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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2018

or

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

For the Transition Period from_____ to _____.

Commission File No. 001-38191

MUSTANG BIO, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-3828760**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
2 Gansevoort Street, 9th Floor **New York, New York 10014**	
(Address of Principal Executive Offices)	**10014** **(Zip Code)**

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

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

(Title of Class)	**(Name of exchange on which registered)**
Common Stock, par value $0.0001 per share	**NASDAQ Global Market**

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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

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

Class of Common Stock	**Outstanding Shares as of March 17, 2019**
Class A Common Stock, $0.0001 par value	1,000,000
Common Stock, $0.0001 par value	27,319,497

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

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

Certain matters discussed in this annual report on Form 10-K ("Form 10-K") may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended (the "Securities Act") and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Risk Factors," and elsewhere in this Form 10-K. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

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

The forward-looking statements contained in this Form 10-K reflect our views and assumptions as of the effective date of this Form 10-K. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements.

PART I

Item 1. Business

OVERVIEW

Mustang Bio, Inc. ("Mustang", "We", "Us" or the "Company") is a clinical-stage biopharmaceutical company focused on translating today's medical breakthroughs in cell and gene therapies into potential cures for hematologic cancers, solid tumors and rare genetic diseases. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

Our pipeline is currently focused in three core areas: gene therapy programs for rare genetic disorders, chimeric antigen receptor ("CAR") engineered T cell ("CAR T") therapies for hematologic malignancies and CAR T therapies for solid tumors. For each therapy we have partnered with world class research institutions. For our gene therapy programs, we have partnered with St. Jude Children's Research Hospital ("St. Jude") in the development of a first-in-class *ex vivo* lentiviral treatment of X-linked severe combined immunodeficiency ("XSCID") and for our CAR T therapies we have partnered with the City of Hope National Medical Center ("COH"), Fred Hutchinson Cancer Research Center ("Fred Hutch") and Nationwide Children's Hospital ("Nationwide").

Gene Therapy

In partnership with St. Jude, our gene therapy program (MB-107) is being conducted under an exclusive license to develop a potentially curative treatment for XSCID, a rare genetic immune system condition in which affected patients do not live beyond infancy without treatment. This first-in-class *ex vivo* lentiviral gene therapy is currently in two Phase 1/2 clinical trials sponsored by St. Jude and the National Institutes of Health ("NIH"). Results in these two trials have been promising and we plan to transfer St. Jude's Investigational New Drug Application ("IND") to Mustang in the second half of 2019 following completion of the technology transfer process.

CAR T Therapies

Mustang's 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 cell processing facility located in Worcester, Massachusetts to conduct Mustang sponsored clinical trials.

We are developing CAR T therapies for hematologic malignancies in partnership with COH targeting CD123 (MB-102) and CS1 (MB-104) and with Fred Hutch targeting CD20 (MB-106). Phase 1 clinical trials sponsored by COH for MB-102 and by Fred Hutch for MB-106 are underway and a COH sponsored Phase 1 clinical trial for MB-104 is scheduled to open during the first half of 2019. Mustang plans to file an IND for the MB-102 program in the first half of 2019 and to initiate a Mustang sponsored Phase 1 clinical trial shortly thereafter for the treatment of patients with acute myelogenous leukemia, blastic plasmacytoid dendritic cell neoplasm, and high-risk myelodysplastic syndrome. We expect to file an IND for MB-104 in the second half of 2019 and to initiate a Mustang sponsored Phase 1 clinical trial shortly thereafter for the treatment of patients with multiple myeloma. We also plan to file an IND and initiate a Mustang sponsored clinical trial for MB-106 for the treatment of patients with non-Hodgkin lymphoma and chronic lymphocytic leukemia.

We are also developing CAR T therapies for solid tumors in partnership with COH targeting IL13Rα2 (MB-101), HER2 (MB-103) and PSCA (MB-105). In addition, we have partnered with Nationwide for C134 (MB-108) in order to enhance the activity of MB-101 for the treatment of patients with glioblastoma multiforme ("GBM"). Phase 1 clinical trials sponsored by COH for MB-101 and MB-103 are underway, and a COH sponsored Phase 1 clinical trial for MB-105 is scheduled to commence during 2019. A Phase 1 clinical trial for MB-108 is scheduled to commence in the first half of 2019. We also plan to file INDs and initiate Mustang sponsored clinical trials for MB-103 for the treatment of patients with metastatic breast cancer to brain and for the combination of MB-101 and MB-108 for the treatment of patients with GBM. Finally, we plan to file an IND and initiate a Mustang sponsored clinical trial for MB-105 for the treatment of patients with prostate cancer.

Additionally, we hold complementary patent licenses relating to the use, delivery and possible enhancement of our proprietary CAR technologies. In particular, we licensed intellectual property from Harvard University pertaining to CRISPR/Cas9 gene editing of CAR T cells, and we hope to use this technology to enhance the activity of our CAR T cell therapies.

To date, we have not received approval for the sale 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, 2018, we have an accumulated deficit of $79.1 million.

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

CORPORATE INFORMATION

Mustang Bio, Inc. was incorporated in Delaware on March 13, 2015. Our executive offices are located at 2 Gansevoort Street, New York, NY 10014. 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 report. 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 Securities and Exchange Commission, or SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. You may read and copy any materials we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov/.

PRODUCTS UNDER DEVELOPMENT

Gene Therapy for Rare Genetic Disorders

Ex vivo Lentiviral Therapy for X-linked Severe Combined Immunodeficiency (MB-107)

X-linked Severe Combined Immunodeficiency ("XSCID") is a rare genetic immune system condition also known as bubble boy disease, in which affected patients do not live beyond infancy without treatment.

This first-in-class *ex vivo* lentiviral gene therapy has already been given to 13 patients in two early stage clinical trials, with highly encouraging results. Eight patients under the age of two years were treated at St. Jude and UCSF Benioff Children's Hospital San Francisco, with results presented at the 21st Annual Meeting of the American Society of Gene & Cell Therapy in 2Q18, and five patients 10-23 years of age were treated in an earlier NIH trial that was published in 2Q16 in *Science Translational Medicine.*

The existing data from these 13 patients is encouraging. In the initial Phase 1/2 NIH trial, the oldest two of the five patients – all of whom had haploidentical hematopoietic stem cell transplantation ("HSCT") in infancy – showed expansion of T, NK, and B cells at 2 to 3 years after treatment. These patients achieved sustained restoration of

humoral responses to immunization and experienced clinical improvement. Similar gene marking levels were achieved in the three youngest patients, albeit with only six to nine months of follow-up. This is important because in prior gene therapy trials with murine gammaretroviral vectors without preconditioning, B cell reconstitution did not occur, and patients therefore still required lifelong intravenous immunoglobulin. The low-dose, nonmyeloablative busulfan pretreatment conditioning was well tolerated, and of a low enough intensity to avoid the need for transfusions of red blood cells or platelets.

Subsequent to the initiation of the NIH trial, eight patients under two years old who had not previously undergone HSCT were treated with the *ex-vivo* gene therapy in a St. Jude/UCSF Phase 1/2 trial, resulting in highly encouraging results. Low-dose busulfan conditioning caused adverse events in only two patients (mild mucositis; mucositis, hair loss), and no patients required blood product support. Six of the eight patients achieved reconstituted T cells within the first half-year, and a seventh patient reconstituted T cells within several months after a gene therapy "boost" that was administered after one year of follow-up. In the final patient, the follow-up was only two months, though clearance of aphthous ulcers suggested early immune recovery. Three of the patients were able to discontinue monthly infusions of intravenous immunoglobulin. In the five patients who had infections at the time of therapy, all infections resolved completely.

CAR T Therapies for Hematologic Malignancies

CD123 CAR T cell Program for AML (MB-102)

CD123 is a subunit of the heterodimeric interleukin-3-receptor ("IL-3R") which is widely expressed on human hematologic malignancies including acute myeloid leukemia ("AML"). In addition, CD123 can be found on the surface of B cell acute lymphoblastic leukemia ("B-ALL"), hairy cell leukemia, blastic plasmacytoid dendritic cell neoplasm ("BPDCN"), chronic myeloid leukemia ("CML") and Hodgkin's lymphoma.

Of these malignancies, we are currently investigating CD123 as a target for adoptive cellular immunotherapy in AML and BPDCN, since high CD123 expression is associated with enhanced AML blast proliferation, increased resistance of blasts to apoptosis, and poor clinical prognosis. CD123 is overexpressed in the vast majority of cases of AML and in essentially all cases of BPDCN.

Acute myeloid leukemia is a cancer of the myeloid line of blood cells characterized by rapid growth of abnormal white blood cells that accumulate in the bone marrow. AML is the most common form of acute leukemia. Although AML is a relatively rare disease, there are approximately 20,000 new cases per year in the US and 10,000 deaths per year, accounting for approximately 1.8% of cancer deaths in the US [The Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute]. AML standard of care involves chemotherapy to induce remission followed by additional chemotherapy or hematopoietic stem cell transplant. Allogeneic stem cell transplantation is the preferred treatment route for AML following a second remission. It can lead to a 5-year disease-free survival in 26% of patients. Unfortunately, however, currently only about half of relapsed patients are able to achieve a second remission with traditional chemotherapy agents. Patients who do not achieve a second remission are much less likely to benefit from transplantation and face a dismal outcome.

BPDCN is categorized by the World Health Organization under AML. Most often, BPDCN presents with features of both lymphoma and leukemia. There are little data about BPDCN and the only approved drug for this disease is tagraxofusp, which is indicated for the treatment of adult and pediatric patients with both treatment-naïve and previously-treated BPDCN. The average age at diagnosis is 60 to 70 years. BPDCN is very often misdiagnosed and under-reported. The skin is the most frequently involved site of disease (80 percent of cases). However, BPDCN usually progresses with bone marrow involvement and a decrease in red blood cell, white blood cell and platelet counts. The lymph nodes and spleen may also be involved. Common misdiagnoses for BPCDN include non-Hodgkin lymphoma ("NHL"), AML, leukemia cutis [a nonspecific term used for cutaneous (skin) manifestation of any type of leukemia], melanoma (a type of skin cancer), and lupus erythematosus (chronic inflammatory disease that occurs when the body's immune system attacks its own tissues and organs). There are no data or clinical trials that can define the best first treatment for patients with BPDCN. In addition to the emerging use of tagraxofusp, which was approved by the FDA in December 2018, treatment sometimes includes therapies that are used for AML, ALL, or lymphoma. The time for which a patient responds to these treatments is usually short. After a relapse, second remissions with conventional chemotherapy are difficult to achieve. Allogeneic hematopoietic stem cell transplant ("allo-SCT"), especially if offered in first remission, may result in longer remissions. The current recommendation is for BPDCN patients to be evaluated for an allo-SCT as soon as possible and to begin searching for a donor.

The use of CAR T immunotherapy in relapsed AML and BPDCN patients may offer the potential to achieve a complete or longer lasting remission. We have developed CD123-targeted CAR T cells designed both to be activated to proliferate and to kill CD123-expressing tumor cells [Mardiros A *et al. Blood*. 2013;122(18):3138-3148]. The therapy is designed to recognize and eliminate leukemic cells, leading to remission in patients with relapsed or refractory AML, and could serve as a bridge to potentially curative allogeneic stem cell transplant. The manufacturing process genetically modifies T cells isolated from peripheral blood mononuclear cells in order to express a CD123-specific, hinge-optimized, CD28 co-stimulatory domain-expressing CAR.

CD20 CAR T cell Program for B cell non-Hodgkin lymphoma (MB-106)

CD20 is a promising target for immunotherapy of B-cell lymphomas. 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 non-Hodgkin lymphoma ("NHL"). CD20 is stable on the cell surface with minimal shedding or internalization upon binding antibody and is present at only nanomolar levels as 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 70,000 new cases of NHL are diagnosed each year in the United States, and more than 19,000 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, which account collectively for ~45% of all cases of NHL, are incurable with available therapies, except for 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 account for 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.

Fred Hutch has an open IND for a Phase 1 clinical study to assess the anti-tumor activity and safety of administering CD20-directed CAR T cells; as of December 31, 2018, five patients have been treated. This IND was submitted on February 24, 2017, with Fred Hutch as the sponsor. The trial will also assess the T cell persistence and determine the potential immunogenicity of the cells, and Mustang together with Fred Hutch will determine a recommended Phase 2 dose.

