expenses that are greater than expected~~ **operations would suffer in the event of computer system failures, cyber- attacks, or deficiencies in our or third parties' cybersecurity** . 5PART IItem 1. BusinessOVERVIEWMustang 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~~ **difficult- to- treat** cancers ~~, solid tumors~~ and **autoimmune** ~~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~~ **two** core areas: CAR T therapies for **autoimmune diseases and** hematologic malignancies ~~,~~ **and** CAR T therapies for solid tumors ~~and gene~~ **. For these** therapies ~~for rare genetic disorders. For each therapy~~ we have partnered with world class research institutions **, including** ~~. 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 "), **and** 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 TherapiesOur 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 **solid tumors in partnership with COH targeting IL13Rα2 (MB- 101). In addition, we have partnered with Nationwide for a herpes simplex virus type 1 (" HSV- 1 ") oncolytic virus (MB- 108) in order to enhance the activity of MB- 101 for the treatment of patients with high- grade malignant brain tumors. The Phase 1 clinical trial sponsored by COH for MB- 101 (ClinicalTrials. gov Identifier: NCT02208362) has completed the treatment phase and patients continue to be assessed for long- term safety. A Phase 1 clinical trial sponsored by the University of Alabama at Birmingham (" UAB ") for MB- 108 (ClinicalTrials. gov Identifier: NCT03657576) has also completed the treatment phase and patients continue to be assessed for long- term safety. In October 2023, we announced that the FDA accepted our IND application for the combination of MB- 101 and MB- 108 – which is referred to as MB- 109 – for the treatment of patients with IL13Rα2 relapsed or refractory glioblastoma (" GBM ") and high- grade astrocytoma. Pursuant to termination of the lease of our cell processing facility in Worcester, MA, we are exploring with COH and Nationwide the possibility of initiating this clinical trial as an investigator- sponsored single- institution study at COH in the fourth quarter of 2025. We are also developing CAR T therapy for** hematologic malignancies **and autoimmune diseases** 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~~ **March 1, ~~2023~~ 2025** , **53** ~~approximately 40~~ patients have been treated in an ongoing ~~phase~~ **Phase** 1 clinical trial sponsored by Fred Hutch (ClinicalTrials. gov Identifier: NCT03277729) ~~,~~ and ~~approximately~~ 20 patients have been treated in **the** ~~an ongoing phase~~ **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~~ **Phase** 1 trial. We presented the latest results, demonstrating a favorable safety profile, complete response rate, and durability, from the ongoing Mustang- sponsored ~~phase~~ **Phase** 1 trial at the 2023 American Society of Hematology (" ASH ") Annual Meeting. ~~As~~ **Pursuant to termination** of ~~December 31, 2023,~~ the ~~MB- 106 Mustang- sponsored~~ **lease for our cell processing center in Worcester, MA, we are exploring with Fred Hutch the possibility of initiating a** ~~phase~~ **Phase** 1 trial ~~is pending one patient to complete~~ **in autoimmune diseases as an investigator-**

sponsored single- institution study at Fred Hutch in the ~~final dose level required~~ **fourth quarter of 2025. MB- 109 (Combination of MB- 101 CAR T Therapy with MB- 108 Oncolytic Virus Therapy for Malignant Brain Tumors) In October 2023, we received a safe-** to ~~advance~~ **- proceed letter from the FDA for our MB- 109 IND application allowing us** to **initiate a** ~~phase~~ **Phase** ~~2 pivotal studies for treatment~~ **1, open- label, non- randomized, multicenter study** of **MB- 109 in** patients with ~~relapsed or refractory indolent B~~ **IL13Rα2 recurrent GBM and high** - **grade astrocytoma** ~~cell non- Hodgkin lymphoma~~. ~~We are also developing~~ **In this Phase 1 clinical study, we intend to evaluate the combination of** CAR **-** T **cells** ~~therapy for solid tumors in partnership with COH targeting IL13Rα2~~ (MB- 101) **and the herpes simplex virus type 1 oncolytic virus (MB- 108) in patients with IL13Rα2 high- grade gliomas** . ~~In addition~~ **The design of this study involves first a lead- in cohort, wherein patients are treated with MB- 101 alone without prior MB- 108 administration. After successful confirmation of the safety profile of MB- 101 alone, the study will then investigate increasing doses of intratumorally administered MB- 108 followed by dual intratumoral (ICT) and intraventricular (ICV) administration of MB- 101. On November 7, 2024** , we ~~have partnered with Nationwide~~ **announced that the FDA granted Orphan Drug Designation to Mustang** for **MB- 108,** 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 **glioma** ~~brain tumors~~. The ~~Phase 1~~ **Orphan Drug Designation provides certain incentives, such as tax 6credits toward the cost of** clinical ~~trial~~ **trials upon approval and prescription drug user fee waivers** ~~sponsored by COH for MB- 101 (ClinicalTrials. gov Identifier: NCT02208362)~~ **If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in which it** has **Orphan Drug Designation** ~~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~~ **independent from intellectual property protection. We are currently exploring with COH and Nationwide** the ~~treatment~~ **possibility** of **conducting an investigator- sponsored single- institution trial under the COH IND to treat** patients with IL13Rα2 ~~relapsed~~ **recurrent GBM and high- grade astrocytoma with MB- 109 that could potentially be initiated in the fourth quarter of 2025. Because cell processing** ~~or~~ **for** ~~refractory glioblastoma~~ **MB- 101 will revert back to COH – where the product continues to be manufactured today for other investigator- sponsored clinical trials being conducted by COH in malignant brain tumors (NCT04003649, NCT04661384, NCT04510051), we believe that it is reasonable to assume that the FDA will not require the aforementioned lead- in cohort. Should this, indeed, be the case, the first patient enrolled will receive the combination of MB- 101 and MB- 108, which will represent a considerable savings of time and money – as well as afford the potential benefit of both therapies to every patient treated on studyMB- 106 (CD20- targeted CAR T cell therapy for Non- Hodgkin Lymphoma, Chronic Lymphocytic Leukemia and Autoimmune Diseases) In the first quarter of 2024, we completed a successful End- of- Phase 1 meeting with the FDA regarding a potential pivotal Phase 2 single- arm clinical trial for the treatment of WM. Per the discussions, the FDA agreed with the proposed overall design of the pivotal trial for Waldenstrom macroglobulinemia** (" ~~GBM~~ **WM** ") ~~and high~~ **at the recommended dose of 1 x 107 CAR** - ~~grade astrocytoma~~ **T cells / kg and requested only minimal modifications to the study protocol** . ~~Finally~~ **No additional nonclinical studies are expected prior to Phase 2 or a Biologics License Application (" BLA ") filing, although the need for additional nonclinical studies after completion of Phase 2 and prior to submission of a BLA is subject to discussions with FDA. Due to limited resources, and as a result of the reduction in work force described below** , we **do not expect** ~~are collaborating with the Mayo Clinic~~ to **initiate our pivotal Phase 2 single- arm clinical trial** ~~develop a novel technology that may be able to transform the administration~~ of ~~CAR T therapies~~ **MB- 106 for the treatment of WM trial in 2025. Subject to available funds, we intend to rely on third party service providers to conduct study** and **manufacturing services to advance our priority** ~~potentially~~ -- **potential** ~~be used as an~~ **product candidates. Also in the first quarter** ~~off~~ - **of - 2024, we completed enrollment of** the **indolent lymphoma arm in our** ~~- 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~~. **The tenth** ~~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 **final patient enrolled on that arm was a patient with follicular lymphoma** ~~the proper allocation of our resources. Following this review, we determined to discontinue development of our MB- 102~~ (~~CD123~~ **FL**) **who achieved** ~~, 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. 6Gene TherapiesIn partnership with St. Jude, our XSCID gene therapy programs (MB- 117 and MB- 217) are being developed under an exclusive license to develop~~ a **complete response** ~~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 **1 x 107 CAR- T cells / kg. As a result, the overall complete response rate for FL in the Phase 1 portion of this trial was sustained at 100 % (N = 6), with no occurrence of cytokine release syndrome (" CRS ") above grade 1 and no immune effector cell- associated neurotoxicity syndrome (" ICANS ") of any grade, despite not using prophylactic tocilizumab or dexamethasone. In March 2024, we announced plans to collaborate with Fred Hutch for a proof- of- concept Phase 1 investigator- sponsored clinical trial evaluating MB- 106 in autoimmune diseases. In March 2024, we were granted the Regenerative Medicine Advanced Therapy (" RMAT ") designation by the FDA for the treatment of**

relapsed or refractory CD20 positive WM and FL, based on potential improvement in response as seen in clinical data to date. Drugs eligible for RMAT designation are ~~the~~ **those** ~~predecessor~~ **intended to treat, modify, reverse or cure a serious or life- threatening disease or condition, and that present preliminary clinical evidence indicating the drug has the potential to address unmet medical needs for such disease or condition. RMAT designation provides regenerative medicine advanced therapy** products ~~(~~**with the same benefits to expedite the development and review of a marketing application that are available to drugs that receive Breakthrough Therapy Designation. These advantages include timely advice and interactive communications with FDA, as well as proactive and collaborative involvement by senior FDA managers and experienced review and regulatory health project management staff. A product** designated **as an RMAT also may be eligible for other FDA- expedited programs, such as Priority Review. The FDA also may conduct a rolling review of products in its expedited programs, reviewing portions of a marketing application before the complete application is submitted. In June 2024, we announced that updated data for** MB- **106** ~~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 **Fred Hutch investigator- sponsored trial showed a favorable safety and efficacy profile in 10 patients with WM. There was an overall response rate (" ORR ") of 90 % with durable responses observed, including three complete responses (" CR "), two very good partial responses (" VGPR "), and four partial responses (" PR "). One of the patients who achieved a CR remained in remission for 31 months, with an immunoglobulin M (IgM) level that decreased rapidly to the normal range after treatment with MB- 106 and remained normal since. Patients had a median of nine prior lines of therapy, and only one patient started additional anti- WM treatment after being treated with MB- 106. From a safety perspective, CRS occurred in nine patients: five patients with grade 1 and four patients with grade 2. One patient experienced grade 1 ICANS. No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS was observed, despite dose escalation. In May 2024, we informed the** clinical **sites participating in** ~~trials involving two different autologous cell products produced via transduction of patients' hematopoietic stem cells. As noted above, these~~ -- **the Mustang** ~~cell products were designated MB-~~ **sponsored** ~~107 and MB- 207, and the respective~~ Phase 1 / 2 **study in non- Hodgkin lymphoma and chronic lymphocytic leukemia, MB106- CD20- 001, that we had decided to close the trial. In June 2024, we similarly informed the** clinical ~~trials were: a multicenter~~ **sites participating in the Mustang- sponsored Long- term Follow- up Study in Patients Previously Treated with Mustang Bio, Inc. CAR- T Cell Investigational Products, MB100- OBS- 001, that we had decided to close that** trial **. As a result, further clinical development** of ~~the~~ MB- ~~107 product in newly diagnosed infants~~ **106 is 7currently focused solely on autoimmune diseases unless funding and resources become available to restart the program for hematologic malignancies. Planning for the aforementioned Phase 1 investigator-** sponsored ~~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~~ **autoimmune diseases is in progress,** 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 **the** ~~a pivotal non- randomized multicenter Phase 2 clinical~~ trial **planned** ~~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~~ -- **for** ~~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~~ **2025** ~~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~~ **2024** , we ~~have~~ **had** an accumulated deficit of $ ~~381~~ **396** . ~~0~~ **7** million. We are a majority- controlled subsidiary of Fortress Biotech, Inc. (" Fortress "). CORPORATE INFORMATIONWe were incorporated in Delaware on March 13, 2015. Our executive offices are located at ~~377 Plantation Street~~ **95 Sawyer Road** , ~~Worcester~~ **Suite 110, Waltham** , Massachusetts ~~01605~~ **02453** . Our telephone number is (781) 652- 4500, and our email address is info @ mustangbio. com. Our website address is www. mustangbio. com. The information set forth on our website is not a part of this Form 10- K. We will make available free of charge through our website our annual reports on Form 10- K, quarterly reports on Form 10- Q and current reports on Form 8- K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this Form 10- K. The SEC maintains a website that contains annual, quarterly, and current reports, proxy and information statements, and other information that issuers (including us) file electronically with the SEC. The SEC' s website address is https: / / www. sec. gov /. ~~7THERAPEUTIC~~ **THERAPEUTIC** PIPELINETherapies for Oncology and Hematologic MalignanciesMB ~~- 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. 