CS1 CAR T for Multiple Myeloma and Light Chain Amyloidosis (MB-104)

CS1 (also known as CD319, CRACC and SLAMF7) was identified as an NK cell receptor regulating immune functions. It is also expressed on B cells, T cells, dendritic cells, NK-T cells, and monocytes. CS1 is overexpressed in multiple myeloma ("MM") and light chain amyloidosis ("AL"), which makes it a good target for immunotherapy. A humanized anti-CS1 antibody, elotuzumab (Empliciti®), has shown promising results in clinical studies. Despite great advances in treatment, MM remains an incurable malignancy of plasma cells. AL is a protein deposition disorder that is a result of a plasma cell dysplasia, similar to MM. Immunotherapy is an attractive approach for AL because of the low burden of disease. Our academic partners at COH have developed a novel second generation CS1-specific CAR T cell therapy. In pre-clinical studies, they have demonstrated efficacy of these CAR T cells, both *in vitro* and *in vivo*, within the context of clinically relevant models of MM and AL. COH will be evaluating the safety of this CS1-specific CAR T cell therapy in a Phase 1/2 trial that is scheduled to commence in the first half of 2019.

CAR T Therapies for Solid Tumors

IL13Rα2 CAR T Cell Program for Glioblastoma (MB-101)

Glioblastoma multiforme ("GBM") is the most common brain and central nervous system ("CNS") cancer, accounting for 45.2% of malignant primary brain and CNS tumors, 54% of all gliomas, and 16% of all primary brain and CNS tumors. An estimated 12,390 new glioblastoma cases were predicted in 2017 in the US. Malignant brain tumors are the most common 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 US. While GBM is a rare disease (2-3 cases per 100,000 persons per year in the US and EU), it is quite lethal, with five-year survival rates historically under 10%. Standard of care therapy consists of maximal surgical resection, radiation and chemotherapy with temozolomide, which, while rarely curative, is shown to extend median overall survival from 4.5 to 15 months. GBM remains difficult to treat due to the inherent resistance of the tumor to conventional therapies.

Immunotherapy approaches targeting brain tumors offer promise over conventional treatments. 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 GBMs. 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. We 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.). We also include the 4-1BB (CD137) co-stimulatory signaling domain for improved survival and maintenance of CAR T cells. Finally, we incorporate the extracellular domain of CD19 as a selection/tracking marker. In order to further improve persistence, either central memory T-cells (T_{CM}; Arms 1 – 4) or enriched CD62L+ naïve and memory T cells ($T_{N/MEM}$; Arm 5) are isolated and enriched. The manufacturing process limits *ex vivo* expansion, which is designed to reduce T cell exhaustion and maintain a T_{CM} or $T_{N/MEM}$ phenotype. These CAR modified T_{CM} and $T_{N/MEM}$ cells are shown to be more potent and persistent than earlier generations of CAR T cells, based on experiments with CAR Ts in mouse xenograft models of GBM.

Our academic partners at COH have an open IND to assess the feasibility and safety of using T_{CM} or $T_{N/MEM}$ enriched IL13Rα2-specific CAR engineered T cells for clinical study participants with recurrent/refractory malignant glioma. This IND was submitted in October 2014, with COH as the sponsor. COH has enrolled and treated 53 patients as of December 31, 2018. In the annual meeting of the American Association for Cancer Research in April 2018, our collaborators at COH presented the preliminary data for patients enrolled on Arm 2 of the protocol (the "Intracavitary Arm"). The investigators reported that the CAR T cells were well-tolerated, meaning that no dose-limiting toxicities were seen to date. The investigators also reported on a patient that they determined had a complete response to treatment based on the imaging and clinical features set forth by the Response Assessment in Neuro-Oncology Criteria (RANO). This clinical response was sustained for 7.5 months after the initiation of CAR T-cell therapy; however, this patient's disease eventually recurred at four new locations that were distinct and non-adjacent to the original tumors. The next step is to continue to enroll patients in this Phase 1 study to determine the maximum tolerated dose and a recommended Phase 2 dose. Additionally, in this Phase 1 study, we are exploring optimal modes of delivery for CAR T cells for the treatment of GBM and optimal T cell selection.

HER2 CAR T for GBM & Metastatic Breast Cancer to Brain (MB-103)

HER2/neu (often shortened to "HER2") is a growth-promoting protein on the outside of all breast cells. Breast cancer cells with higher than normal levels of HER2 are called HER2-positive ("HER2+"). These cancers tend to grow and spread faster than other breast cancers. Breast cancer is the most commonly diagnosed cancer in women, with over 40,000 women in the United States expected to die from advanced metastatic disease in 2018. Approximately 20% to 25% of breast cancers overexpress HER2, which is an established therapeutic target of both monoclonal antibodies (mAbs) and receptor tyrosine kinase inhibitors. With the advent of effective mAbs directed against HER2, the median overall survival of patients with metastatic HER2+ breast cancer has improved. However, management of metastatic disease in the brain and/or central nervous system (CNS), observed in up to 50% of HER2+ breast cancer patients, continues to be a clinical challenge in large part due to the inability of mAbs to sufficiently cross the blood-brain barrier. Although small-molecule inhibitors of HER2 exist and have been clinically approved, their single-agent efficacy in the context of metastatic disease to the brain has been limited. While HER2-targeted therapy in combination with conventional agents has shown some promise for the treatment of patients with metastatic breast cancer, control of brain metastases remains a significant unmet clinical need, as most patients survive less than two years following CNS involvement. Recent advances in cellular immunotherapy approaches have underscored the potential for potent antitumor immune responses and clinical benefit against solid cancers, and these approaches may be effective in the treatment of HER2+ breast cancer that has metastasized to the brain. Likewise, HER2 has been suggested as a suitable target for glioblastoma (GBM), wherein elevated HER2 protein levels have been correlated with impaired survival.

CAR-based T-cell immunotherapy is being actively investigated for the treatment of solid tumors, including HER2+ cancers. Our academic partners at COH have developed a second-generation HER2-specific CAR T-cell for the treatment of breast cancer that has metastasized to the brain, as well as for the treatment of refractory/relapsed HER2+ GBM. COH's preclinical data demonstrate effective targeting of breast cancer brain metastases with intraventricular delivery of HER2-BB CAR T cells. COH will be evaluating the safety of this HER2-specific CAR T cell therapy in two Phase 1/2 clinical trials that commenced in Q4 2018.

PSCA CAR T for Prostate & Pancreatic Cancers (MB-105)

PSCA is a glycosylphosphatidylinositol-anchored cell membrane glycoprotein. In addition to being highly expressed in the prostate it is also expressed in the bladder, placenta, colon, kidney, and stomach. This gene is upregulated in a large proportion of prostate cancers and is also detected in cancers of the bladder and pancreas. The gene includes a polymorphism that results in an upstream start codon in some individuals; this polymorphism is thought to be associated with a risk for certain gastric and bladder cancers. Prostate cancer may be amenable to T cell-based immunotherapy since several tumor antigens, including prostate stem-cell antigen ("PSCA"), are widely over-expressed in metastatic disease. Our academic partners at COH have developed a second-generation PSCA specific CAR T cell therapy that has demonstrated robust *in vitro* and *in vivo* anti-tumor activity in patient-derived, clinically relevant, bone-metastatic prostate cancer xenograft models. COH will be evaluating the safety of this PSCA-specific CAR T cell therapy in a Phase 1/2 trial that is scheduled to commence in the second half of 2019.

Technology to Convert GBM from an Immunologically Cold Tumor to an Immunologically Hot Tumor

HSV-1 oncolytic virus C134 (MB-108)

C134 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, that allows it to replicate better in the tumor cells than its first-generation predecessors. However, the virus has also been genetically engineered to minimize the production of any toxic effects for the patient receiving the therapy.

To improve this virus over its first-generation predecessors, modifications have focused on improving viral replication, spread within the tumor bed, and enhancing bystander damage to uninfected tumor cells. These effects cumulatively should result in converting an immunologically cold tumor to an immunologically hot tumor, which Mustang anticipates will increase the efficacy of its IL13Rα2-direct CAR T for the treatment of GBM.

The University of Alabama at Birmingham ("UAB") is the clinical trial site for the Phase 1 trial of C134, and they have filed an IND for an investigator-initiated Phase 1 trial that we expect will start enrolling patients in the first half of 2019. The primary objective of this study is to determine the safety and tolerability of stereotactic intracerebral injections of escalating doses of C134 virus, and to determine the maximally tolerated dose (MTD) of C134. Secondary objectives are to obtain preliminary information about the potential benefit of C134 in the treatment of patients with recurrent malignant gliomas, including relevant data on markers of efficacy, including time to tumor progression and patient survival.

INTELLECTUAL PROPERTY AND PATENTS

General

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the US 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 US 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 have a few patents and patent applications related to our compounds and other technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the US are maintained in secrecy for a period of 18 months or more. There is even an opportunity under specific circumstances to keep the contents of patent applications hidden until the patent application matures to an issued patent. 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 US that claim technology also claimed by us, we may have to participate in interference or derivation proceedings declared by the US Patent and Trademark Office (PTO) to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability to be extended through the patent restoration program, although any such extension could still be minimal. Additionally, statutory caps impose further limitation on any such extensions.

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

In March 2015, we licensed intellectual property related to CAR T technology from COH. The intellectual property licensed thereunder includes two granted US patents and pending patent applications in a number of countries, including the US and the EU, as well as pending patent applications in Japan, China, South Korea, Australia and the developing world. These granted patents include claims directed to nucleic acids and expression vectors encoding CARs targeting IL13Rα2 and CD123. The granted patents and any patents maturing from these pending applications will expire no sooner than October 2033. The pending applications in these patent families also include various claims relating to CARs, T cells that express the CARs, methods of treatment utilizing the CAR T cells and additional specific features to optimize administration of CAR T cells, targeting, binding specificity, cell stimulation and persistence. Additional applications and pending claims from COH that we have rights to include the use of optimized hinge region for many targeted CAR constructions such as CD19 along with compositions and methods to isolate and transfect T memory cells to improve cellular persistence, as well as applications and claims related to CS1-, HER2-, and PSCA-targeted CARs.

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 entered the national stage of multiple countries including the US, EU, Japan, China, and Canada, among others. 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. In May 2018, national stage applications claiming priority to the PCT application were filed in several jurisdictions around the world, including the US and Europe, 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"). The intellectual property includes multiple granted patents and pending applications from around the world including the US, EU, Japan, China, and Canada. The granted patents and patents maturing from the pending applications will expire no sooner than March 2027.

In November 2017, we licensed intellectual property related to the use of CRISPR technology in preparing CAR T cells from Harvard. The intellectual property includes one granted US patent and multiple pending US and foreign applications. The granted patent and patents maturing from the pending applications will expire no sooner than April 2024.

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 Children's Hospital in Columbus, Ohio.

In total, we have in-licensed six granted patents and twelve pending applications in the US, with counterparts pending in foreign jurisdictions, for most of the patent families, in Australia, Brazil, Canada, China, Europe, Korea, Russia, Japan, Hong Kong, Israel, and Mexico and New Zealand.

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

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, knowhow 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, or 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 US, or diseases that affect more than 200,000 individuals in the US 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 Food and Drug Administration ("FDA"), will be granted a seven-year period of marketing exclusivity for such FDA approved orphan product.

LICENSE, CLINICAL TRIAL AND SPONSORED RESEARCH AGREEMENTS

St. Jude Children's Research Hospital License

On August 2, 2018, the Company entered into an exclusive worldwide license agreement with St. Jude Children's Research Hospital ("St. Jude") for the development of a first-in-class *ex vivo* lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("X-SCID"). The Company 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.

City of Hope Licenses

In February 2017, the Company and COH amended and restated their license agreement, dated March 17, 2015 (the "Original Agreement"), by entering into three separate amended and restated exclusive license agreements, one relating to CD123, one relating to IL13Rα2 and one relating to the Spacer technology (described below). The total potential consideration payable to COH by the Company, in equity or cash, did not in the aggregate change materially from the Original Agreement. As of December 31, 2018, COH owns 1,000,000 shares of Class A common stock and 293,588 shares of common stock, representing approximately 4.7% of ownership, and has the right to appoint a director to the Board of Directors (the "Board"). The Company considers COH to be a related party, due to the foregoing rights and ownership, as well as the high proportion of the Company's assets that are licensed from COH.

In addition, the Company entered into a sponsored research agreement with COH under which the Company has and will fund continued research in the amount of $2.0 million per year, payable in four equal installments, until 2020. The research covered under this arrangement is for IL13Rα2, CD123 and the Spacer technology.

CD123 License

In February 2017, the Company entered into an Amended and Restated Exclusive License Agreement with COH to acquire intellectual property rights pertaining to patent rights related to CD123 (the "CD123 License"). Pursuant to the CD123 License, the Company and COH acknowledged that an upfront fee had already been paid under the Original Agreement. In addition, COH is eligible to receive an annual maintenance fee of $25,000 and milestone payments totaling up to approximately $14.5 million, upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense ranging from the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product. In addition, equity grants made under the Original Agreement were acknowledged, and the anti-dilution provisions of the Original Agreement were carried forward.

CD123 CRA

In February 2017, the Company entered into a Clinical Research Support Agreement for CD123 (the "CD123 CRA"). Pursuant to the terms of the CD123 CRA, the Company made an upfront payment of $19,450 and will contribute an additional $97,490 per patient in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately $76,000 annually pertaining to the clinical development of CD123.

IL13Rα2 License

In February 2017, the Company entered into an Amended and Restated Exclusive License Agreement with COH to acquire intellectual property rights pertaining to patent rights related to IL13Rα2 (the "IL13Rα2 License"). Pursuant to the IL13Rα2 License, the Company and COH acknowledged that an upfront fee had already been paid under the Original Agreement. In addition, COH is eligible to receive an annual maintenance fee of $25,000 and milestone payments totaling up to approximately $14.5 million, upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense ranging from the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product. In addition, equity grants made under the Original Agreement were acknowledged, and the anti-dilution provisions of the Original Agreement were carried forward.

IL13Rα2 *CRA*

In February 2017, the Company entered into a Clinical Research Support Agreement for IL13Rα2 (the "IL13Rα2 CRA"). Pursuant to the terms of the IL13Rα2 CRA, the Company made an upfront payment of approximately $9,300 and will contribute an additional $136,311 per patient in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately $66,000 annually pertaining to the clinical development of IL13Rα2.

Spacer License

In February 2017, the Company 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, the Company and COH acknowledged that an upfront fee had already been paid under the Original Agreement. In addition, COH will receive an annual maintenance fee of $10,000. No royalties are due if the Spacer technology is used in conjunction with a CD123 CAR or 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. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-thirties, but no such payments are due in connection with sublicenses that are granted in conjunction with the sublicense other CARs that are licensed from COH to the Company. In addition, equity grants made under the Original Agreement were acknowledged, and the anti-dilution provisions of the Original Agreement were carried forward.

IV/ICV License

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

HER2 Technology License

On May 31, 2017, the Company entered into an exclusive license agreement (the "HER2 Agreement) with COH for the use of human epidermal growth factor receptor 2 ("HER2") CAR T technology ("HER2 Technology"), which will initially be applied in the treatment of glioblastoma multiforme. Pursuant to the HER2 Agreement, the Company paid an upfront fee of $0.6 million and will owe an annual maintenance fee of $50,000 (beginning in 2019). In addition, COH is eligible to receive milestone payments totaling up to $14.9 million, upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense ranging from the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product.

CS1 Technology License

On May 31, 2017, the Company entered into an exclusive license agreement (the "CS1 Agreement") with COH for the use of CS1-specific CAR T technology ("CS1 Technology") to be directed against multiple myeloma. Pursuant to the CS1 Agreement, the Company paid an upfront fee of $0.6 million and will owe an annual maintenance fee of $50,000 (beginning in 2019). In addition, COH is eligible to receive milestone payments totaling up to $14.9 million, upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense ranging from the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product.

PSCA Technology License

On May 31, 2017, the Company entered into an exclusive license agreement (the "PSCA Agreement") with COH for the use of prostate stem cell antigen ("PSCA") CAR T technology ("PSCA Technology") to be used in the treatment of prostate cancer. Pursuant to the PSCA Agreement, the Company paid an upfront fee of $0.3 million and will owe an annual maintenance fee of $50,000 (beginning in 2019). In addition, COH is eligible to receive milestone payments totaling up to $14.9 million, upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense ranging from the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product.

Manufacturing License

On January 3, 2018, the Company 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. The Company 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.

City of Hope SRA

On January 3, 2018, the Company entered into a Sponsored Research Agreement ("SRA") with COH to optimize and develop CAR T cell processing procedures. Pursuant to the SRA, the Company will fund continued research in the amount of $0.9 million for the program, which has an initial term of two (2) years.

University of California License

On March 17, 2017, the Company 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, the Company paid UCLA the upfront fee of $0.2 million and will owe an annual maintenance fee of $15,000 for the first two years, $25,000 for years three and four, and $50,000 per year thereafter. In addition, UCLA is eligible to receive milestone payments totaling up to $14.3 million, upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products.

Fred Hutchinson Cancer Research Center License

CD20 Technology License

Effective July 3, 2017, Mustang 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 chimeric antigen receptor (the "CD20 Technology License"). Pursuant to the CD 20 Technology License, the Company paid Fred Hutch an upfront fee of $0.3 million and will owe an annual maintenance fee of $50,000 on each anniversary of the license until the achievement by the Company of regulatory approval of a licensed product using CD20 Technology. Additional payments are due for the achievement of eleven development milestones totaling $39.1 million. Royalty payments in the mid-single digits are due on net sales of licensed products.

CD20 CTA

Also, on July 3, 2017, in conjunction with the CD20 Technology License from Fred Hutch, Mustang 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. In connection with the CD20 CTA, the Company agreed to fund up to $5.3 million of costs associated with the clinical trial, which commenced during the fourth quarter of 2017.

Fred Hutchinson Cancer Research Center SRA

On March 17, 2018, the Company entered into an SRA with the Fred Hutchinson Cancer Research Center ("Fred Hutch") related to developing and optimizing processes and systems associated with CD20 cell processing. Pursuant to the SRA, the Company will fund continued research in the amount of $0.6 million during the term of the SRA which expires one year from the effective date.

Harvard University License

On November 20, 2017, Mustang entered into a license agreement with Harvard for intellectual property pertaining to CRISPR/Cas9-enhanced CAR T therapies for the treatment of cancer (the "CRISPR License"). Under the licensing agreement with Harvard's Office of Technology Development, technologies related to the development of off-the-shelf CAR T, as well as CRISPR/Cas9 gene editing platforms, will be utilized in conjunction with Mustang's CAR T cell therapies for the development of treatments for hematologic malignancies and solid tumors. The Harvard technologies were developed in the lab of Chad Cowan, Ph.D., Associate Professor in the Department of Stem Cell and Regenerative Biology and a Principal Investigator at the Harvard Stem Cell Institute. Pursuant to the CRISPR License, the Company paid Harvard University an upfront fee of $0.3 million and will owe an annual maintenance fee of $25,000 on the first anniversary of the license, $50,000 on the second anniversary of the license and $0.1M for each subsequent anniversary of the license during the term of the agreement. In addition, Harvard is eligible to receive milestone payments totaling up to $16.7 million, upon and subject to the achievement of certain milestones. Royalty payments in the low single digits are due on net sales of licensed products.

Nationwide Children's Hospital License

On February 20, 2019, the Company entered into an exclusive worldwide license agreement with Nationwide Children's Hospital ("Nationwide") for the development of an oncolytic virus (C134) for the treatment of glioblastoma multiforme. The Company 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 ten development and commercialization milestones. Royalty payments in the low-single digits are due on net sales of licensed products.

COMPETITION

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

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

The field of CAR T therapy is extremely active. Companies and partnerships currently engaged in clinical trials with CAR T modalities include Celgene, Novartis/University of Pennsylvania, Bluebird Bio, Celgene/Baylor College of Medicine, Allogene, Cellectis, Gilead, Bellicum, MD Anderson/Ziopharm, Atara Biotherapeutics, Celyad, Autolus and Intrexon.

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, Audentes Therapeutics, AVROBIO, Axovant Sciences, Bluebird Bio, BioMarin Pharmaceutical, Krystal Biotech, MeiraGTx, Nightstar Therapeutics, Orchard Therapeutics, REGENXBIO, Rocket Pharmaceuticals, Sarepta Therapeutics, Solid Biosciences, Spark Therapeutics, Ultragenyx Pharmaceuticals, uniQure and Voyager Therapeutics, as well as several companies addressing other methods for delivering or modifying genes and regulating gene expression.

EMPLOYEES

As of December 31, 2018, we had thirty-eight full-time employees. None of our employees are represented by a labor union or covered under a collective bargaining agreement and we consider our employee relations to be good. Employees of Fortress also make valuable financial, legal, scientific and other strategic contributions to Mustang on a regular basis.

SUPPLY AND MANUFACTURING

As an early stage development company, we rely on our research partners to manufacture all materials currently used in the clinical development programs we are sponsoring at COH, Fred Hutch, St. Jude, and the University of Alabama at Birmingham ("UAB") under the IND applications filed by these institutions. UAB is the clinical trial site for the Phase 1 trial of Nationwide's C134 oncolytic virus. Pursuant to the March 2015 Licensing Agreement with COH, we have the right to make and have made the products, and we have negotiated Investigator-Initiated Clinical Research Support Agreements with COH and Fred Hutch which specify the manufacturing 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.

We have limited experience in processing cells for clinical or commercial purposes. In 2018 we opened our own cell processing facility in Worcester, Massachusetts, in order to manufacture and supply product candidates for all clinical trials that will be conducted under IND applications to be filed by us. We are preparing to file our first IND in the first half of 2019. 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 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 potential future non-CAR T products would be subject to ongoing periodic and unannounced inspections by the FDA, the US Drug Enforcement Administration ("DEA") and corresponding state agencies to ensure strict compliance with 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 potential future non-CAR T products after commercialization, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

GOVERNMENT AND INDUSTRY REGULATIONS

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and 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 in which we have marketing rights. Before marketing in the US, 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, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical 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 US. 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, pre-clinical 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.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the new drug application (NDA). To receive fast track designation, an applicant must demonstrate:

- that the drug is intended to treat a serious or life-threatening condition;
- that the drug is intended to treat a serious aspect of the condition; and
- that the drug has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

The FDA must respond to a request for fast track designation within 60 calendar days of receipt of the request. Over the course of drug development, a product in a fast track development program must continue to meet the criteria for fast track designation. Sponsors of products in fast track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in fast track drug development programs ordinarily are eligible for priority review of a completed application in six months or less and also may be permitted to submit portions of an NDA to the FDA for review before the complete application is submitted.

Sponsors of drugs designated as fast track also may seek approval under the FDA's accelerated approval regulations. Under this authority, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval will be subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. Post-marketing studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing studies with due diligence. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all, and, therefore, could not submit the NDA to the FDA or foreign regulatory authorities for marketing approval.

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.

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

Sponsors of drugs may apply for a special protocol assessment (SPA) from the FDA. 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. 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 Phase 3 trial. The SPA may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical 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 for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy, or REMS, as part of an NDA. The REMS plan contains post-market obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and conduct sufficient Phase 4 follow-up studies and 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 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. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any significant changes to labeling, require 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 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.

Other Healthcare Laws and Compliance Requirements

In the US, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments.

Pharmaceutical Coverage, Pricing and Reimbursement

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

International Regulation

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

Item 1A. Risk Factors

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*, 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.*

Risks Related to Our Business and Industry

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

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

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

- developing our technology platform;
- identifying, developing, manufacturing and commercializing product candidates;
- entering into successful licensing and other arrangements with product development partners;
- participating in regulatory approval processes;
- formulating and manufacturing products;
- obtaining sufficient quantities of our product candidates from our third-party manufacturers as required to meet clinical trial needs and 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 later establish; and
- maintaining patent protection and regulatory exclusivity for our product candidates.

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

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

Preclinical development is highly speculative and has a high risk of failure.

We currently have both preclinical and clinical-stage product candidates. Our preclinical product candidates have never been used in humans. Preclinical development is highly speculative and carries a high risk of failure. We can provide no assurances that preclinical toxicology and/or preclinical activity of our product candidates will support moving any of these product candidates into clinical development. If we are unsuccessful in our preclinical development efforts for any of these product candidates and they fail to reach clinical development, it would have a material adverse effect on our business and financial condition.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we are planning for certain clinical trials relating to our product candidates, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- clinical sites deviating from trial protocol or dropping out of a trial;

- having patients complete a trial or return for post-treatment follow-up;
- developing and validating companion diagnostics on a timely basis, if required;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities; however, we will have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may not receive regulatory approval for our product candidates, or their approval may be further delayed, which would have a material adverse effect on our business and financial condition.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the US and by the European Medicines Agency and similar regulatory authorities outside the US. Failure to obtain marketing approval for one or more of our product candidates or any future product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. One or more of our product candidates or any future product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates or any future product candidate receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of one or more of our product candidates or any future product candidate, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our 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. Any of these scenarios could compromise the commercial prospects for one or more of our product candidates or any future product candidate.