8In November 2021, Mustang was awarded a grant of approximately $ 2. 0 million from NCI of the National Institutes of Health. This two- year award partially funded the Mustang- sponsored multicenter trial to assess the safety, tolerability and efficacy of MB- 106. In August 2023, we fully utilized the grant. In June 2022, MB- 106 received Orphan Drug Designation for the treatment of Waldenstrom macroglobulinemia (" WM "). In December 2023, Mustang presented preliminary clinical data for the indolent lymphoma patients treated in the ongoing Phase 1 / 2 clinical study at the American Society of Hematology (ASH) annual meeting. All 9 patients responded clinically to treatment; the observed overall response rate was 100 %. All 5 follicular lymphoma patients achieved a complete response. Among the WN patients 1 patient attained a very good partial response, and 2 patients attained a partial response. The single patient with a hairy cell leukemia variant experienced stable disease. The safety profile demonstrated that MB- 106 was well tolerated with no occurrences of 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 (IL13Rα2 CAR T Cell Program for Glioblastoma) and MB- 108 (HSV- 1 oncolytic virus C134) as a Potential Treatment for IL13Rα2 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 IL13Rα2- 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 IL13Rα2- 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 IL13Rα2- 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 IL13Rα2 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 IL13Rα2 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~~ **evaluation** of the safety profile of MB- 101 alone, the study will then investigate increasing doses of intratumorally administered MB- 108 followed by dual intratumoral (ICT) and intraventricular (ICV) administration of MB- 101. We are currently ~~evaluating~~ **exploring with COH and Nationwide** the ~~extent~~ **possibility of conducting an investigator- sponsored single- institution trial under the COH IND** to **treat patients with IL13Ra2 recurrent GBM and high- grade astrocytoma with MB- 109 that could potentially be initiated in the fourth quarter of 2025. 8On November 7, 2024, we announced that the FDA granted Orphan Drug Designation to Mustang for MB- 108, a herpes simplex virus type 1 (“ HSV- 1 ”) oncolytic virus, for the treatment of malignant glioma. The Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials upon approval and prescription drug user fee waivers. If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in** which ~~we can initiate this study~~ **it has Orphan Drug designation** , ~~subject to allocation of resources~~ **which is independent from intellectual property protection** . MB- 101 (IL13Rα2 CAR T Cell Program for Glioblastoma) GBM is the most common brain and central nervous system (“ CNS ”) cancer, accounting for approximately **52** ~~49. 1~~ % of malignant primary brain and CNS tumors ~~,~~ **and** approximately **14** ~~54 % of all gliomas, and approximately 16~~ % of all primary brain and CNS tumors. **On average during the years 2017 through 2021,** ~~More~~ **more** than ~~14~~ **13** , ~~490~~ **000** new **cases of** GBM ~~cases~~ were ~~predicted to be~~ diagnosed **per** ~~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-~~ **, with only 3.** 3 cases per 100, 000 persons per year in the U. S. ~~and European Union (“ EU ”)~~ , it is quite lethal, with **a median** ~~five- year~~ survival **of only 9 months** ~~rate historically under 10 %, which has been virtually unchanged for decades~~ . Standard of care therapy **for patients less than 70 years of age** consists of maximal surgical resection, ~~9radiation -~~ **radiation** , ~~and~~ chemotherapy with temozolomide, ~~which~~ **and alternating electric field therapy. This front- line regimen has remained relatively unchanged for the last 20 years due to the failure of novel therapies to improve survival** , **and there** ~~while rarely curative,~~ is **no standard of care whatsoever for recurrent** ~~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. IL13Rα2 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 IL13Rα2 and reduced binding to IL13Rα1 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 (TCM) or enriched CD62L naïve and memory T cells (TN / MEM) are isolated and enriched. Our manufacturing process limits ex vivo expansion, which is designed to reduce T cell exhaustion and maintain a TCM or TN / MEM phenotype. Based on experiments with CAR- Ts in mouse xenograft models of GBM, these CAR- modified TCM and TN / MEM cells have been shown to be more potent and persistent than earlier generations of CAR- T cells. Our academic partners at COH have recently completed the treatment phase of their Phase 1 study, which was designed to assess the feasibility and safety of using TCM or TN / MEM enriched IL13Rα2- specific CAR- engineered T cells for clinical study participants with IL13Rα2 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 IL13Rα2- 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 IL13Rα2- 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 IL13Rα2. Results from this COH study have laid the foundation for three ~~new~~ MB- 101 studies **that are currently enrolling patients and one possible combination study in the future** : 1. MB- 101 with or without nivolumab and ipilimumab in treating patients with recurrent or refractory glioblastoma (currently enrolling patients; ClinicalTrials. gov Identifier: NCT04003649) sponsored by COH; ~~2~~ **92** . MB- 101 in treating patients with recurrent or refractory glioblastoma with a substantial component of leptomeningeal disease (currently enrolling patients; ClinicalTrials. gov Identifier: NCT04661384) sponsored by COH; 3. **MB-** ~~MB101 --~~ **101 in treating children with recurrent or refractory IL13Rα2 positive brain tumors (currently enrolling patients; ClinicalTrials. gov Identifier: NCT04510051) sponsored by COH; 4. MB- 101** in combination with the herpes simplex virus type 1 oncolytic virus (MB108) in treating patients with recurrent or refractory glioblastoma or high- grade astrocytoma, as described above. **We refer to** ~~This~~ **this** combination therapy **as MB- 109** , **and we are currently exploring with COH and Nationwide the possibility of conducting a Phase 1 trial with this therapy** to **treat patients with these poor- prognosis malignant brain tumors. This trial would** be **an investigator** ~~administered in a phase 1 two- center~~ **sponsored single- institution** trial under ~~our~~ **the COH** IND ~~, will~~ **and could potentially** be **initiated in the fourth quarter of 2025MB** ~~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 ~~10in~~ **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 IL13Rα2- directed CAR T for the treatment of GBM and high- grade astrocytoma. The O' Neal Comprehensive Cancer Center at the UAB is the single clinical trial site for the **first** Phase 1 trial of MB- 108 **.** ~~, and this~~ **This** site ~~has~~ initiated ~~a Phase 1 trial that began enrolling patients~~ in 2019 (ClinicalTrials. gov Identifier: NCT03657576) **and, after enrolling 19 patients, has completed the treatment phase, and patients continue to be assessed for long- term safety** . The primary objective of this study is to determine the safety and tolerability of a single dose of MB- 108 administered via a stereotactic intracerebral injection and to determine the maximally tolerated dose (" MTD ") of the oncolytic virus. Secondary objectives are to obtain preliminary information about the potential benefit of MB- 108 in the treatment of patients with recurrent malignant gliomas, including relevant data on markers of efficacy, including time to tumor progression and patient survival. ~~As~~ **Results from this trial were used to determine the dose** of ~~April 2023, 9~~ **MB- 108 approved by the FDA for combination with MB- 101 in the treatment of** patients ~~had been enrolled in this study~~ **with IL13Rα2 recurrent GBM and high- grade astrocytoma under the originally proposed Mustang IND multicenter trial** . ~~In Vivo~~ **We believe that the same doses of both therapies will be appropriate for the Phase 1 investigator- sponsored single- institution combination trial currently under discussion with COH and Nationwide. Also listed on ClinicalTrials. gov are two additional Phase 1 trials at UAB involving MB- 108 administered as a single agent to patients with recurrent malignant glioma: (1) a trial designed to determine safety and tolerability of administering a second dose of MB- 108 to patients who previously completed the aforementioned first- in- human 19- patient Phase 1 trial (ClinicalTrials. gov Identifier: NCT06193174; enrolling by invitation) and (2) a trial that contemplates two treatments of 1 x 105 plaque forming units (PFU) each, with the timing and qualification for the second treatment outlined in detail by the protocol (ClinicalTrials. gov Identifier: NCT06614855; not yet recruiting).. MB- 106 (CD20** CAR T ~~Platform TechnologyWe are collaborating~~ **for B cell non- Hodgkin lymphoma (NHL), chronic lymphocytic leukemia (CLL) and autoimmune diseases) 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** ~~the Mayo Clinic to develop a novel technology that may be able to transform the administration of CAR T therapies~~ and ~~potentially be used~~ **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** ~~off -~~ **of B** - **NHL patients treated with rituximab and** ~~the~~ **other anti** - ~~shelf therapy~~ **CD20 antibodies** . **Importantly** ~~The technology~~ , **CD20 continues to be expressed on** ~~developed by Larry R. Pease, Ph. D., principal investigator and former director of~~ the ~~Center for Immunology and Immune Therapies at Mayo Clinic~~ **lymphoma cells of most patients with relapsed B- NHL despite repetitive rituximab treatments** , **and loss of CD20**

expression is **not** a **major contributor** ~~new platform to administer CAR T therapy using a two-~~ **to treatment resistance** ~~- step approach~~. ~~First~~ **Thus** , **there** ~~a peptide~~ is **strong rationale** ~~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 --~~ **for testing CD20** CAR T cells **as** ~~in vivo in the patient. Successful implementation may lead to~~ an ~~off-~~ **immunotherapy for NHL. 10Under** ~~the~~ **their** ~~- 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~~ **, Fred Hutch is currently conducting** a ~~multicenter~~ Phase ~~1 clinical trial once a lead construct has been identified, subject to allocation of resources. Gene Therapies for Rare Genetic DisordersMB- 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~~ **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** ~~(1~~) ~~a multicenter trial~~ **. Secondary endpoints** of ~~MB~~ **this study include safety and toxicity, preliminary antitumor activity as measured by overall response rate and complete remission rate, progression** ~~- 107~~ **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 ~~newly diagnosed patients~~ **this study, which is** being led by ~~St~~ **the Principal Investigator Mazyar Shadman, M** . ~~Jude and including also UCSF Benioff Children~~ **D., M. P. H., Associate Professor of Fred Hutch** ' s ~~Hospital~~ **Clinical Research Division. The Fred Hutch IND was amended in 2019 to incorporate** ~~San --~~ **an optimized manufacturing process that had been developed in collaboration with us** ~~Francisco (" UCSF ") and Seattle Children' s Hospital (" Seattle Children' s ") (ClinicalTrials . gov Identifier: NCT01512888) and (2)~~ **In May 2021, we announced that the FDA issued** a ~~single~~ **safe to proceed letter for our IND application allowing for initiation of a multi-** 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 intent 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. 11MB- 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~~ **study of MB- 106** in ~~Europe~~ **patients with relapsed or refractory B cell NHL or CLL (Clinicaltrials** . ~~The ongoing clinical trial has enrolled its~~ **gov Identifier: NCT05360238). In August 2022, the** first patient **was treated** ~~, and additional clinical sites are expected to be added~~ in **our study** ~~the near future~~ . ~~The RAG1- SCID program has been~~ **In November 2021, Mustang was awarded a** ~~granted --~~ **grant of approximately $ 2. 0 million from NCI of the National Institutes of Health. This two- year award partially funded the Mustang- sponsored multicenter trial to assess the safety, tolerability and efficacy of MB- 106. In August 2023, we fully utilized the grant. In June 2022, MB- 106 received** Orphan Drug Designation **for the treatment of Waldenstrom macroglobulinemia (" WM "). In December 2023, Mustang presented preliminary clinical data for the indolent lymphoma patients treated in the ongoing Phase 1 / 2 clinical study at the American Society of Hematology (ASH) annual meeting. All 9 patients responded clinically to treatment; the observed overall response rate was 100 %. All 5 follicular lymphoma patients achieved a complete response. Among the WN patients 1 patient attained a very good partial response, and 2 patients attained a partial response. The single patient with a hairy cell leukemia variant experienced stable disease. The safety profile demonstrated that MB- 106 was well tolerated with no occurrences of CRS above grade 1, and no ICANS of any grade was reported. Cell expansion and persistence were also demonstrated. In the first quarter of 2024, we completed a successful End- of- Phase 1 meeting with the FDA regarding a potential pivotal Phase 2 single- arm clinical trial for the**