Moreover, in all interactions with regulatory authorities, we are exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

If any of our product candidates is approved and we or our contract manufacturer(s) fail to produce 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 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 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 facilities inspection program, and 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, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product and customer confidence in our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

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

Our approach to the discovery and 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 products candidates are emerging technologies and, consequently, it is conceivable that such technologies may ultimately fail to identify commercially viable drugs to treat human patients with cancer or other diseases.

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 our 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 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 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 side effects that prevented further development of the compound. In the event that our clinical trials reveal a high or unacceptable severity and prevalence of side effects, 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. 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, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating market acceptance and revenues from the sale of that product candidate. Drug-related 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, specific warnings or a contraindication;

- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may 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 from its 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.

One or more of our product candidates that we may license or acquire will also be subject to ongoing requirements and review of 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 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 closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations 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;
- 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 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. 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 lose 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 US or other countries until we have completed a rigorous and extensive regulatory review processes, 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 US Patent and Trademark Office (PTO). The FDA typically conducts a review of proposed product brand names, including an evaluation of 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.

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 US 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, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of certain approved drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014 and is annually updated; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA 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, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the US generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, corrective advertising, injunctions or criminal prosecution, any of which could harm our business.

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

In the US and some foreign jurisdictions, there have been a number of proposed and enacted legislative and regulatory changes regarding the healthcare system that could prevent or delay marketing approval of one or more of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our product candidates for which we obtain marketing approval.

Among policy makers and payors in the US and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the US, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, Texas federal district court judge Reed O'Connor issued a ruling declaring that the ACA in it is entirety is unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome through the appeals process may have a significant impact on our business.

The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services ("HHS") finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program, which has been overturned by the courts. HHS also has signaled its intent to pursue reimbursement policy changes for Medicare Part B drugs as a whole that likely would reduce hospital and physician reimbursement for these drugs.

HHS has made numerous other proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. These proposals include giving Medicare Advantage and Part D plans flexibility in the availability of drugs in "protected classes," more transparency in the cost of drugs, including the beneficiary's financial liability, and less costly alternatives and permitting the use of step therapy as a means of prior authorization. HHS has also proposed requiring pharmaceutical manufacturers disclose the prices of certain drugs in direct-to-consumer television advertisements.

HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits and less generous coverage. The Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

We expect that the ACA, as well as 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 approved drug. 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 drugs.

Legislative proposals such as expanding the Medicaid drug rebate program to the Medicare Part D program, providing authority for the government to negotiate drug prices under the Medicare Part D program and lowering reimbursement for drugs covered under the Medicare Part B program have been raised in Congress, but have been met with opposition and have not been enacted so far.

The administration can rely on its existing statutory authority to make policy changes that could have an impact on the drug industry. For example, the Medicare program has in the past proposed to test alternative payment methodologies for drugs covered under the Part B program and currently is proposing to pay hospitals less for Part B-covered drugs purchased through the 340B Drug Pricing Program.

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 our product candidates, if any, may be. In addition, increased scrutiny by the US Congress 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.

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

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

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

We may not be able to initiate or continue clinical trials for one or more of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as 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 candidate or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Our product candidates are in scientific areas of intense competition from many large pharmaceutical and biotechnology companies, many of which are significantly further along in development or are already on the market with competing products. We expect competition for our product candidates will intensify, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

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 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.

Our commercial success depends upon us attaining significant market acceptance of our product candidates, if approved for sale, among physicians, patients, healthcare payors and major operators of cancer and other clinics.

Even if we obtain regulatory approval for one or more of our product candidates, the product may not gain market acceptance among physicians, health care payors, patients and the medical community, which are critical to commercial success. Market acceptance of any product candidate for which we receive approval depends 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 product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the safety of such product candidate seen in a broader patient group, including its use outside the approved indications;
- 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;
- 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.

If approved, our product candidates will face competition from less expensive generic products of competitors, and, if we are unable to differentiate the benefits of our product candidates over these less expensive alternatives, we may never generate meaningful product revenues.

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 that have lost or will lose their patent exclusivity. In the future, we may face additional competition from a generic form when the patents covering it 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.

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 US, the EU and other selected foreign jurisdictions. Market acceptance and sales of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future health care reform measures. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. 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 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 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 country.

If we are unable to establish sales, marketing and distribution capabilities or to enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when 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 product candidate that receives marketing approval, we would need to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development and regulatory approval of one or more of our product candidates or any future product candidate, 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 products 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 an independent sales and marketing organization.

As an alternative to establishing our own sales force, we may choose to partner with third parties that have well-established direct sales forces to sell, market and distribute our products.

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

We rely on third-party contract research organizations and site management organizations to conduct some of our preclinical studies and all of our clinical trials for our product candidates and for any future product candidate. We expect to continue to rely on third parties, such as contract research organizations, 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 will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are 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 practice (GLP) 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 clinical research organizations 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 given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing 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 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 any of our relationships with these third-party contract research organizations or site management organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or site management organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new contract research organization or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and may also do so for commercialization. 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.

While we have opened our own cell processing facility in Worcester, Massachusetts, in order to supply product candidates for all clinical trials that will be conducted under IND applications to be filed by us (See Note 6 to Audited Financial Statements), currently we rely on third parties for the manufacture of our product candidates for preclinical and clinical testing. 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 or quality, which could delay, prevent or impair our development or commercialization efforts.

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers 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. 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 drugs, and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials and equipment necessary to produce our product candidates for our preclinical and clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials or equipment by our third-party manufacturers. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing preclinical or clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials or equipment after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

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

One or more of the product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers. The DEA restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for one or more of our product candidates.

Our current and anticipated 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 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, producing additional losses and depriving us of potential product revenue.

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 validated 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.

If we breach any of the agreements under which we license rights to one or more of product candidates from others, we could lose the ability to continue to develop and commercialize such product candidate.

Because we have in-licensed the rights to all of our product candidates from COH, Fred Hutch, St. Jude and Nationwide, and in the future will continue to in-license from additional third parties, if there is any dispute between us and our licensor regarding our rights under our license agreement, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under our license agreement could result in our loss of exclusive rights to our product candidate and may lead to a complete termination of our related product development efforts.

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 may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, 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 could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee 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. 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 sanctions.

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 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 we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- suspension or termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

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.

Our future growth depends on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on *ex vivo* lentiviral gene therapy for rare genetic diseases and on novel combinations of CAR T cells with immuno-oncology antibodies, other biologics, and small molecule kinase inhibitors. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including, but not necessarily limited to:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

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 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 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.

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

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

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

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

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. 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 results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of one or more of our product candidates may be delayed.

We are currently reliant on the City of Hope National Medical Center, the Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, and the University of Alabama at Birmingham for a substantial portion of our research and development efforts and the early clinical testing of our product candidates.

A substantial portion of our research and development has been and will continue to be conducted by COH, Fred Hutch, St. Jude, and UAB pursuant to a sponsored research agreement and/or clinical trial agreements with each of those parties. As a result, our future success is heavily dependent on the results of research and development efforts of Dr. Stephen Forman and his laboratory team at COH, of Dr. Brian Till and his laboratory team at Fred Hutch, of Drs. Stephen Gottschalk and Ewelina Mamcarz at St. Jude, and of Dr. James M. Markert at UAB. 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.

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

We have concentrated 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 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 products;
- educating medical personnel regarding the potential side effect profile of each of our products;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive our product candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for types of cancers beyond those addressed by our current product candidates.

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 products 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 drug 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, or 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 investigational new drug application, or 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 commercialization of these treatment candidates or lead to significant post-approval studies, limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research 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 gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, the success of our gene therapy platform 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 with 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 are approved and a decrease in demand for any such product candidates. Concern about environmental spread of our product, whether real or anticipated, may hinder the commercialization of our products.

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 Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, 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 commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the US and other countries with respect to our product candidates or any future product candidate that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them in the market they are being used or developed.

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 US. The patent situation outside the US is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the US, 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 US law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US 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 US 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 PTO to determine priority of invention in the US. We might also become involved in derivation proceedings in an event that a third party misappropriates one or more of our inventions and files their own patent application directed to such one or more inventions. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention (or that a third party derived an invention from us) would be unsuccessful, resulting in a material adverse effect on our US 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 US 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 US 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 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 US. 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.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include changes to transition from a "first-to-invent" system to a "first inventor-to-file" system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a less burdensome, quicker and less expensive process for challenging issued patents. The PTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the PTO, 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 (or that another derived an invention from us or one of our licensors) would be unsuccessful, resulting in a material adverse effect on our US patent position. 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 technology 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.

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.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We depend on our licensors for the maintenance and enforcement of intellectual property covering certain of our product candidates and have limited control, if any, over the amount or timing of resources that our licensors devote on our behalf, or whether any financial difficulties experienced by our licensors could result in their unwillingness or inability to secure, maintain and enforce patents protecting certain of 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 US 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.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

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

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate our product candidates or any future product candidate technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the scope of our issued patents may not extend to competitive products developed or produced by others;
- the issued patents covering our product candidates or any future product candidate may not provide a basis for market exclusivity for active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- intellectual property rights of others may have an adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

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 PTO 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 US patents may affect related patents in our global portfolio.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell one or more of our product candidates or any future product candidate that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous US and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of fully human immuno-oncology targeted antibodies and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims asserted by third parties, which could have a material adverse effect on our results or operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications that are unknown to us, which may later result in issued patents that one or more of our product candidates may infringe. There could also be existing patents of which we are not aware that one or more of our product candidates may infringe, even if only inadvertently.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third-party claims that we infringe their patents or misappropriated their technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;

- substantial damages for past infringement which we may have to pay if a court decides that our product infringes a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds, time, and may result in an inferior or less-desirable process or product.

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.

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

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

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

We are currently a party to license agreements with St. Jude, the City of Hope, the Fred Hutchinson Cancer Research Center, the Regents of the University of California, 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 have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Even if frivolous or unsubstantiated in nature, litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and the implicated employee(s).

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

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

Because we in-license intellectual property pertaining to certain product candidates from third parties, 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 sublicensing of patent and other rights under our license agreements and/or collaborative development relationships, and the rights and obligations associated with such sublicensing;
- 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;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

Risks Related to Our Finances and Capital Requirements

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are an emerging growth company with a limited operating history. We have focused primarily on in-licensing and developing our product candidates, with the goal of supporting regulatory approval for these product candidates. We have incurred losses since our inception in March 2015 and have an accumulated deficit of $79.1 million as of December 31, 2018. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

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

- one or more of our product candidates are approved for commercial sale, due to our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for 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 and the timing of payments we may make or receive under these arrangements;
- 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;
- there are any regulatory developments affecting product candidates of our competitors; and
- one or more of our product candidates receives regulatory approval.

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 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.

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

We have only been conducting operations since our incorporation in March 2015. Our operations to date have been limited to preclinical operations and the in-licensing of our product candidates. 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 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 not generated any product related revenues to date, and do not expect to generate any such revenues for at least the next several years, if at all. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

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 expect 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 receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures. As of December 31, 2018, we had $34.6 million in cash and short-term investments (certificates of deposit) and restricted cash. We cannot provide any assurance that we will be able to raise funds to complete the development of our product candidates. Additionally, we may have to delay or terminate the development of certain product candidates if we are unable to secure additional funding; 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 debt and equity securities.

We cannot be certain that additional funding will be available on acceptable terms, or at all. 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 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 timing, design and conduct of, and results from, preclinical and clinical trials for our product candidates;
- the potential for delays in our efforts to seek regulatory approval for our product candidates, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute our product candidates;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA 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; and
- the success of the commercialization of one or more of our product candidates.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time 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 sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidates or marketing territories.

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

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and license and development agreements in connection with any collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing 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.

On August 22, 2017, we became a listed and traded public company. As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and the rules of the Nasdaq Stock Exchange. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, 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. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. 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.

Compliance with the Sarbanes-Oxley Act of 2002 will require substantial financial and management resources and may increase the time and costs of completing an acquisition.

A business that we identify as a potential acquisition target may not be in compliance with the provisions of the Sarbanes-Oxley Act regarding the adequacy of internal controls. The development of the internal controls of any such entity to achieve compliance with the Sarbanes-Oxley Act may increase the time and costs necessary to complete any such acquisition. Furthermore, any failure to implement required new or improved controls, or difficulties encountered in the implementation of adequate controls over our financial processes and reporting in the future, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

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

We are an "emerging growth company" as that term is used in the JOBS Act, and may remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the initial public offering of our common stock, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our outstanding common stock that are held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report on Form 10-K;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected to opt out of such extended transition period which means that when a standard is issued or revised, and it has different application dates for public or private companies, we, as an emerging growth company, will adopt the new or revised standard. This may make comparison of our financial statements with another public company which has opted into using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

We are also 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. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

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

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

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

Risks Relating to Securities Markets and Investment in Our Stock

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

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

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

- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize our product candidates or any future product candidate, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching these product candidates, if approved;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of one or more of our product candidates or any future product candidate, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;

- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

Fortress controls a voting majority of our common stock.

Pursuant to the terms of the Class A Preferred Stock held by Fortress, Fortress is entitled to cast, for each share of Class A Preferred held by Fortress, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding common stock and (B) the whole shares of common stock into which the shares of outstanding Class A common shares and the Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Accordingly, Fortress is able to control or significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of Fortress may not always coincide with the interests of other stockholders, and Fortress may take actions that advance its own interests and are contrary to the desires of our other stockholders. Moreover, this concentration of voting power may delay, prevent or deter a change in control of us even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of Mustang 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, 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 Mustang has not grown proportionately over the prior year, would result in a reduction in the value of your shares. The Second Amended and Restated 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 Second Amended and Restated 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 officers and 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, and in addition, under the Management Services Agreement, we will also share some officers with Fortress. This 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 Mustang, and they are not required to notify Mustang prior to pursuing such opportunities. Any such conflict of interest or pursuit by Fortress of a corporate opportunity independent of Mustang could expose us to claims by our investors and creditors and could harm our results of operations.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate and executive office is located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. We are currently under a desk-sharing agreement at 2 Gansevoort Street.

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

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

Item 3. Legal Proceedings

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

On January 15, 2016, Dr. Winson Tang ("Tang") filed a Complaint against us in the Superior Court of the State of California, County of Los Angeles. Winson Tang v. Lindsay Rosenwald et al., Case No. BC607346. As amended, the Complaint alleged a breach of contract by us and two of our officers, Dr. Rosenwald and Mr. Weiss, and two claims against other Defendants, including Mustang. On November 3, 2017, Tang and Defendants entered into a Settlement Agreement regarding this matter. The Settlement Agreement did not require issuance of any new shares by Mustang.

In connection with the legal settlement, above, Fortress delivered 200,000 Mustang common shares, held by Fortress, to Tang. During the year ended December 31, 2017, the Company recorded this transaction as a capital contribution from Fortress and a corresponding expense of approximately $2.0 million based upon the closing share price of Mustang shares as of the date of the Settlement Agreement. In addition to the share issuance, the Company paid, in November 2017, a $0.2 million cash settlement to the plaintiff, which was recorded in general and administrative expenses on the Statements of Operations.

Item 4. Mine Safety Disclosures

Not applicable

PART II

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

Market information

Our common stock has been quoted on the NASDAQ Global Market since August 22, 2017, under the symbol "MBIO." Prior to this there was no public market for our common stock.

Securities Authorized for Issuance Under Equity Compensation Plans

On November 30, 2017, we filed a registration statement on Form S-8 under the Securities Act registering the common stock issued, issuable or reserved for issuance under our 2016 Plan. That registration statement became effective immediately upon filing, and shares covered by the registration statement are eligible for sale in the public markets, subject to grant of the underlying awards, vesting provisions and Rule 144 limitations applicable to our affiliates.

Holders of Record

As of December 31, 2018, there were approximately 579 holders of record of our common stock and one holder of record for our Class A common stock. The actual number of stockholders of our common shares is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

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

Recent Sales of Unregistered Securities

On March 31, 2017, the Company closed the seventh round of financing totaling gross proceeds of $0.4 million, before expenses, in a private placement of shares and warrants for which NSC was the placement agent and received a fee of approximately $46,000 or approximately 10% of the gross proceeds. The Company issued 64,000 unregistered shares of common stock and 16,000 warrants in connection with this transaction. In addition, NSC received 6,400 warrants or approximately 10% of the shares issued.

On August 3, 2017, the Company closed the final round of financing totaling gross proceeds of $65,000. The Company issued 10,000 unregistered shares of common stock and 2,500 warrants in connection with this transaction. In addition, NSC received 1,000 warrants or approximately 10% of the shares issued.

We expect to use the net proceeds from the above transaction primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments.

Item 6. Selected Financial Data

Not applicable.

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

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

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

Overview

Mustang Bio, Inc. ("Mustang", "We", "Us" or the "Company") is a clinical-stage biopharmaceutical company focused on translating today's medical breakthroughs in cell and gene therapies into potential cures for hematologic cancers, solid tumors and rare genetic diseases. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market.

Our pipeline is currently focused in three core areas: gene therapy programs for rare genetic disorders, chimeric antigen receptor ("CAR") engineered T cell ("CAR T") therapies for hematologic malignancies and CAR T therapies for solid tumors. For each therapy we have partnered with world class research institutions. For our gene therapy programs we have partnered with St. Jude Children's Research Hospital ("St. Jude") in the development of a first-in-class ex vivo lentiviral treatment of X-linked severe combined immunodeficiency ("XSCID") and for our CAR T therapies we have partnered with the City of Hope National Medical Center ("COH"), Fred Hutchinson Cancer Research Center ("Fred Hutch") and Nationwide Children's Hospital ("Nationwide").

Gene Therapy

In partnership with St. Jude, our gene therapy program (MB-107) is being conducted under an exclusive license to develop a potentially curative treatment for XSCID, a rare genetic immune system condition in which affected patients do not live beyond infancy without treatment. This first-in-class *ex vivo* lentiviral gene therapy is currently in two Phase 1/2 clinical trials sponsored by St. Jude and the National Institutes of Health ("NIH"). Results in these two trials have been promising and we plan to transfer St. Jude's Investigational New Drug Application ("IND") to Mustang in the second half of 2019 following completion of the technology transfer.

CAR T Therapies

Mustang's pipeline of CAR T therapies are 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 cell processing facility located in Worcester, Massachusetts to conduct Mustang sponsored clinical trials.

We are developing CAR T therapies for hematologic malignancies in partnership with COH targeting CD123 (MB-102) and CS1 (MB-104) and with Fred Hutch targeting CD20 (MB-106). Phase 1 clinical trials sponsored by COH for MB-102 and by Fred Hutch for MB-106 are underway and a COH sponsored Phase 1 clinical trial for MB-104 is scheduled to open during the first half of 2019. Mustang plans to file an IND for the MB-102 program in the first half of 2019 and to initiate a Mustang sponsored Phase 1 clinical trial shortly thereafter for the treatment of patients with acute myelogenous leukemia, blastic plasmacytoid dendritic cell neoplasm, and high-risk myelodysplastic syndrome. We expect to file an IND for MB-104 in the second half of 2019 and to initiate a Mustang sponsored Phase 1 clinical trial shortly thereafter for the treatment of patients with multiple myeloma. We also plan to file an IND and initiate a Mustang sponsored clinical trial for MB-106 for the treatment of patients with non-Hodgkin lymphoma and chronic lymphocytic leukemia.

We are also developing CAR T therapies for solid tumors in partnership with COH targeting IL13Rα2 (MB-101), HER2 (MB-103) and PSCA (MB-105). In addition, we have partnered with Nationwide for C134 (MB-108) in order to enhance the activity of MB-101 for the treatment of patients with glioblastoma multiforme ("GBM"). Phase 1 clinical trials sponsored by COH for MB-101 and MB-103 are underway, and a COH sponsored Phase 1 clinical trial for MB-105 is scheduled to commence during 2019. A Phase 1 clinical trial for MB-108 is scheduled to commence in the first half of 2019. We also plan to file INDs and initiate Mustang sponsored clinical trials for MB-103 for the treatment of patients with metastatic breast cancer to brain and for the combination of MB-101 and MB-108 for the treatment of patients with GBM. Finally, we plan to file an IND and initiate a Mustang sponsored clinical trial for MB-105 for the treatment of patients with prostate cancer.

Additionally, we hold complementary patent licenses relating to the use, delivery and possible enhancement of our proprietary CAR technologies. In particular, we licensed intellectual property from Harvard University pertaining to CRISPR/Cas9 gene editing of CAR T cells, and we hope to use this technology to enhance the activity of our CAR T cell therapies.

In January 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 are required to pay $75,000 in consideration for the licenses to the patent rights and the licensed know-how, which we paid in March of 2018, in addition to an annual maintenance fee. Royalty payments in the low-single digits are due on net sales of licensed products. Simultaneous with the execution of this agreement, the Company entered into a sponsored research agreement with COH to optimize and develop CAR T cell processing procedures. Pursuant to the SRA, we will fund continued research in the amount of $0.9 million which we paid in March of 2018.

In March 2018, we entered into a sponsored research agreement ("SRA") with Fred Hutch related to developing and optimizing processes and systems associated with CD20 cell processing ("Fred Hutch SRA"). Pursuant to the Fred Hutch SRA, we will fund continued research in the amount of $0.6 million for a term of one year from the effective date.

In May 2018, we announced the publication of preclinical data in JCI Insight demonstrating that glioblastoma-targeted CD4+ CAR T cells mediate superior antitumor activity over CD8+ CAR T cells. The data, published by research partner City of Hope, will be applied in the ongoing Phase 1 trial of IL13Rα2-specific CAR T MB-101 in glioblastoma.

In June 2018, we announced the opening of our cell processing facility in Worcester, Massachusetts located at the UMass Medicine Science Park. The facility will support clinical development and commercialization of our cell and gene therapy pipeline.

On August 2, 2018, we entered into an exclusive worldwide license agreement with St. Jude for the development of a first-in-class ex vivo lentiviral gene therapy for the treatment of XSCID. We paid an upfront fee of $1.0 million in August 2018 in consideration for the exclusive license. Additional payments are due to St. Jude upon the achievement of five development and commercialization milestones totaling $13.5 million. The acquisition of this license expands our pipeline into gene therapy, allowing us to leverage existing synergies for our Worcester, Massachusetts cell-processing facility.

On October 15, 2018, Mustang announced the appointment of Martina A. Sersch, M.D., Ph.D., as Chief Medical Officer ("CMO"). Dr. Sersch will oversee the clinical development of Mustang's pipeline in CAR T technology and gene therapies.

In November 2018, we announced that additional safety and efficacy Phase 1 data evaluating MB-102 (CD123 CAR) in relapsed or refractory AML and BPDCN were presented in an oral session at the American Association for Cancer Research ("AACR") Special Conference on Tumor Immunology and Immunotherapy.

In December 2018, the FDA granted Orphan Drug Designation to MB-102 (CD123 CAR T) for the treatment of BPDCN, a rare and incurable blood cancer.

In February 2019, we announced that we partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital to develop an oncolytic virus (C134) for the treatment of glioblastoma multiforme. We intend to combine the oncolytic virus with MB-101 (IL13Rα2-specific CAR) to potentially enhance efficacy in treating glioblastoma multiforme.

To date, we have not received approval for the sale 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, 2018, we have an accumulated deficit of $79.1 million.

We are a majority-controlled subsidiary of Fortress Biotech, Inc. ("Fortress"). As a "Controlled Company" we rely on the exemption provided by Nasdaq Listing Rule 5615(c)(2), which permits us to maintain less than a majority of independent directors on our board.