treatment of WM. Per the discussions, the FDA agreed with the proposed overall design of the pivotal trial for WM at the recommended dose of 1 x 107 CAR- T cells / kg and requested only minimal modifications to the study protocol. No additional nonclinical studies are expected prior to Phase 2 or a Biologics License Application (" BLA ") filing, although the need for additional nonclinical studies after completion of Phase 2 and prior to submission of a BLA is subject to discussions with FDA. Due to limited resources, and as a result of the reduction in work force described below, we do not expect to initiate our pivotal Phase 2 single- arm clinical trial of MB- 106 for the treatment of WM trial in 2025. Subject to available funds, we intend to rely on third party service providers to conduct study and manufacturing services to advance our priority potential product candidates. Also in the first quarter of 2024, we completed enrollment of the indolent lymphoma arm in our multicenter Phase 1 trial. The tenth and final patient enrolled on that arm was a patient with follicular lymphoma (FL) who achieved a complete response following treatment with 1 x 107 CAR- T cells / kg. As a result, the overall complete response rate for FL in the Phase 1 portion of this trial was sustained at 100 % (N = 6), with no occurrence of CRS above grade 1 and no ICANS of any grade, despite not using prophylactic tocilizumab or dexamethasone. In March 2024, we announced plans to collaborate with Fred Hutch for a proof- of- concept Phase 1 investigator- sponsored clinical trial evaluating MB- 106 in autoimmune diseases. In March 2024, we were granted the Regenerative Medicine Advanced Therapy (" RMAT ") designation by the ~~European~~ **FDA for the treatment of relapsed or refractory CD20 positive WM and FL, based on potential improvement in response as seen in clinical data to date. Drugs eligible for RMAT designation are those intended to treat, modify, reverse or cure a serious or life- threatening disease or condition, and that present preliminary clinical evidence indicating the drug has the potential to address unmet medical needs for such disease or condition. RMAT designation provides regenerative** ~~Medicines~~ **medicine** ~~Agency~~ **advanced therapy products with the same benefits to expedite the development and review of a marketing application that are available to drugs that receive Breakthrough Therapy Designation . In June 2024, we announced that updated data for MB- 106 in the Phase 1 / 2 Fred Hutch investigator- sponsored trial showed a favorable safety and efficacy profile in 10 patients with WM. There was an overall response rate (" ORR ") of 90 % with durable responses observed, including three complete responses (" CR "), two very good partial responses (" VGPR "), and four partial responses (" PR "). One of the patients 11who achieved a CR remained in remission for 31 months, with an immunoglobulin M (IgM) level that decreased rapidly to the normal range after treatment with MB- 106 and remained normal since. Patients had a median of nine prior lines of therapy, and only one patient started additional anti- WM treatment after being treated with MB- 106. From a safety perspective, CRS occurred in nine patients: five patients with grade 1 and four patients with grade 2. One patient experienced grade 1 ICANS. No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS was observed, despite dose escalation. In May 2024, we informed the clinical sites participating in the Mustang-sponsored Phase 1 / 2 study in non- Hodgkin lymphoma and chronic lymphocytic leukemia, MB106- CD20- 001, that we had decided to close the trial. In June 2024, we similarly informed the clinical sites participating in the Mustang-sponsored Long- term Follow- up Study in Patients Previously Treated with Mustang Bio, Inc. CAR- T Cell Investigational Products, MB100- OBS- 001, that we had decided to close that trial. As a result, further clinical development of MB- 106 is currently focused solely on autoimmune diseases unless funding and resources become available to restart the program for hematologic malignancies. Planning for the aforementioned Phase 1 investigator-sponsored clinical trial in autoimmune diseases is in progress, with initiation anticipated in the fourth quarter of 2025. Terminated Product Candidates (CAR- T Therapies, Gene Therapies and in vivo CAR- T)** We ~~also established~~ **previously developed four additional CAR- T product candidates licensed from City of Hope, which included MB- 102 (CD123), MB- 103 (HER2), MB- 104 (CS1)** ~~an~~ **and** ~~ongoing partnership~~ **MB- 105 (PSCA) programs. In May 2023, we announced a series of changes resulting from a review of our portfolio of product candidates to determine the future strategy of our programs and the proper allocation of our resources. Following this review, we determined to discontinue development of these four programs and terminated the associated license agreements. In addition, we previously developed several gene therapy product candidates, which included MB- 117 and MB- 217 (based on technologies licensed from St. Jude Children' s Research Hospital (" St. Jude ")) and MB- 110 (based on technologies licensed from Leiden University Medical Centre (" LUMC ")). In April 2024, we entered into a termination and release agreement** with **St** ~~Frank J. Staal~~ **Jude** , **pursuant** ~~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 **agreed to terminate** ~~have certain rights under~~ the **license** agreement **underpinning the MB- 117 and MB- 217 product candidates in exchange for a mutual release of liability and forgiveness by St. Jude of all amounts previously owing to them. Also in April 2024, we delivered a termination notice to LUMC pursuant to which we terminated the license agreement underpinning the MB- 110 product candidate; we are currently in discussions with LUMC regarding the terms that will govern such termination. In June 2024, we also agreed with Mayo Foundation for Medical Education and Research (" Mayo Clinic ") to terminate the license agreement underpinning our (now former) preclinical in vivo CAR-T program, together with a related sponsored research agreement, in exchange for a mutual release of liability and forgiveness by Mayo Clinic of all amounts previously owed to them** . INTELLECTUAL PROPERTY AND PATENTSGeneralOur 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~~ **12Generally**, 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. ~~12If~~ **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 IL13Rα2, 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 IL13Rα2- 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 IL13Rα2- targeting CAR will expire no sooner than 2035. The licensed intellectual property relating to relating modified CAR hinge regions includes issues 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 issues 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 CytegrityTM stable producer cell line developed and used by St. Jude. The CytegrityTM 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 LentiBOOSTTM 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.~~ 13In ~~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- idiotype 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 RightsWe 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 ~~AGREEMENTSSt~~ **AGREEMENTSCity** ~~. Jude Children' s Research HospitalXSCID LicenseOn 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 AgreementIn 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. 14XSCID Data Transfer AgreementIn 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 CenterIn 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 IL13Rα2- directed CAR T program, and one relating to the Spacer technology (described below). As of **March** ~~December 31, 2023~~ **2025** , COH owns 845, 385 shares of our Class A common stock, which are convertible into ~~56~~ **1** , ~~359~~ **127** shares of Common Stock, and has the right to appoint a member to our Board of Directors (the " Board ") **until the tenth anniversary, March 15, 2025** . In addition, we entered into a sponsored research agreement with COH under which we have funded continued research in the amount of $ 2. 0 million per year, payable in four equal installments, which ended in the first quarter of 2020. The research covered under this arrangement was for the IL13Rα2- 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~~ **four** ~~portfolio of~~ CAR ~~-~~ T ~~therapies~~ **Therapies licensed from** ~~being developed by us in partnership with the~~ City of Hope **listed above under " Terminated Product Candidates** . **"** IL13Rα2 LicenseIn 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 IL13Rα2- directed CAR T program (the " IL13Rα2 License "). Pursuant to the IL13Rα2 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. IL13Rα2 CRA (Glioblastoma) In February 2017, we entered into a Clinical Research Support Agreement for the IL13Rα2- directed CAR T program (the " IL13Rα2 GBM CRA "). Pursuant to the terms of the IL13Rα2 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 IL13Rα2- directed CAR T therapy (also known as MB- 101). ~~IL13Rα2~~ **14IL13Rα2** CRA (Leptomeningeal Glioblastoma) In October 2020, we entered into a Clinical Research Support Agreement for the IL13Rα2- directed CAR T program for adult patients with leptomeningeal glioblastoma, ependymoma or medulloblastoma (the " IL13Rα2 Leptomeningeal CRA "). Pursuant to the terms of the IL13Rα2 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 IL13Rα2- directed CAR T therapy. ~~15Sponsored --~~ **Sponsored** Research Agreement- IL13Rα2 and C134 CombinationIn October 2020, we entered into a Sponsored Research Agreement (" SRA ") with COH to conduct combination studies of a potential IL13Rα2 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 LicenseIn 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 IL13Rα2 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 LicenseIn 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 LicenseOn 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 LicenseOn 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 CenterCD20 Technology LicenseEffective 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. ~~16In~~ **15In** 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 LicenseOn 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) LicenseOn August 23, 2019, we entered into a non- exclusive license agreement with CSL Behring (Calimmune) for the CytegrityTM stable producer cell line for the production of lentiviral gene therapy for the XSCID gene therapy program. The CytegritTM 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 LicenseOn 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 ResearchCAR T Technology LicenseOn 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. 17Pursuant 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 AgreementIn 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 CentreRAG1- SCID Technology LicenseOn 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 AgreementIn 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. COMPETITIONCompetition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors. The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same conditions that we are targeting. Other companies have products or product candidates in various stages of pre- clinical or clinical development, or with marketing approvals, to treat conditions for which we are also seeking to discover and develop product candidates. Some of these potential competing drugs are further advanced in development than our product candidates and may be commercialized earlier. The field of CAR T therapy is extremely active. Companies and partnerships currently engaged in clinical trials with CAR T modalities include Bristol Myers Squibb, Novartis, AstraZeneca, Janssen Pharmaceutical Company, **Legend Biotech,** Gilead Sciences, **Arcellx,** Galapagos NV, Autolus Therapeutics, 2seventy bio, Kyverna Therapeutics, CARGO Therapeutics, ImmPACT Bio, **TG Therapeutics,** 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. 18EMPLOYEESAs -- **EMPLOYEESAs** of December 31, 2023 **2024** , we had 80 **6** full- time employees. None of our employees is represented by a labor union or covered under a collective bargaining agreement, and we consider our employee relations to be good. Employees of Fortress also make valuable financial, legal **, business development** , scientific and other strategic contributions to our Company on a regular basis. SUPPLY AND MANUFACTURINGAs an early-