Critical Accounting Policies and Use of Estimates

See Note 2 to our Financial Statements.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

	For the year ended December 31,		Change	
	2018	2017	$	%
($ in thousands)				
Operating expenses:				
Research and development	$ 21,104	$ 7,943	$ 13,161	166%
Research and development – licenses acquired	3,360	12,433	(9,073)	-73%
General and administrative	6,759	11,409	(4,650)	-41%
Total operating expenses	31,223	31,785	(562)	-2%
Loss from operations	(31,223)	(31,785)	562	-2%
Other income (expense)				
Interest income	569	505	64	13%
Interest expense	(8)	(8)	-	0%
Total other income (expense)	561	497	64	13%
Net Loss	**$ (30,662)**	**$ (31,288)**	**$ 626**	**-2%**

Research and Development Expenses

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

For the year ended December 31, 2018, research and development expenses were approximately $21.1 million, compared to approximately $7.9 million, an increase of $13.2 million. For the year ended December 31, 2018, research and development expenses primarily consisted of $5.7 million for Sponsored Research and Clinical Trial Agreements with our academic partners, $4.3 million for personnel compensation, $3.4 million for stock compensation expense, $2.3 million for laboratory supplies, $1.1 million related to consulting and outside services, $0.5 million related to facility costs, and $0.4 million related to license maintenance fees. For the year ended December 31, 2017, we incurred $5.5 million for Sponsored Research and Clinical Trial Agreements with our academic partners, $0.8 million for personnel compensation, $0.7 million for stock compensation expense, $0.2 million related to consulting and outside services, $0.1 million related to facility costs, and $0.1 million related to license maintenance fees.

For the year ended December 31, 2018, research and development expenses - licenses acquired were approximately $3.4 million, compared to approximately $12.4 million, a decrease of $9.0 million. For the year ended December 31, 2018, research and development expenses - licenses acquired consisted of $2.1 million for the annual stock dividend to Fortress, $1.0 million for an upfront fee for our license with St. Jude for the treatment of XSCID and $0.3 million in connection with our licenses with COH. For the year ended December 31, 2017, research and development expenses - licenses acquired consisted primarily of $9.6 million for the annual stock dividend to Fortress and $2.1 million in connection with our licenses with COH.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with the following:

- employee-related expenses, which include salaries and benefits, and rent expense;
- license fees and milestone payments related to in-licensed products and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and our preclinical activities;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

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

For the year ended December 31, 2018, general and administrative expenses were approximately $6.8 million, compared to approximately $11.4 million, a decrease of $4.6 million. For the year ended December 31, 2018, general and administrative expenses consisted primarily of $1.3 million for legal and professional fees, $1.5 million for personnel compensation, $1.5 million for stock compensation expense and $0.6 million for insurance and taxes. For the year ended December 31, 2017, general and administrative expenses consisted primarily of $6.6 million for legal and professional fees, $2.6 million for stock compensation expense, $0.5 million for personnel compensation and $0.3 million for insurance and taxes.

We anticipate general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

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

Other Income (Expense)

Other income (expense) consists primarily of interest income earned on the short-term investments. For the year ended December 31, 2018 and 2017, total other income (expense) were approximately $0.6 million and $0.5 million, respectively.

Liquidity and Capital Resources

The Company has incurred substantial operating losses and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2018, the Company had an accumulated deficit of $79.1 million.

The Company has funded its operations to date primarily through the sale of equity. The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, including financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its cash and cash equivalents balances at December 31, 2018 are sufficient to fund its anticipated operating cash requirements for at least one year from the date of this Form 10-K.

The Company will be required to expend significant funds in order to advance the development of its product candidates. The Company's estimates as to how long it expects its existing cash to be able to continue to fund its operations is based on assumptions that may prove to be inaccurate, and it could use its available capital resources sooner than it currently expects, as a result of unforeseen events. Such changes in circumstances may require that the Company alter development plans of certain of its product candidates. Accordingly, the Company will require additional financings through equity and debt offerings, collaborations and licensing arrangements or other sources to fully develop, prepare regulatory filings, obtain regulatory approvals and commercialize its existing and any new product candidates. If the Company is unable to arrange for such financings, or unable to arrange for them on terms acceptable to the Company, the Company's current development plans and plans for expansion of its facility and general and administrative infrastructure will be curtailed.

Cash Flows for the Years Ended December 31, 2018 and 2017

	For the year ended December 31,	
	2018	**2017**
($ in thousands)		
Statement of cash flows data:		
Total cash (used in) provided by:		
Operating activities	$ (19,244)	$ (12,948)
Investing activities	557	(29,052)
Financing activities	181	49,976
Net change in cash, cash equivalents and restricted cash	$ (18,506)	$ 7,976

Operating Activities

Net cash used in operating activities was $19.2 million for the year ended December 31, 2018, compared to $12.9 million for the year ended December 31, 2017. Net cash used in operating activities during the year ended December 31, 2018 was primarily due to approximately $30.7 million in net loss, partially offset by $5.0 million of non-cash stock compensation expenses, $1.3 million of research and development-licenses acquired, $2.1 million of common shares issuable for Founder shares, $2.5 million in change in operating assets and liabilities, and $0.6 million of depreciation expense.

Net cash used in operating activities during the year ended December 31, 2017 was primarily due to approximately $31.3 million in net loss, partially offset by $2.0 million of non-cash stock compensation expenses, $2.9 million of research and development-licenses acquired, $9.6 million of common shares issuable for Founder shares, $2.1 million related to a capital contribution from Fortress, $1.2 million for the issuance of common shares – Founders Agreement, and $0.7 million in change in operating assets and liabilities.

Investing Activities

Net cash provided by investing activities was $0.6 million for the year ended December 31, 2018, representing our purchase of $52.5 million investment in certificates of deposits held to maturity, $6.9 million in purchases of fixed assets and construction in process, $1.1 million in acquisition costs of acquired licenses, offset by $61.0 million in maturities of certificates of deposits.

Net cash used in investing activities was $29.1 million for the year ended December 31, 2017, representing our $46.0 million investment in certificates of deposits held to maturity, $2.4 million related to upfront payments relating to our licenses, $0.4 million in fixed asset purchases, $0.3 million in security deposits paid, offset by the maturity of a certificate of deposit of $20.0 million.

Financing Activities

Net cash provided by financing activities was $0.2 million during the year ended December 31, 2018, due to net proceeds from the exercise of warrants.

Net cash provided by financing activities was $50.0 million for the year ended December 31, 2017, due to $50.3 million of net proceeds from issuance of common stock, offset by approximately $0.3 million of proceeds used to repay the Fortress Note.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risks

Not applicable.

Item 8. Financial Statements and Supplementary Data.

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

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

Not applicable.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Controls and Procedures

Disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) are designed only to provide reasonable assurance that they will meet their objectives. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of December 31, 2018, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making the assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework (2013).*

Based on our assessment, our management has concluded that, as of December 31, 2018, our internal controls over financial reporting were effective based upon those criteria.

Changes in Internal Controls over Financial Reporting.

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

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements.

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

(b) Exhibits.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Mustang Bio, Inc. (formerly Mustang Therapeutics, Inc.), dated July 26, 2016. * Filed as Exhibit 3.1 on the Company's Form 10-12G filed on July 28, 2016.
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporate of Mustang Bio, Inc., dated June 14, 2018. * Filed as Exhibit 3.1 on the Company's Form 10-Q filed on August 13, 2018.
3.3	Bylaws of Mustang Bio, Inc. * Filed as Exhibit 3.2 on the Company's Form 10-12G filed on July 28, 2016.
4.1	Specimen certificates evidencing shares of common stock, Class A common stock and Class A preferred stock. * Filed as Exhibit 4.1 on the Company's Form 10-12G filed on July 28, 2016.
4.2	Form of warrant agreement. * Filed as Exhibit 4.2 on the Company's Form 10-12G filed on July 28, 2016.
10.1	Second Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Mustang Bio, Inc., dated July 26, 2016. * Filed as Exhibit 10.1 on the Company's Form 10-12G filed on July 28, 2016.
10.2	Management Services Agreement between Fortress Biotech, Inc. and Mustang Bio, Inc., dated March 13, 2015. * Filed as Exhibit 10.2 on the Company's Form 10-12G filed on July 28, 2016.
10.3	Future Advance Promissory Note to Fortress Biotech, Inc., dated May 5, 2016. * Filed as Exhibit 10.3 on the Company's Form 10-12G filed on July 28, 2016.
10.4	Promissory Note to NSC Biotech Venture Fund I, LLC, dated July 5, 2016. * Filed as Exhibit 10.4 on the Company's Form 10-12G filed on July 28, 2016.
10.5	Common Stock Warrant issued by Mustang Bio, Inc. to NSC Biotech Venture Fund I, LLC, dated July 5, 2016. * Filed as Exhibit 10.5 on the Company's Form 10-12G filed on July 28, 2016.
10.6	License Agreement by and between Mustang Bio, Inc. and City of Hope, dated March 17, 2015. # Filed as Exhibit 10.6 on the Company's Form 10-12G filed on July 28, 2016.
10.7	Sponsored Research Agreement by and between Mustang Bio, Inc. and City of Hope, dated March 17, 2015. * Filed as Exhibit 10.7 on the Company's Form 10-12G filed on July 28, 2016.
10.8	Mustang Bio, Inc. 2016 Incentive Plan. †* Filed as Exhibit 10.8 on the Company's Form 10-12G filed on July 28, 2016.
10.9	Non-Employee Directors Compensation Plan. †* Filed as Exhibit 10.9 on the Company's Form 10-12G filed on July 28, 2016.
10.10	Agreement with Chord Advisors, LLC, dated April 8, 2016. * Filed as Exhibit 10.10 on the Company's Form 10-12G filed on July 28, 2016.
10.11	Agreement with Caribe BioAdvisors, LLC, dated January 1, 2017. Filed as Exhibit 10.11 on the Company's Form 10-K filed on March 31, 2017.
10.12	Exclusive License Agreement with The Regents of the University of California, dated March 17, 2017. # Filed as Exhibit 10.4 on the Company's Form 10-Q filed on August 14, 2017.

10.13	Exclusive License Agreement - IV/ICV with City of Hope, dated February 17, 2017. # Filed as Exhibit 10.5 on the Company's Form 10-Q filed on August 14, 2017.
10.14	Amended and Restated Exclusive License Agreement - CD123 with City of Hope, dated February 17, 2017. # Filed as Exhibit 10.14 on the Company's Form 10-K filed on March 31, 2017.
10.15	Amended and Restated Exclusive License Agreement - *IL13Rα2* with City of Hope, dated February 17, 2017. # Filed as Exhibit 10.15 on the Company's Form 10-K filed on March 31, 2017.
10.16	Amended and Restated Exclusive License Agreement - Spacer with City of Hope, dated February 17, 2017. # Filed as Exhibit 10.16 on the Company's Form 10-K filed on March 31, 2017.
10.17	Employment Agreement between Manuel Litchman and Mustang Bio, Inc., made effective as of April 24, 2017 Filed as Exhibit 10.1 on the Company's Form 8-K filed on April 24, 2017.
10.18	License Agreement dated May 31, 2017 by and between Mustang Bio, Inc. and City of Hope (CSI). # Filed as Exhibit 10.1 on the Company's Form 10-Q/A filed on November 14, 2017.
10.19	License Agreement dated May 31, 2017 by and between Mustang Bio, Inc. and City of Hope (PSCA). # Filed as Exhibit 10.2 on the Company's Form 10-Q/A filed on November 14, 2017.
10.20	License Agreement dated May 31, 2017 by and between Mustang Bio, Inc. and City of Hope (HER2). # Filed as Exhibit 10.3 on the Company's Form 10-Q/A filed on November 14, 2017.
10.21	Lease Agreement, by and between the Company and WCS - 377 Plantation Street, Inc., dated October 27, 2017. Filed as Exhibit 10.1 on the Company's Form 10-Q filed on November 14, 2017.
10.22	Executive Employment Agreement, by and between Mustang Bio, Inc. and Martina A. Sersch, M.D., Ph.D., dated October 4, 2018.† Filed as Exhibit 10.1 on the Company's Form 10-Q filed on November 13, 2018.
23.1	Consent of Independent Registered Public Accounting Firm, BDO USA, LLC
24.1	Power of Attorney (included on signature page).
31.1	Certification of President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from Mustang Bio, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statement of Stockholders' Equity, (iv) the Statements of Cash Flows, and (v) Notes to the Financial Statements (filed herewith).

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

† Indicates management contract or compensatory plan or arrangement.

* Previously Filed.

Item 16. Form 10-K Summary.

None.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Mustang Bio, Inc.
New York, New York

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Mustang Bio, Inc. (the "Company") as of December 31, 2018 and 2017, the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2016.