stage development company, we rely on our research partners to manufacture or have manufactured all LV vectors used in the clinical development programs currently in progress at COH ~~,~~ **and** Fred Hutch ~~, 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 **the aforementioned** UAB ~~, the clinical trial site for the~~ Phase 1 ~~trial~~ **trials** 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 **potentially** ~~oncolytic virus for our IND trials until such time~~ as **well for the Phase 1 investigator- sponsored single- institution MB- 109 combination** ~~material~~ --- **trial** ~~is available from our contract manufacturing organizations~~ **currently under discussion with COH and Nationwide** . Pursuant to the March 2015 Licensing Agreement with COH, we have the right to make and have made the cellular products, and we have negotiated Investigator- Initiated Clinical Research Support Agreements with COH 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~~ **16We** 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~~ **would** be conducted under IND applications to be filed by us. In May 2023 **, we entered into an Asset Purchase Agreement (the " Prior Asset Purchase Agreement ") with uBriGene (Boston) Biosciences, Inc. (" uBriGene "), pursuant to which we agreed to sell our leasehold interests in our cell processing facility and associated assets relating to the manufacturing and production of cell and gene therapies. On July 28, 2023, we completed the sale of all of our assets relating to our operations primarily relating to the manufacturing and production of cell and gene therapies. In June 2024** , we entered into an Asset Purchase Agreement with uBriGene ~~(Boston) Biosciences~~ **to repurchase the assets, properties and rights previously transferred by the Company to uBriGene under the Prior Asset Purchase Agreement, excluding any inventory transferred under the Prior Asset Purchase Agreement that has been consumed or transferred to a third party by uBriGene since the closing of the Prior Asset Purchase Agreement. Finally, on February 7, 2025, we entered into the First Amendment to the lease agreement with WCS- 377 Plantation Street** , Inc., pursuant to which **the lease was terminated, which became effective on February 21, 2025. On February 27, 2025,** we ~~agreed to sell~~ **announced the relocation of** our ~~leasehold interests in~~ **corporate headquarters to 95 Sawyer Road, Waltham, Massachusetts. Going forward, we expect to continue to rely on** our **academic partners and future contract manufacturing relationships to support** cell processing **for clinical trials of our CAR T** ~~facility and associated assets relating to the manufacturing and production~~ **products** ~~of cell and gene therapies~~ . **Furthermore** ~~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~~ **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 REGULATIONSNumerous 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., ~~19any~~ -- **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 DevelopmentThe 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~~ **17FDA** Expedited Review and Approval ProgramsFDA has various programs, including fast track designation, regenerative medicine advanced therapy (RMAT) designation, breakthrough therapy designation (BTD), accelerated approval, and priority review that are intended to expedite the process for the development and FDA review of drugs that are intended for the treatment of serious or life- threatening diseases or conditions and demonstrate the potential to address existing unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. To be eligible for fast track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life- threatening disease or condition and based on preclinical or preliminary clinical data that demonstrates the potential to address an unmet medical need in the intended patient population. The FDA will determine that a product will fulfill an unmet medical need if it will provide a therapy where either none exists or provide a therapy that may be potentially superior to an existing therapy based on efficacy or safety factors. A drug is eligible for RMAT designation if it is a regenerative medicine therapy which is defined as either a cell therapy, therapeutic tissue engineered product, human cell and tissue product, or a combination therapy using any such therapies or products, it is intended to treat, modify, reverse, or cure a serious condition; and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address the unmet medical needs for such conditions. Advantages of RMAT designation include all the benefits of the fast track designation, including early interactions with FDA. The FDA must respond to a request for RMAT designation within 60 calendar days of receipt of the request. As with other expedited development programs, if RMAT designation has been granted but, later in development, the product no longer meets the qualifying criteria, then CBER may rescind the RMAT designation. Moreover, a sponsor can request designation of a product candidate as a " breakthrough therapy. " A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval ~~,~~of a breakthrough therapy. The FDA may give a priority review designation within 60 days of submission of a BLA or NDA to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. If granted, a priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Products that are eligible for fast track, RMAT or breakthrough therapy designation may be eligible to receive a priority review if the criteria for priority review are met at the time of the BLA or NDA submission. In addition, **drugs** studied for their safety and effectiveness in treating serious or life- threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Approval is determined on the basis of adequate and well- controlled clinical trials that establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the ~~20availability~~ -- **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~~ **18Clinical** TrialsTo 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. ~~21Sponsors~~ -- **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~~ **19The** 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~~ **an** NDA or BLA application. Measures to observe for delayed adverse effects in subjects who have been exposed to investigational gene therapies are required. Per the guidelines, FDA requires that sponsors observe subjects for potential gene therapy- related delayed adverse events which can be, dependent upon various factors, up to a period of 15 years post treatment. FDA Review and ApprovalBefore 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. ~~22Post~~ **20Post** - Marketing RequirementsFollowing 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 InformationUnder 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 planed NDA of 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. ~~23Orphan~~ **21Orphan** Drug Designation and ExclusivityThe 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 RequirementsManufacturing, 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; ~~24~~ **Pharmaceutical Coverage** ~~the Affordable Care Act (" ACA ") commonly referred to as the Sunshine Act~~ , **Pricing** ~~which requires applicable manufacturers of covered drugs,devices,biologics~~ and **ReimbursementIn** ~~medical supplies to track and annually report to CMS payments and other~~ ~~--~~ **the** ~~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~~ **and markets** ~~adequate system of internal accounting controls.Additionally,~~ in ~~many~~ other countries, **sales** ~~the health care providers who prescribe pharmaceuticals are employed by their government,and the purchasers~~ of **any products for** ~~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 **we** ~~may differ in substance and application from state- to- state thereby complicating compliance efforts.Pharmaceutical Coverage,Pricing and ReimbursementThe ability to successfully commercialize any product candidate which receives~~ ~~-~~ **receive** ~~marketing authorization~~ **regulatory approval for commercial sale will** ~~depends~~ ~~--~~ **depend** in part on the **availability of** ~~extent to which coverage and~~ reimbursement ~~for these products and related treatments will be available~~ from ~~government health administration authorities,private health insurers and other organizations.Government authorities and other~~ third- party payors, ~~such as~~ **including government health administrative authorities,managed care providers,** private health insurers and **other** ~~health maintenance~~ organizations ~~,decide which medications~~ **.Third- party payors are increasingly examining** ~~they~~ ~~--~~ **the medical necessity** ~~will pay for~~ and ~~establish reimbursement levels.A primary trend in the healthcare industry in the United States and elsewhere is cost containment.The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system,including implementing~~ cost- ~~containment programs~~ **effectiveness of medical products and services,in addition** to ~~limit the~~ **their** ~~growth~~ **safety and efficacy,and,accordingly,significant uncertainty exists as to the reimbursement status** of ~~government~~ **newly approved therapeutics.Adequate third** ~~-~~ ~~paid~~ **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** ~~healthcare~~ ~~----~~ **health** ~~costs~~ **care legislation and regulations** ,including **regulations that will be issued to implement provisions** ~~price controls,restrictions on reimbursement and requirements for substitution~~ of ~~generic products for branded prescription drugs.In~~ the ~~United States~~ **health care reform legislation enacted in 2010** , **known as** the Affordable Care Act ~~was intended to broaden access to health insurance,reduce or constrain the growth of healthcare spending,enhance remedies against fraud and abuse,add transparency requirements for the healthcare and health insurance industries,impose new taxes and fees on the health industry and impose additional health policy reforms~~ . ~~There~~ ~~--~~ **The** ~~have been significant ongoing judicial,administrative,executive and legislative efforts to modify or eliminate the~~ Affordable Care Act ~~.Changes to~~ and **further** ~~under the Affordable Care Act remain possible but it is unknown what form any such~~ changes ~~or any~~ **in the** law ~~proposed to replace or revise the Affordable Care Act would take,and how or whether it may affect our~~ ~~--~~ **or regulatory framework** ~~business in the future.We expect that changes to the Affordable Care Act,the Medicare and Medicaid programs,changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures,especially with regard to healthcare access,financing or other legislation in individual states,~~ could have a material adverse effect on ~~the healthcare industry.We also expect that the Affordable Care Act,as well as other healthcare reform measures that have and may be adopted in the future,may result in more rigorous coverage criteria and in additional downward pressure on the price that can be charged for drug products.Any reduction in reimbursement from Medicare,Medicaid,or~~ **our business** ~~other government~~

~~programs may result in a similar reduction in payments from private payers.The Inflation Reduction Act of 2022 (the " IRA ") contains substantial drug pricing reforms,including the establishment of a drug price negotiation program within the U.S.Department of Health and Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance,the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation,and requires manufacturers to provide discounts on Part D drugs.Orphan drugs that treat only one rare disease are exempt from the IRA' s drug negotiation program.Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA.23At the state level,legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing,including price or patient reimbursement constraints,discounts,restrictions on certain product access and marketing cost disclosure and transparency measures,and,in some cases,designed to encourage importation from other countries and bulk purchasing.Additional federal,state and foreign healthcare reform measures will be adopted in the future,any of which could limit the amounts that federal and state governments will pay for healthcare products and services,which could result in limited coverage and reimbursement and reduced demand or additional pricing pressures.These and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any current product or future product candidate.Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors.The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue,attain profitability or commercialize our products.Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for drugs.It is uncertain whether additional legislative changes will be enacted,or whether the FDA regulations,guidance or interpretations will be changed,or what the impact of such may be.In addition,increased Congressional scrutiny of the FDA' s approval process may significantly delay or prevent marketing approval,as well as subject the industry to more stringent product labeling and post- marketing testing and other requirements.It is also unclear what impact any changes made by the new presidential administration will have on the industry.Such actions may impact the development and commercialization of drug products~~ .International RegulationIn 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 **FactorsInvesting** ~~Factors Investing~~ in our common stock or any other type of equity or debt securities we may offer (together,our " Securities ") involves a high degree of risk.The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward- looking statements we have made in this Form 10- K and those we may make from time to time.You should carefully consider the risks described below,in addition to the other information contained in this Form 10- K,including our consolidated financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations " before making an investment decision.Our business,financial condition or results of operations could be harmed by any of these risks.The risks and uncertainties described below are not the only ones we face.Additional risks not presently known to us,or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.Some of the statements in the following risk factors constitute forward- looking statements.Please see the section titled " Special ~~Cautionary~~ Note Regarding Forward- Looking Statements." ~~Risks~~ **25Risks** Related to Our Finances and Capital RequirementsWe 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 $ ~~15~~ **51** . ~~8~~ **6** million and $ ~~51~~ **77** . ~~6~~ **5** million for the years ended December 31, ~~2024 and~~ 2023 **and 2022** ,respectively,and we had an accumulated deficit of $ ~~396~~ **381** . ~~7~~ **0** million as of December 31, ~~2024~~ **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. ~~24Because~~ -- **Because** of the numerous risks and uncertainties associated with developing pharmaceutical products,we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve profitability.Our net losses may fluctuate significantly from quarter to quarter and year to year.We anticipate that our expenses will increase substantially if:● one or more of our product candidates receive regulatory approval and are approved for commercial sale,due to our need to establish the necessary commercial infrastructure to launch and commercialize this product candidate without substantial delays,including hiring sales and marketing personnel and contracting with third parties for manufacturing,testing,warehousing,distribution,cash collection and related commercial activities;● we are required by the FDA or foreign regulatory authorities to perform studies in addition to those currently expected;● there are any delays in completing our clinical trials or the development of any of our product candidates;● we execute other collaborative,licensing or similar arrangements that require us to make payments to collaborators or licensors;● there are variations in the level of expenses related to our future development programs;● there are any product liability or intellectual property infringement lawsuits in which we may become involved;and ● there are any regulatory developments affecting product candidates of our competitors.Our ability to become profitable depends upon our ability to generate revenue.To date,we have not generated any revenue from our development stage products,and we do not know when,or if,we will generate any revenue.Our ability to generate revenue depends on a number of factors,including,but not limited to,our ability to:● obtain regulatory approval for one or more of our product candidates,or any future product candidate that we may license or acquire;● manufacture or have manufactured

commercial quantities of one or more of our product candidates or any future product candidate,if approved,at acceptable cost levels;and ● develop a commercial organization and the supporting infrastructure required to successfully market and sell one or more of our product candidates or any future product candidate,if approved.Even if we do achieve profitability,we may not be able to sustain or increase profitability on a quarterly or annual basis.Our failure to become and remain profitable would depress the value of our Company and could impair our ability to raise capital,expand our business,maintain our research and development efforts,diversify our product offerings or even continue our operations.A decline in the value of our Company could also cause you to lose all or part of your investment in our Securities.There is substantial doubt regarding our ability to continue as a going concern.We will need to raise additional funding **,** (which may not be available on acceptable terms to us,or at all) and / or delay,limit or terminate our product development efforts or other operations. ~~If we are unable to raise capital,we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.~~ We are currently advancing our programs in hematologic cancers, ~~autoimmune diseases and~~ 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~~ **26revenues** 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, ~~2024~~ **2023** ,our cash and cash equivalents were $ 6. ~~8~~ **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, ~~2024~~ **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 ~~25adversely~~ -- **adversely** impact our ability to conduct our business.We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us,any of which may have a material adverse effect on our business,operating results and prospects.In addition,in order to address our current funding constraints,we may be required to further revise our business plan and strategy,which may result in us (i) further curtailing,delaying or discontinuing one or more of our research or development programs or the commercialization of any product candidates,(ii) selling certain of our assets and / or (iii) may result in our being unable to expand our operations or otherwise capitalize on our business opportunities.Such actions may become necessary whether or not we are able to raise additional capital.As a result,our business,financial condition,and results of operations could be materially affected. ~~Furthermore,if we are unable to raise capital,we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.~~ Our short operating history makes it difficult to evaluate our business and prospects.We have been conducting operations only since our incorporation in March 2015.Our operations to date have been limited.We have not yet demonstrated an ability to successfully complete clinical trials,obtain regulatory approvals,manufacture a clinical scale or commercial scale product,or arrange for a third party to do so on our behalf,or conduct sales and marketing activities necessary for successful product commercialization.Consequently,any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.In addition,as a young business,we may encounter unforeseen expenses,difficulties,complications,delays and other known and unknown factors.We will need to expand our capabilities to support commercial activities.We may not be successful in adding such capabilities.We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors,many of which are beyond our control.Accordingly,you should not rely upon the results of any past quarterly period as an indication of future operating performance.We will require substantial additional funding which may not be available to us on acceptable terms,or at all.If we fail to raise the necessary additional capital,we may be unable to complete the development and commercialization of our product candidates or continue our development programs.Our operations have consumed substantial amounts of cash since inception.We will need to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidates for which we may receive regulatory approval,including building our own commercial organizations to address certain markets.We will require substantial additional capital for the further development and,if approved,commercialization of our product candidates,as well as to fund our other operating expenses and capital expenditures.As of December 31, ~~2024~~ **2023** ,we had $ ~~6~~ **7** . ~~8~~ **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 ~~terms~~ **27terms** ,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; ~~26~~ ● 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 ~~.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.SEC regulations limit the amount of funds we can raise during any 12- month period pursuant to our shelf registration statement on Form S- 3~~ .Under current SEC regulations,if at the time we file our Annual Report on Form 10- K our public float is less than $ 75 million,and for so long as our public float remains less than $ 75 million,the amount we can raise through primary public offerings of securities in any twelve- month period using shelf registration statements is limited to an aggregate of one- third of our public float,which is 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 exceeds 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 ~~number~~ **amount** of securities we may sell under our Form S- 3 shelf registration statements will also decrease. ~~Furthermore~~ **Our inability to raise capital when needed would harm our business** , ~~if we are~~ **financial condition and results of operations,and could cause our stock value to decline or** ~~required~~ **require that we wind down** ~~or~~ **our operations altogether** ~~choose to file a new registration statement on a form other than Form S- 3,we may incur additional costs and be subject to delays due to review by the SEC staff~~ . ~~Raising~~ **28Raising** 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 ~~27additional~~ -- **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~~ **the** Nasdaq Stock **Exchange** ~~Market LLC (“ Nasdaq ”)~~ .These rules impose various requirements on public companies,including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices.Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives.Moreover,these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly.For example,these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance,and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.As a result,it may be more difficult for us to attract and retain qualified persons to serve on our Board,our Board committees or as executive officers.The Sarbanes- Oxley Act

requires,among other things,that we maintain effective internal controls for financial reporting and disclosure controls and procedures.As a result,we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls,as required by Section 404 of the Sarbanes- Oxley Act.These efforts to comply with Section 404 and related regulations have required,and continue to require,the commitment of significant financial and managerial resources.While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404,we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future.If a material weakness is identified,we could be subject to sanctions or investigations by the SEC or other regulatory authorities,which would require additional financial and management resources,costly litigation or a loss of public confidence in our internal controls,which could have an adverse effect on the market price of our stock.We are a" smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.We are a smaller reporting company,and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non- voting common shares held by non- affiliates is more than $ 250 million measured on the last business day of our second fiscal quarter,or our annual revenues are more than $ 100 million during the most recently completed fiscal year and our voting and non- voting common shares held by non- affiliates is more than $ 700 million measured on the last business day of our second fiscal quarter.Smaller reporting companies are able to provide simplified executive compensation disclosure,are exempt from the auditor attestation requirements of Section 404,and have certain other reduced disclosure obligations,including,among other things,being required to provide only two years of audited financial statements and not being required to provide selected financial data,supplemental financial information or risk factors.We have elected to take advantage of certain of the reduced reporting obligations available to us.We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions.If some investors find our common stock less attractive as a result,there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. ~~Our~~ **29Our** 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 ~~28period~~ -- **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 OrganizationWe currently have no products for sale.We are heavily dependent on the success of our product candidates,and we cannot give any assurances that any of our product candidates will receive regulatory approval or be successfully commercialized.To date,we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates.We have not demonstrated our ability to perform the functions necessary for the successful acquisition,development or commercialization of the technologies we are seeking to develop.As an early stage company,we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields,particularly in the biopharmaceutical area.Our future success is substantially dependent on our ability to successfully develop,obtain regulatory approval for,and then commercialize such product candidates.Most of our product candidates are currently in early stage clinical trials.Our business depends entirely on the successful development and commercialization of our product candidates,which may never occur.We currently have no drug products for sale,currently generate no revenues from sales of any drug products,and may never be able to develop or commercialize a marketable product.The successful development,and any commercialization,of our technologies and any product candidates that may occur would require us to successfully perform a variety of functions,including:● developing our technology platform;● identifying,developing,formulating,manufacturing and,if approved,commercializing product candidates;● entering into successful licensing and other arrangements with product development partners;● participating in regulatory approval processes,including ultimately gaining approval to market a drug product,which may not occur;● obtaining sufficient quantities of our product candidates from our third- party manufacturers to meet clinical trial needs and,if approved,to meet commercial demand at launch and thereafter;● establishing and maintaining agreements with wholesalers,distributors and group purchasing organizations on commercially reasonable terms;● conducting sales and marketing activities including hiring,training,deploying and supporting our sales force and creating market demand for our product candidates through our own marketing and sales activities,and any other arrangements to promote our product candidates that we may establish;● maintaining patent protection and regulatory exclusivity for our product candidates;and ● raising additional required capital on acceptable terms.Our operations have historically been limited to organizing ~~the Company~~ ,acquiring,developing and securing our proprietary technology and identifying and obtaining preclinical data or clinical data for various product candidates.These operations provide a limited basis ~~for you~~ to assess our ability to continue to develop our technology,identify product candidates,develop and commercialize any product candidates we are able to identify and enter into successful collaborative arrangements with other companies,as well as for you to assess the advisability of investing in our securities.Each of these requirements will require substantial time,effort and financial resources. ~~Each~~ **30Each** 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 ~~29or~~ **or** promote any of our product candidates in the U.S.or any other jurisdiction before we receive regulatory approval from the FDA or comparable foreign regulatory authority,respectively,and we may never receive such

regulatory approval for any of our product candidates.Our approach to the development of our product candidates is unproven,and we do not know whether we will be able to develop any products of commercial value.Our product candidates are emerging technologies and,consequently,it is conceivable that such technologies may ultimately fail to develop into commercially viable therapies to treat human patients with cancer or other diseases.One of the reasons for the lack of commercial viability could be our inability to obtain regulatory approval for such technologies.CAR T is a ~~relatively~~ new approach to cancer treatment that presents significant challenges.We have concentrated much of our research and development efforts on CAR T technology,and our future success is highly dependent on the successful development of T cell immunotherapies in general and our CAR T technology and product 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 ~~indications~~ **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. ~~30Risks~~ **31Risks** Inherent in Drug Development and CommercializationDelays 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. ~~31Changes~~ **32Changes** 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; ~~32~~ **33** ● the FDA may determine that our manufacturing processes or facilities or those of third- party manufacturers with which we or our respective collaborators currently contract for clinical supplies and plan to contract for commercial supplies do not satisfactorily comply with cGMPs;or ● the approval policies or interpretation of regulations of the FDA may significantly change in a manner rendering the clinical data insufficient for approval or the product characteristics or benefit- risk profile unfavorable for approval.With respect to foreign markets,approval procedures vary among countries and,in addition to the aforementioned risks,can involve additional product testing,administrative review periods and agreements with pricing authorities.In addition,rapid drug and biological development during the COVID- 19 pandemic has raised questions about the safety and efficacy of certain marketed pharmaceuticals and may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety,efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.Any delay in obtaining,or inability to obtain,applicable regulatory approvals would prevent us from commercializing our product candidates ~~.It is also unclear what actions will be taken by the current presidential administration or through legislative action that could impact the FDA and our ability to obtain regulatory approvals~~ .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 ~~33defect~~ -- **defect** or error discovered after products have been produced and distributed could result in even more significant consequences,including costly recalls,re-stocking costs,damage to our reputation and potential for product liability claims. ~~If~~ **34If** 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 ~~34the~~ -- **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** ~~in a way which is not consistent with the~~ **their** approved ~~labeling~~ **indications** ,we may be subject to enforcement action for off- label marketing.Violations of the Federal Food,Drug and Cosmetics Act (" FDCA ") relating to the promotion of prescription ~~drugs~~ **35drugs** 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 ~~.There is added uncertainty in light of actions that may be taken by the current presidential administration or Congress with respect to the FDA~~ .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. ~~35Public~~ **36Public** 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 ~~expanded~~ **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. ~~36If~~ **37If** 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; ~~37~~ **38** ● the safety of such product candidates seen in a broader patient group,(i.e.,based on actual use);● the availability,cost and potential advantages of alternative treatments,including less expensive generic drugs;● the availability of adequate reimbursement and pricing by third- party payors and government authorities;● changes in regulatory requirements by government authorities for our product candidates;● the relative convenience and ease of administration of the product candidate for clinical practices;● the product labeling or product insert required by the FDA or regulatory authority in other countries,including any contradictions,warnings,drug interactions,or other precautions;● changes in the standard of care for the targeted indications for our product candidate or future product candidates,which could reduce the marketing impact of any labeling or marketing claims that we could make following FDA approval;● the approval,availability,market acceptance and reimbursement for a companion diagnostic,if any;● the prevalence and severity of adverse side effects;and ● the effectiveness of our sales and marketing efforts.If any product candidate that we develop does not provide a treatment regimen that is as beneficial as,or is not perceived as being as beneficial as,the current standard of care or otherwise does not provide patient benefit,that product candidate,if approved for commercial sale by the FDA or other regulatory authorities,likely will not achieve market acceptance.Our ability to effectively promote and sell any approved products will also depend on pricing and cost- effectiveness,including our ability to produce a product at a competitive price and our ability to obtain sufficient third- party coverage or reimbursement.If any product candidate is approved but does not achieve an adequate level of acceptance by physicians,patients and third- party payors,our ability to generate revenues from that product would be substantially reduced.In addition,our efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources,may be constrained by FDA rules and policies on product promotion,and may never be successful.Reimbursement may be limited or unavailable in certain market segments for our product candidates,which could make it difficult for us to sell our products profitably.There is significant uncertainty related to the third- party coverage and reimbursement of newly approved drugs.Such third- party payors include government health

programs such as Medicare,managed care providers,private health insurers and other organizations.We intend to seek approval to market our product candidates in the U.S.,the ~~European Union (“~~ EU ~~”)~~ and other selected foreign jurisdictions.Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for any of our product candidates and may be affected by existing and future health care reform measures.Government and other third- party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and,as a result,they may not cover or provide adequate payment for our product candidates,if approved.These payors may conclude that our product candidates are less safe,less effective or less cost- effective than existing or future introduced products,and third-party payors may not approve our product candidates,if approved,for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates.Obtaining coverage and reimbursement approval for a product from a government or other third- party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific,clinical and cost- effectiveness data for the use of our products.We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement.If reimbursement of our future products is unavailable or limited in scope or amount,or if pricing is set at unsatisfactory levels,we may be unable to achieve or sustain profitability.In some foreign countries,particularly in the EU,the pricing of prescription pharmaceuticals is subject to governmental control.In these countries,pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate.To obtain reimbursement or pricing approval in some countries,we may be required to conduct additional clinical trials that compare the cost- effectiveness of our product candidates to other available therapies.If reimbursement of our product candidates,if approved,is unavailable or limited in scope or amount in a particular country,or if pricing is set at unsatisfactory levels,we may be unable to achieve or sustain profitability of our products in such a country. ~~38If~~ **39If** 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, ~~we may license or acquire and~~ may have to limit their commercialization.The use of one or more of our product candidates and any future product candidate we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims.For example,we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing,manufacturing,and,if approved,during marketing or sale.Any such product liability claims may include allegations of defects in manufacturing,defects in design,a failure to warn of dangers inherent in the product,negligence,strict liability or a breach of warranties.Product liability claims might be brought against us by consumers,health care providers or others using,administering or selling our products.If we cannot successfully defend ourselves against these claims,we will incur substantial liabilities.Regardless of merit or eventual outcome,liability claims may result in:● withdrawal of clinical trial participants;● suspension or termination of clinical trial sites or entire trial programs;● decreased demand for any product candidates or products that we may develop;● initiation of investigations by regulators;● impairment of our business reputation;● costs of related litigation;● substantial monetary awards to patients or other claimants;● loss of revenues;● reduced resources of our management to pursue our business strategy; ~~and39~~ **and40** ● 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~~ **41Negative** 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 PartiesWe 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 ~~40complies~~ **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~~ **42We** are currently reliant on COH,Fred Hutch, ~~Nationwide and~~ **St.Jude,the NIH,** UAB **,Mayo Clinic,and LUMC** for ~~all~~ **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, ~~Nationwide~~ **St.Jude** , ~~and~~ UAB **,Mayo Clinic and LUMC** pursuant to a sponsored research agreement and / or clinical trial agreements **with** ~~between Mustang Bio and~~ each of **those parties** ~~COH and Fred Hutch,as well as a Memorandum of Understanding between Nationwide and UAB under which UAB is conducting its MB- 108 Phase 1 clinical trials~~ .As a result,our future success is heavily dependent on the results of research and development efforts of ~~these institutions~~ **Dr.Stephen Forman and his team at COH,of Drs.Brian Till and Mazyar Shadman** and their ~~personnel~~ **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** ~~Due to limited resources,and in light of our reduction in work force in April 2024,we~~ may **rely** ~~increase our reliance~~ on third- party manufacturers or third- party collaborators for the manufacture of commercial supply of one or more product candidates for which our collaborators or we obtain marketing approval.We may be unable to establish any agreements with third- party manufacturers or to do so on acceptable terms.Even if we are able to establish agreements with third- party manufacturers,reliance on third- party manufacturers entails additional risks,including,but not necessarily limited