Boston, Massachusetts
March 18, 2019

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

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 16,469	$ 34,975
Short-term investments (certificates of deposit)	17,604	26,002
Interest receivable on short-term investments (certificates of deposit)	37	106
Prepaid expenses	1,015	278
Total current assets	35,125	61,361
Property, plant and equipment, net	6,465	140
Fixed assets - construction in process	393	1,241
Restricted cash	500	500
Other assets	271	251
Total Assets	**$ 42,754**	**$ 63,493**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,381	$ 3,474
Payables and accrued expenses - related party	236	137
Total current liabilities	**5,617**	**3,611**
Deferred Rent Payable	741	50
Total Liabilities	**6,358**	**3,661**
Commitments and Contingencies		
Stockholders' Equity		
Preferred stock ($0.0001 par value), 2,000,000 shares authorized, 250,000 shares of Class A preferred stock issued and outstanding as of December 31, 2018 and December 31, 2017	-	-
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Class A common shares, 1,000,000 shares issued and outstanding as of December 31, 2018 and December 31, 2017	-	-
Common shares, 26,610,183 and 25,236,255 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	3	3
Common stock issuable,709,314 and 834,756 shares as of December 31, 2018 and December 31, 2017, respectively	2,085	9,558
Additional paid-in capital	113,378	98,679
Accumulated deficit	(79,070)	(48,408)
Total Stockholders' Equity	**36,396**	**59,832**
Total Liabilities and Stockholders' Equity	**$ 42,754**	**$ 63,493**

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

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

	For the year ended December 31,	
	2018	**2017**
Operating expenses:		
Research and development	$ 21,104	$ 7,943
Research and development – licenses acquired	3,360	12,433
General and administrative	6,759	11,409
Total operating expenses	31,223	31,785
Loss from operations	(31,223)	(31,785)
Other income (expense)		
Interest income	569	505
Interest expense	(8)	(8)
Total other income (expense)	561	497
Net Loss	**$ (30,662)**	**$ (31,288)**
Net loss per common share outstanding, basic and diluted	$ (1.14)	$ (1.24)
Weighted average number of common shares outstanding, basic and diluted	26,949,374	25,252,832

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

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

	Class A Preferred Stock		Class A Common Shares		Class B Common Shares		Common Shares		Common Stock	Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Issuable	Capital	Deficit	Equity (Deficit)
Balances at December 31, 2016	**250,000**	**$ -**	**1,000,000**	**$ -**	**-**	**$ -**	**15,165,244**	**$ 2**	**$ 4,396**	**$ 36,998**	**$ (17,120)**	**$ 24,276**
Common stock issuable - Founders Agreement	-	-	-	-	-	-	-	-	9,558	-	-	9,558
Issuance of common shares - Founders Agreement	-	-	-	-	-	-	982,533	-	(4,396)	5,630	-	1,234
Issuance of common shares for license expenses	-	-	-	-	-	-	293,588	-	-	1,682	-	1,682
Issuance of common shares and warrants for cash	-	-	-	-	-	-	8,610,774	1	-	55,969	-	55,970
Offering cost	-	-	-	-	-	-	-	-	-	(5,674)	-	(5,674)
Stock-based compensation expenses	-	-	-	-	-	-	180,000	-	-	2,012	-	2,012
Capital contribution from Fortress	-	-	-	-	-	-	-	-	-	2,062	-	2,062
Exercise of NSC warrants	-	-	-	-	-	-	4,116	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	-	(31,288)	(31,288)
Balances at December 31, 2017	**250,000**	**$ -**	**1,000,000**	**$ -**	**-**	**$ -**	**25,236,255**	**$ 3**	**$ 9,558**	**$ 98,679**	**$ (48,408)**	**$ 59,832**
Common stock issuable - Founders Agreement	-	-	-	-			-	-	2,085	-	-	2,085
Issuance of common shares - Founders Agreement	-	-	-	-	-	-	834,756	-	(9,558)	9,558	-	-
Stock-based compensation expenses	-	-	-	-	-	-	496,552	-	-	4,960	-	4,960
Exercise of warrants	-	-	-	-	-	-	42,620	-	-	181	-	181
Net loss	-	-	-	-	-	-	-	-	-	-	(30,662)	(30,662)
Balances at December 31, 2018	**250,000**	**$ -**	**1,000,000**	**$ -**	**-**	**$ -**	**26,610,183**	**$ 3**	**$ 2,085**	**$ 113,378**	**$ (79,070)**	**$ 36,396**

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

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

	For the year ended December 31,	
	2018	**2017**
Cash Flows from Operating Activities:		
Net loss	$ (30,662)	$ (31,288)
Research and development - licenses acquired	1,275	2,875
Issuance of common shares - Founders Agreement	-	1,234
Common shares issuable for Founders Agreement	2,085	9,558
Stock-based compensation expenses	4,960	2,012
Depreciation expense	630	2
Capital contribution from Fortress	-	2,062
Adjustments to reconcile net loss to net cash used in operating activities:		
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(757)	(278)
Interest receivables	(35)	(106)
Accounts payable and accrued expenses	2,470	1,332
Payable and accrued expenses - related party	99	12
Accrued interest - related party	-	(413)
Deferred rent	691	50
Net cash used in operating activities	(19,244)	(12,948)
Cash Flows from Investing Activities:		
Purchase of short-term investment (certificates of deposit)	(52,500)	(46,002)
Maturity of certificate of deposit	61,002	20,000
Purchase of research and development licenses	(1,075)	(2,375)
Purchase of fixed assets	(6,870)	(424)
Security deposits paid	-	(251)
Net cash used in investing activities	557	(29,052)
Cash Flows from Financing Activities:		
Payment of Fortress Note	-	(320)
Proceeds from issuance of common stock and warrants, net of offering cost of $0 and $5,674, respectively	-	50,296
Proceeds from exercise of warrants	181	-
Net cash provided by financing activities	181	49,976
Net change in cash, cash equivalents and restricted cash	(18,506)	7,976
Cash, cash equivalents and restricted cash, beginning of the period	35,475	27,499
Cash, cash equivalents and restricted cash, end of the period	**$ 16,969**	**$ 35,475**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ 413
Supplemental disclosure of noncash investing and financing activities:		
Fixed assets (acquired but not paid)	$ 196	$ 959
Issuance of common shares - Founders Agreement	$ 9,558	$ 4,396
Research and development licenses included in accounts payable and accrued liabilities	$ 200	$ 500
Common shares issuable for license acquired	$ -	$ 1,682

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

Note 1 - Organization and Description of Business

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

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

Liquidity and Capital Resources

The Company has incurred substantial operating losses and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2018, the Company had an accumulated deficit of $79.1 million.

The Company has funded its operations to date primarily through the sale of equity. The Company expects to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, including financing the Company's growth, developing new or existing product candidates, and funding capital expenditures, acquisitions and investments. The Company currently anticipates that its cash and cash equivalents balances at December 31, 2018 are sufficient to fund its anticipated operating cash requirements for at least one year from the date of this Form 10-K.

The Company will be required to expend significant funds in order to advance the development of its product candidates. The Company's estimates as to how long it expects its existing cash to be able to continue to fund its operations is based on assumptions that may prove to be inaccurate, and it could use its available capital resources sooner than it currently expects, as a result of unforeseen events. Such changes in circumstances may require that the Company alter development plans of certain of its product candidates. Accordingly, the Company will require additional financings through equity and debt offerings, collaborations and licensing arrangements or other sources to fully develop, prepare regulatory filings, obtain regulatory approvals and commercialize its existing and any new product candidates. If the Company is unable to arrange for such financings, or unable to arrange for them on terms acceptable to the Company, the Company's current development plans and plans for expansion of its facility and general and administrative infrastructure will be curtailed.

Note 2 - Significant Accounting Policies

Basis of Presentation

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

The financial statements may not be indicative of future performance and may not reflect what the Company's results of operations, financial position, and cash flows would have been had Mustang operated as an independent entity. Certain estimates have been made to provide financial statements for stand-alone reporting purposes. All inter-company transactions between Fortress and Mustang are classified as due to related party in the financial statements. The Company believes that the assumptions underlying the financial statements are reasonable.

Segments

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

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2018 and at December 31, 2017 consisted of cash, money market funds and certificates of deposit in institutions in the United States. Balances at certain institutions have exceeded Federal Deposit Insurance Corporation ("FDIC") insured limits.

Restricted Cash

The Company records cash held in an escrow account as a security deposit for the manufacturing facility in Worcester, Massachusetts as restricted cash. The Facility initiated cell processing operations for personalized CAR T and gene therapies in late 2018.

Short-term Investments

The Company classifies its certificates of deposit as cash and cash equivalents or held to maturity in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 320, *Investments - Debt and Equity Securities*. The Company considers all investments with an original maturity in excess of three months when purchased to be short-term investments. Investments consist of short-term FDIC insured certificates of deposit carried at amortized cost using the effective interest method. The cost of the Company's certificates of deposit approximated fair value. The Company reassesses the appropriateness of the classification of its investments at the end of each reporting period.

At December 31, 2018, the Company had approximately $27.6 million in certificates of deposit. The Company classified $10.0 million as cash and cash equivalents and classified $17.6 million of its certificates of deposits as short-term investments as of December 31, 2018. At December 31, 2017, the Company had approximately $40.0 million in certificates of deposit. The Company classified $14.0 million as cash and cash equivalents and classified $26.0 million of its certificates of deposits as short-term investments as of December 31, 2017. The classification was based upon management's determination that it has the positive intent and ability to hold the securities until their maturity dates, as its investments mature within one year and the underlying cash invested in these securities is not required for current operations.

Property, plant and equipment, net

Property and equipment, net, which consists mainly of laboratory equipment, are carried at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets, generally five years, using the straight-line method.

Property and equipment - Construction in Process

In connection with the Company's cell processing facility, the Company incurred $0.4 million related to the design and construction of the facility and the purchase of equipment which are recorded in fixed assets on the balance sheet at December 31, 2018. Upon completion of the facility's construction all costs associated with the buildout will be recorded as leasehold improvements and amortized over the shorter of the estimated useful lives or the term of the respective leases, upon the improvement being placed in service.

Research and Development Costs

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

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

Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired is reflected as research and development - licenses acquired on the Company's Statements of Operations.

Annual Stock Dividend

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

In 2017, the Company recorded the Annual Stock Dividend due to Fortress as contingent consideration. Contingent consideration is recorded when probable and reasonably estimable. The Company's future share prices cannot be estimated due to the nature of its assets and the Company's stage of development. Due to these uncertainties, the Company concluded that it could not reasonably estimate the contingent consideration until shares were actually issued on March 13, 2018. Because the issuance of shares on March 13, 2018 occurred prior to the issuance of the December 31, 2017 financial statements, the Company recorded approximately $9.6 million in research and development - licenses acquired for the year ended December 31, 2017.

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

Pursuant to the Amended and Restated Articles of Incorporation, the Company issued 709,314 shares of common stock to Fortress for the Annual Stock Dividend, representing 2.0%, on a pro rata basis, of the fully-diluted outstanding equity of Mustang on January 1, 2019.

Fair Value Measurement

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

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

Level 1:	Quoted prices in active markets for identical assets or liabilities.
Level 2:	Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.
Level 3:	Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

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

Stock-Based Compensation Expenses

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates. For stock-based compensation awards to non-employees, the Company re-measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as stock-based compensation expense in the period of change.

The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Income Taxes

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

Net Loss per Share

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period less unvested restricted stock. Since dividends are declared, paid and set aside among the holders of shares of common stock and Class A common shares pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of warrants or outstanding Class A preferred shares, as their inclusion would be anti-dilutive.

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

	For the year ended December 31,	
	2018	**2017**
Warrants	5,210,698	5,253,318
Options	1,241,675	1,241,675
Class A Preferred Shares	250,000	250,000
Unvested restricted stock awards	502,636	180,000
Unvested restricted stock units	1,032,084	134,000
Total	8,237,093	7,058,993

Comprehensive Loss

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

Recently Adopted Accounting Pronouncements

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. ASU 2017-09 provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The Company adopted ASU No. 2017-09 as of January 1, 2018. The adoption of this update did not impact the Company's financial statements and related disclosures.

In January 2017, the FASB issued an ASU 2017-01, "*Business Combinations (Topic 805) Clarifying the Definition of a Business*". The amendments in this ASU clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company adopted ASU 2017-01 on January 1, 2018. The adoption of this update did not impact the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, *"Improvements to Nonemployee Share-Based Payment Accounting"*, which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU No. 2018-07 as of January 1, 2019. The adoption of this update did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019 rather than as of the earliest period presented, and elected the package of practical expedients described above. The Company is still finalizing its analysis, but expects to recognize additional operating liabilities of $1.9 million, with corresponding ROU assets of approximately the same amount as of January 1, 2019 based on the present value of the remaining lease payments.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, “Disclosure Update and Simplification”, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company does not expect the adoption of this guidance to have a material impact on its financial statements and anticipates its first presentation of changes in stockholders’ equity will be included in its Form 10-Q for the quarter ended March 31, 2019.