to:● reliance on the third party for regulatory compliance and quality assurance,while still being required by law to establish adequate oversight and control over products furnished by that third party;● the possible breach of the manufacturing agreement by the third party;● manufacturing delays if our third- party manufacturers are unable to obtain raw materials due to supply chain disruptions,give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;● the possible misappropriation of our proprietary information,including our trade secrets and know- how;and ● the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.We rely on our third- party manufacturers to produce or purchase from third- party suppliers the materials and equipment necessary to produce our product candidates for our preclinical and clinical trials.Forces beyond our control **,including the continuing effects of the COVID- 19 pandemic,** could disrupt the global supply chain ~~,including imposition of tariffs,~~ and impact our or our third- party manufacturers’ ability to obtain raw materials or other products necessary to manufacture our product candidates.There are a limited number of suppliers for raw materials and equipment that we use (or that are used on our behalf) to manufacture our product candidates,and there may be a need to assess alternate suppliers to prevent a possible disruption ~~41of~~ **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** ~~a New Drug Application (“~~ NDA ~~”)~~ or BLA to the FDA.We are required by law to establish adequate oversight and control over raw materials,components and finished products furnished by our contract manufacturers,but we do not control the day- to- day manufacturing operations of,and are dependent on,the contract manufacturers for compliance with ~~current Good Manufacturing Practices (“~~ cGMP ~~”)~~ regulations for manufacture of our product candidates.Third- party manufacturers may not be able to comply with the cGMP regulations or similar regulatory requirements outside the United States.Our failure,or the failure of our third- party manufacturers,to comply with applicable regulations could result in sanctions being imposed on us,including clinical holds,fines,injunctions,restrictions on imports and exports,civil penalties,delays,suspension or withdrawal of approvals,license revocation,seizures or recalls of product candidates or products,operating restrictions and criminal prosecutions,any of which could significantly and adversely affect supplies of our products. ~~One~~ **43One** 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 ~~,commercialize~~ ,we will remain responsible for ensuring that each of our IND- enabling studies and clinical studies is conducted in accordance with the study plan and protocols,and that our LV vectors are manufactured in accordance with GMP as applied in the relevant jurisdictions.If these third parties do not successfully carry out their contractual duties,meet expected deadlines,conduct our studies in accordance with regulatory requirements or our stated study plans and protocols,or manufacture our LV vectors in accordance with GMP,we will not be able to complete,or may be delayed in completing,the preclinical and clinical studies and manufacturing process validation activities required to support future IND,market authorization application and BLA submissions and approval of our product candidates,or to support commercialization of our products,if approved.Many of our agreements with these third parties contain termination provisions that allow these third parties to terminate their relationships with us at any time.If we need to enter into alternative arrangements,our product development and commercialization activities could be delayed.We may be forced to enter into an agreement with a different manufacturer,which we may not be able to do on reasonable terms,if at all.In some cases,the technical skills required to manufacture LV vector for our drug product candidates may be unique or proprietary to the original manufacturer,and we may have difficulty or there may be contractual restrictions prohibiting us from,transferring such skills to a back- up or alternate supplier,or we may be unable to transfer such skills at all.Any of these events could lead to clinical study delays or ~~42failure~~ -- **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~~ **44in** 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 IndustriesWe 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 ~~43and~~ -- **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** eliminated the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024.With the elimination of the rebate cap,manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug.Additionally,the Inflation Reduction Act of 2022 ~~(" IRA ")~~ contains substantial drug pricing reforms,including the establishment of a drug price negotiation program within the U.S.Department of Health and Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance,the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation,and requires manufacturers to provide discounts on Part D drugs.Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the **Inflation Reduction Act of 2022** ~~IRA.Although the IRA exempts orphan drugs that treat only one rare disease from the drug pricing negotiation provisions,we do not know if additional drug pricing reforms could eliminate this exemption~~ .The ~~IRA~~ **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 ~~the IRA~~ **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. ~~We~~ **45We** 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 ~~and scrutiny by the current presidential administration~~ 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. ~~There is added uncertainty in light of actions that may be taken by the current presidential administration or Congress with respect to the FDA.~~ 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. ~~44Our~~ -- **Our** current and future relationships with customers and third- party payors in the United States and elsewhere may be subject,directly or indirectly,to applicable anti-kickback,fraud and abuse,false claims,transparency,health information privacy and security and other healthcare laws and regulations,which could expose us to criminal sanctions,civil penalties,contractual damages,reputational harm,administrative burdens and diminished profits and future earnings.Healthcare providers,physicians and third- party payors in the U.S.and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval.Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations,including,without limitation,the federal Anti- Kickback Statute and the federal False Claims Act,which may constrain the business or financial arrangements and relationships through which we sell,market and distribute any product candidates for which we obtain marketing approval.In addition,we may be subject to transparency laws and patient privacy regulation by the federal and state governments and by governments in foreign jurisdictions in which we conduct our business.The applicable federal,state and foreign healthcare laws and regulations that may affect our ability to operate include,but are not necessarily limited to:● The federal Anti- Kickback Statute,which prohibits,among other things,persons from knowingly and willfully soliciting,receiving,offering or paying remuneration,directly or indirectly,in cash or in kind,to induce or reward,or in return for,either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, ~~or~~ **46or** (2) the purchase,lease,order or recommendation thereof of any good,facility,service or item for which payment is available under a federal ~~healthcare~~ ---- **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.** · 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 ReimbursementIn the.....- 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~~ **45statutes** , 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 ~~47laws~~ -- **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 ThereofIf 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~~ **46In** 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 ~~48protect~~ **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~~ **47unsuccessful** , 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. ~~49We~~ **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~~ **48Protecting** 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; ~~50~~ ● 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~~ **49There** 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. ~~51Intellectual~~ -- **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~~ **50believe** 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. ~~52We~~ **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~~ **51In** 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. ~~53Risks~~ -- **Risks** Relating to Our Control by FortressFortress 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~~ **52General** ~~RisksOur~~ --- **Risks and Risks Associated with Ownership of our Common StockOur** 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 ~~54confidential --~~ **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~~ **53attention** . 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. ~~55Our --~~ **Our** business could be adversely affected by the effects of health pandemics or epidemics, which could cause significant disruptions in our operations. Health pandemics or epidemics, such as the COVID- 19 pandemic, have in the past and could again in the future result in quarantines, stay- at- home orders, remote work policies or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third- party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. In addition, impact on the operations of the FDA or other regulatory authorities could negatively affect our planned approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated. The effects of epidemics and pandemic are highly uncertain and subject to change. If we are not able to respond to and manage

the impact of such events effectively, our business, operating results, financial condition and cash flows could be adversely affected. Our growth is subject to economic and geopolitical conditions. Our business is affected by global and local economic and geopolitical conditions as well as the state of the financial markets, inflation, recession, financial liquidity, currency volatility, growth, and policy initiatives. There can be no assurance that global economic conditions and financial markets will not worsen and that we will not experience any adverse effects that may be material to our consolidated cash flows, results of operations, financial position or our ability to access capital, such as the adverse effects resulting from a prolonged shutdown in government operations both in the United States and internationally. Geopolitical changes, including war or other conflicts (including the conflicts between Russia and Ukraine and Israel and Hamas), some of which may be disruptive, could interfere with our supply chain, our customers and all of our activities in a particular location. **Additionally, trade policies and geopolitical disputes and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures occur in regions where drug products are manufactured or raw materials are sourced. Tensions between the United States and China have led to a series of tariffs being imposed by the United States on imports from China mainland, as well as other business restrictions. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain. As these tensions continue to rise, more targeted approaches by the U. S. or Chinese governments on certain products, industries or companies could significantly impact our development and commercialization efforts. The Trump administration may impose additional and higher tariffs and sanctions on goods imported from China and other countries which could increase the cost of goods needed to commercialize our products and continue development of our product candidates. Further, such actions by the U. S. could result in retaliatory action by those countries which could impact our ability to profitably commercialize our products in those jurisdictions. As a result, our business, operations, and financial condition could be materially harmed.** We may not be able to manage our business effectively if we are unable to attract and retain key personnel. We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. Our employees, consultants, or third- party partners may engage in misconduct or other improper activities, including but not necessarily limited to noncompliance with regulatory standards and requirements or internal procedures, policies or agreements to which such employees, consultants and partners are subject, any of which could have a material adverse effect on our business. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third- party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with cGMPs, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, comply with internal procedures, policies or agreements to which such employees, consultants or partners are subject, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to ~~prevent~~ **54prevent** 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. ~~56We~~ **We** rely on information technology, and any internet or internal computer system failures, inadequacies, interruptions or compromises of our systems or the security of confidential information could damage our reputation and harm our business. Although a significant portion of our business is conducted using traditional methods of contact and communications such as face- to- face meetings, our business is increasingly dependent on critical, complex and interdependent information technology systems, including internet- based systems, to support business processes as well as internal and external communications. We could experience system failures and degradations in the future. We cannot assure you that we will be able to prevent an extended and / or material system failure if any of the following or similar events occurs: ● human error; ● subsystem, component, or software failure; ● a power or telecommunications failure; ● hacker attacks, cyber- attacks, software viruses, security breaches, unauthorized access or intentional acts of vandalism; or ● terrorist acts or war. If any of the foregoing events were to occur, our business operations could be disrupted in ways that would require the incurrence of substantial expenditures to remedy. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of

clinical trial data from completed clinical trials for one or more of our product conducts could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data and applications, or inappropriate / unauthorized disclosure of confidential or proprietary information (including trade secrets), we could incur liability and our business and financial condition could be harmed. The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits, or we could lose key data which could cause us to curtail or cease operations. We are vulnerable to damage and / or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, health epidemics and pandemics, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our businesses could be seriously impaired. We have property, liability and business interruption insurance that may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects. Any of the aforementioned circumstances, including without limitation the resurgence of COVID- 19 virus, may also impede our employees' and consultants' abilities to provide services in- person and / or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of " force majeure " clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such " force majeure " clauses, or the ~~enforceability~~ **55enforceability** of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time- consuming. **The market** ~~Our stock may be subject to substantial~~ price **for** ~~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~~ **has been volatile and may continue to fluctuate or may decline significantly in the future** . ~~The~~ **An active, liquid and orderly market for our common stock may not be sustained, which could depress the trading price of our common stock or cause it to continue to be highly volatile or subject to wide fluctuations. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include, among other things: · the commencement, enrollment, or results of our current and future preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector; · regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process; · manufacturing, supply or distribution delays or shortages; · our ability to identify and successfully acquire or in- license new product candidates on acceptable terms; · FDA, state or international regulatory actions, including actions on regulatory applications any of our product candidates; · legislative or regulatory changes; · judicial pronouncements interpreting laws and regulations; · changes in government programs; · announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors; · market conditions in the pharmaceutical and biotechnology sectors; · fluctuations in stock** market prices ~~for securities of biotechnology~~ and ~~pharmaceutical~~ **trading volumes of similar** companies ~~have historically been highly volatile, and~~ **; · changes in accounting principles; · litigation or public concern about** the **safety of our product candidates or similar product candidates; · sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders; and · our ability to obtain additional financing to advance our development operations. These broad** market **and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. The stock market in general** has from time to time experienced ~~significant~~ **extreme** price and volume fluctuations ~~that are unrelated to the operating performance of particular companies~~ . ~~The~~ **In addition, in the past, following periods of volatility in the overall market and decreases in the** market price of **a company' s securities** ~~our common stock is likely to be highly volatile and may fluctuate substantially due to many factors~~ , ~~including: ● announcements concerning~~ **securities class action litigation has often been instituted against** ~~the~~ **these companies. This litigation** ~~progress of our efforts to obtain regulatory approval for and~~ , if ~~approved~~ **instituted against us** , **could** ~~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~~ **substantial costs and a diversion of** ~~or~~ **our management' s attention** ~~launching these product candidates, if approved; 57 ● market conditions in the pharmaceutical~~ and **resources** ~~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~~ **56stock** 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~~ **If we are unable** to ~~Sale~~ **maintain compliance with all applicable continued listing requirements and standards** of **Nasdaq, our common stock may be delisted from Nasdaq.** Our ~~Manufacturing FacilityAs discussed in~~ **common stock is listed on the Nasdaq Capital Market under the symbol** " **MBIO.** ~~Management' s Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments,~~ " ~~on May 18~~ **The Nasdaq Capital Market requires that listed companies satisfy continued listing standards to maintain their listing. On March 13** , ~~2023~~ **2024** , we **received a deficiency letter** ~~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~~ **Letter** ") **from** . ~~The following discussion of risks relating to~~ the **Listing Qualifications Department** ~~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~~ (**the** " ~~CFIUS~~ **Staff** ") ~~determines to implement mitigating measures, including the potential divestment~~ of ~~some~~ **Nasdaq notifying us that we were not in compliance with the minimum stockholders' equity requirement** ~~or~~ **for** ~~all of~~ **continued listing on** the ~~Transferred Assets by uBriGene; any such mitigating measures may limit~~ **Nasdaq Capital Market under Nasdaq Listing Rule 5550 (b) (1) (the " Equity Rule "). The Equity Rule requires companies listed on The Nasdaq Capital Market to maintain stockholders' equity of at least $ 2. 5 million (** ~~our~~ **or** ~~ability~~ **, in the alternative, a market value of listed securities of $ 35 million or net income from continued operations of $ 500, 000 in the most recently completed fiscal year or in** ~~to~~ **two** ~~realize~~ **of the last** ~~the~~ **three** ~~anticipated cost~~ **most** ~~savings of~~ **recently completed fiscal years). Our Annual Report on Form 10- K for** the ~~sale of the Facility and may have~~ **fiscal year ended December 31, 2024, reported** a ~~material adverse~~ **stockholders' deficit of $ 3. 7 million. The Letter had no immediate** effect on our **continued listing Nasdaq** ~~financial condition. Pursuant to the Amended Asset Purchase Agreement~~ , **subject** ~~we and uBriGene agreed~~ to ~~cause~~ our **compliance with the** ~~respective affiliates to use their~~ **other continued listing requirements** ~~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 **Nasdaq Listing Rules** ~~Amended Asset Purchase Agreement~~ , ~~together~~ **we were provided 45 calendar days, or until April 29, 2024, to submit a plan to regain compliance** with ~~uBriGene~~ **the Equity Rule (the " Compliance Plan "). We submitted our Compliance Plan on April 29** , **2024, and the Staff granted our request for an extension of 180 calendar days, through September 9, 2024, to regain compliance with the Equity Rule. We were unable to demonstrate compliance with the Equity Rule by September 9, 2024. On September 10, 2024, the Staff formally notified us that it had determined to delist our securities from Nasdaq based upon our continued non- compliance with Equity Rule unless** we ~~submitted~~ **timely request** a ~~joint~~ **hearing before the Nasdaq Hearings Panel (the " Panel "). On September 17, 2024, we requested a hearing before the Panel, which stayed any further action by Nasdaq at least pending completion of the hearing and the expiration of any extension that may be granted by the Panel to us following the hearing. The hearing took place on October 29, 2024, and we are currently awaiting the decision of the Panel. On May 16, 2024, we received a** notice ~~to CFIUS~~ **(the " Second Letter ") from the Staff indicating that the bid price of our common stock had closed below $ 1. 00 per share for 30 consecutive business days and, as a result, we were not in compliance with Nasdaq Listing Rule 5550 (a) (2), which sets forth the minimum bid price requirement for continued listing** on ~~August~~ **the Nasdaq Capital Market (the " Bid Price Rule "). Pursuant to Nasdaq Listing Rule 5810 (c) (3) (A), we were afforded a 180- calendar day grace period, or until November 12, 2024, to regain compliance with the Bid Price Rule, which necessitates a closing bid price of at least $ 1. 00 per share for a minimum of ten consecutive business days by November 12, 2024. The hearing before the Panel occurred on October 29, 2024. By decision dated November 8, 2024, the Panel granted our request for an extension to evidence compliance with all applicable criteria for continued listing on the Nasdaq Capital Market, including the Bid Price Rule, through January 31, 2025, and the Equity Rule through February 18, 2025. On February** 10, ~~2023~~ **2025 , the Company completed a best- efforts public offering for net proceeds of approximately $ 6. 9 million** . Following **the closing, the Company provided** an ~~initial 45- day review period and subsequent 45- day investigation period~~ **updated forecast to the Panel evidencing compliance with the Equity Rule. On February 26** , **2025, the Company was notified by the Staff that it had regained compliance with the Equity Rule and is subject to mandatory monitoring by the Panel for** ~~on~~ **one** ~~November 13, 2023, CFIUS requested~~ **year. There can be no assurance** that we **will be able** ~~and uBriGene withdraw and re- file our joint voluntary notice~~ to **maintain compliance with Nasdaq** ~~allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction. Upon CFIUS~~ ' s ~~request,~~ **continued listing rules in the future. If** we ~~and uBriGene submitted a request to withdraw and re~~ **are** ~~- file our 58joint 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 **able** ~~concluded its review by December 28, 2023, the proceeding transitioned~~ to **maintain compliance** ~~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 **may be delisted from Nasdaq. In** ~~and uBriGene requested permission to withdraw and re- file their~~ -- **the event we** ~~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 **delisted from Nasdaq** ~~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 **our common stock** such third- party purchaser will continue **be eligible for trading on another stock exchange or quotation on an over- the- counter market. If we are not able** to contract **obtain a listing on another stock exchange or quotation service for our common stock, it may be extremely difficult or impossible for stockholders to sell their shares. Additionally, if we are delisted from Nasdaq, but obtain a substitute listing or quotation service for our common stock, it will likely be on a market** with us for **less liquidity and** our **common stock** 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 **therefore experience potentially more price volatility than it has historically experienced on Nasdaq** . **Stockholders** In addition, a third- party purchaser may not be able to **sell** comply with cGMP or similar regulatory requirements related to the **their** production **shares** of **common stock on any such substitute market in the quantities, at the times,** our - **or at the prices that could potentially** lead product candidates or otherwise may not be **available** able to provide manufacturing services on **a more liquid trading market** quality and timeliness standards that are acceptable to us . **As a result of** In either such case, the **these** manufacturing of **factors, if** our lead product candidate may need to **common stock is delisted from Nasdaq, the value and liquidity of our common stock would likely** be **adversely affected. A delisting** transferred to an unknown CDMO and may be at risk of delays, disruptions or **our common stock from Nasdaq** quality issues, any of which could **also** significantly and adversely affect supplies of our lead product candidate and our ability to **obtain financing for our** 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 **operations and / or result in a loss** of **confidence** the Facility. In addition to the payment of the repurchase price of the Facility, we will cease to be reimbursed by **investors** uBriGene for our CDMO Manufacturing Services and , **employees** 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 **business partners57** 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 59