Note 3 - License, Clinical Trial and Sponsored Research Agreements

Research and Development Expenses – All Licenses

For the years ended December 31, 2018 and 2017, the Company recorded the following expense in research and development for licenses acquired:

	For the year ended December 31,	
($ in thousands)	**2018**	**2017**
City of Hope		
Manufacturing	$ 75	$ -
IL13Rα2	-	500
IV/ICV	-	125
PSCA	-	300
HER2	200	600
CS1	-	600
Harvard University - CRISPR	-	250
UCLA	-	200
Fred Hutch - CD20	-	300
St. Jude - XSCID	1,000	-
Fortress PIK Dividend	2,085	9,558
Total	$ 3,360	$ 12,433

License Agreements

City of Hope

In March 2015, the Company entered into an exclusive license agreement with City of Hope National Medical Center ("City of Hope" or "COH") to acquire intellectual property rights pertaining to CAR-T (the "Original Agreement"). Pursuant to the Original Agreement, the Company paid COH an upfront fee of $2.0 million in April 2015 (included in *research and development-licenses acquired expenses* on the Statement of Operations) and granted COH 1.0 million Class A common shares of the Company, representing 10% ownership. The Class A common shares provide the COH with the right to appoint a Director, to the Board of Directors of the Company, as of December 31, 2017 COH has not exercised this right. Additional payments totaling $2.0 million were due upon the completion of two financial milestones, and payments totaling $14.5 million, for each patent, upon the completion of six development goals. Future mid-single digit royalty payments were due on net sales of licensed products, with a minimum annual royalty of $1.0 million

The Company valued the stock grant to COH utilizing a discounted cash flow model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8%, weighted average cost of capital of 30%, and net of debt utilized, resulting in a value of $0.147 per share or $0.1 million on March 31, 2015.

Effective October 2016, Mustang closed on gross proceeds of $10.0 million from third party investors in connection with its private placement, which triggered the issuance of additional 293,588 shares of Mustang Class A common stock to COH (the "COH Anti-Dilution Shares") in connection with the COH License. The shares were valued utilizing a weighted market model at approximately $5.73 per share or $1.7 million in total. Since Mustang only had 1.0 million Class A common shares authorized at December 31, 2016, of which all were issued to COH, Mustang recorded the contingent issuance as a current liability. In February 2017, COH executed a waiver and acknowledgement agreement permitting issuance of the COH Anti-Dilution Shares in the form of Mustang Common Stock, and such shares were issued.

In February 2017, the Company and COH amended and restated the Original Agreement by entering into three separate amended and restated exclusive license agreements, one relating to CD123, one relating to IL13Rα2 and one relating to the Spacer technology, that amended the Original Agreement in certain other respects, and collectively replace the Original Agreement in its entirety. The total potential consideration payable to COH by the Company, in equity or cash, did not, in the aggregate, change materially from the Original Agreement.

CD123 License

In February 2017, the Company entered into an Amended and Restated Exclusive License Agreement with COH to acquire intellectual property rights pertaining to patent rights related to CD123 (the "CD123 License"). Pursuant to the CD123 License, the Company and COH acknowledge that an upfront fee has already been paid under the Original Agreement. In addition, COH is eligible to receive an annual maintenance fee of $25,000 and milestone payments totaling approximately $14.5 million upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product. In addition, equity grants made under the Original Agreement were acknowledged, and the anti-dilution provisions of the Original Agreement were carried forward.

IL13Rα2 License

In February 2017, the Company entered into an Amended and Restated Exclusive License Agreement with COH to acquire intellectual property rights pertaining to patent rights related to IL13Rα2 (the "IL13Rα2 License"). Pursuant to the IL13Rα2 License, the Company and COH acknowledge that an upfront fee has already been paid under the Original Agreement. In addition, COH is eligible to receive an annual maintenance fee of $25,000 and milestone payments totaling approximately $14.5 million upon and subject to the achievement of certain milestones. Royalty payments in the mid-single digits are due on net sales of licensed products. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-teens to mid-thirties, depending on the timing of the sublicense in the development of any product. In addition, equity grants made under the Original Agreement were acknowledged, and the anti-dilution provisions of the Original Agreement were carried forward.

Spacer License

In February 2017, the Company 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, the Company and COH acknowledged that an upfront fee has already been paid under the Original Agreement. In addition, COH will receive an annual maintenance fee of $10,000. No royalties are due if the Spacer technology is used in conjunction with a CD123 CAR or 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. The Company is obligated to pay COH a percentage of certain revenues received in connection with a sublicense in the mid-thirties. In addition, equity grants made under the Original Agreement were acknowledged, and the anti-dilution provisions of the Original Agreement were carried forward.

IV/ICV License

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

HER2 Technology License

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

CS1 Technology License

On May 31, 2017, the Company entered into an exclusive license agreement (the "CS1 Agreement) with the COH for the use of CS1-specific CAR T technology ("CS1 Technology") to be directed against multiple myeloma. Pursuant to the CS1 Agreement, the Company paid an upfront fee of $0.6 million and will owe an annual maintenance fee of $50,000 (beginning in 2019). Additional payments are due for the achievement of ten development milestones totaling $14.9 million and royalty payments in the mid-single digits are due on net sales of licensed products.

PSCA Technology License

On May 31, 2017, the Company entered into an exclusive license agreement (the "PSCA Agreement") with the COH for the use of prostate stem cell antigen ("PSCA") CAR T technology ("PSCA Technology") to be used in the treatment of prostate cancer. Pursuant to the PSCA Agreement, the Company paid an upfront fee of $0.3 million and will owe an annual maintenance fee of $50,000 (beginning in 2019). Additional payments are due for the achievement of ten development milestones totaling $14.9 million and royalty payments in the mid-single digits are due on net sales of licensed products.

Manufacturing License

On January 3, 2018, the Company 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. The Company paid $75,000 in consideration for the licenses to the patent rights and the licensed know-how in addition to an annual maintenance fee. Royalty payments in the low-single digits are due on net sales of licensed products.

University of California License

On March 17, 2017, the Company entered into an exclusive license agreement with the Regents of the University of California (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, the Company paid UCLA the upfront fee of $0.2 million and will owe an annual maintenance fee of $15,000 for the first two years, $25,000 for years three and four, and $50,000 per year thereafter. Additional payments are due for the achievement of seven development milestones, totaling $14.3 million, and royalty payments in the mid-single digits are due on net sales of licensed products.

Fred Hutchinson Cancer Research Center License

On July 3, 2017, Mustang entered into an exclusive, worldwide licensing agreement with Fred Hutchinson Cancer Research Center ("Fred Hutch") for the use of a CAR T therapy related to autologous T cells engineered to express a CD20-specific chimeric antigen receptor (the "CD20 Technology License"). Pursuant to the CD20 Technology License, the Company paid Fred Hutch an upfront fee of $0.3 million and will owe an annual maintenance fee of $50,000 on each anniversary of the license until the achievement by the Company of regulatory approval of a licensed product using CD20 Technology. Additional payments are due for the achievement of eleven development milestones totaling $39.1 million and royalty payments in the mid-single digits are due on net sales of licensed products.

Harvard College License

On November 20, 2017, the Company entered into an exclusive, worldwide license agreement with President and Fellows of Harvard College (the "Harvard Agreement") for the use of gene editing, via the use of CRISPR/Cas9, to be used in enhancing the efficacy of chimeric antigen receptor T (CAR T) cell therapies for solid tumor indications and to generate universal off the shelf CAR T cell therapies for both liquid and solid tumor indications. Pursuant to the Harvard Agreement, the Company paid Harvard College an upfront fee of $0.3 million and will owe an annual maintenance fee of $25,000 and $50,000 for calendar years 2018 and 2019, respectively, and $100,000 for each subsequent calendar year during the term of the agreement. Additional payments are due for the achievement of seven development milestones totaling $16.7 million and royalty payments in the low-single digits are due on the net sales of licensed products.

St. Jude Children's Research Hospital

On August 2, 2018, the Company entered into an exclusive worldwide license agreement with St. Jude Children's Research Hospital ("St. Jude") for the development of a first-in-class *ex vivo* lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID"). The Company 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.

Research and Development Expenses - Sponsored Research and Clinical Trial Agreements

For the years ended December 31, 2018 and, the Company recorded the following expense in research and development for sponsored research and clinical trial agreements:

	For the year ended December 31,	
	2018	**2017**
($ in thousands)		
City of Hope	$ 2,000	$ 2,000
City of Hope - CD123	835	1,227
City of Hope - IL13Rα2	1,056	1,578
City of Hope - Manufacturing	458	-
Fred Hutch - CD20	1,301	614
BIDMC - CRISPR	69	138
Total	$ 5,719	$ 5,557

City of Hope

In March 2015, the Company entered into a sponsored research agreement with COH in which the Company will fund continued research in the amount of $2.0 million per year, payable in four equal installments, until 2020. The research covered under this arrangement is for IL13Rα2, CD123 and the Spacer technology. For the year ended December 31, 2018 and 2017, the Company recorded $2.0 million and $2.0 million, respectively, in research and development expenses on the statement of operations in connection with this agreement.

CD123 Clinical Research Support Agreement

In February 2017, the Company entered into a Clinical Research Support Agreement for CD123 (the "CD123 CRA"). Pursuant to the terms of the CD123 CRA the Company made an upfront payment of $19,450 and will contribute an additional $97,490 per patient in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately $0.2 million over three years pertaining to the clinical development of CD123. For the year ended December 31, 2018 and 2017 the Company recorded $0.8 million and $1.4 million, respectively, in research and development expenses under the CD123 CRA on the statement of operations.

IL13Rα2 Clinical Research Support Agreement

In February 2017, the Company entered into a Clinical Research Support Agreement for IL13Rα2 (the "IL13Rα2 CRA"). Pursuant to the terms of the IL13Rα2 CRA the Company made an upfront payment of approximately $9,300 and will contribute an additional $0.1 million related to patient costs in connection with the on-going investigator-initiated study. Further, the Company agreed to fund approximately $0.2 million over three years pertaining to the clinical development of IL13Rα2. For the year ended December 31, 2018 and 2017 the Company recorded $1.1 million and $1.4 million, respectively, in research and development expenses under the IL13Rα2 CRA on the statement of operations.

City of Hope Sponsored Research Agreement

On January 3, 2018, the Company entered into a Sponsored Research Agreement ("SRA") with COH to optimize and develop CAR T cell processing procedures. Pursuant to the SRA, the Company will fund continued research in the amount of $0.9 million for the program, which has an initial term of two (2) years.

CD20 Clinical Trial Agreement with Fred Hutch

Also, on July 3, 2017, in conjunction with the CD20 Technology License from Fred Hutch, Mustang entered into an investigator-initiated clinical trial agreement ("CD20 CTA") to provide partial funding for a Phase 1/2 clinical trial at Fred Hutch evaluating the safety and efficacy of the CD20 Technology in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. In connection with the CD20 CTA, the Company agreed to fund up to $5.3 million of costs associated with the clinical trial, which commenced during the fourth quarter of 2017. For the year ended December 31, 2018 and 2017, the Company recorded $1.3 million and $0.6 million, respectively, of expense in connection with this agreement.

Fred Hutch Cancer Research Center Sponsored Research Agreement

On March 17, 2018, the Company entered into an SRA with The Fred Hutch Cancer Research Center ("Fred Hutch") related to developing and optimizing processes and systems associated with CD20 cell processing. Pursuant to the SRA, the Company will fund continued research in the amount of $0.6 million during the term of the SRA which expires one year from the effective date.

CRISPR Sponsored Research Agreement with Beth Israel Deaconess Medical Center, Inc.

On November 28, 2017, the Company entered into a Sponsored Research Agreement (the "SRA") with Beth Israel Deaconess Medical Center Inc. ("BIDMC") to perform research relating to gene editing, via the use of CRISPR/Cas9, to be used in enhancing the efficacy of chimeric antigen receptor T (CAR T) cell therapies for solid tumor indications and to generate universal off the shelf CAR T cell therapies for both liquid and solid tumor indications. The Company agreed to fund approximately $0.8 million over a three-year period. For the year ended December 31, 2018 and 2017, the Company recorded approximately $0.1 million and $0.1 million, respectively, of expense in connection with this agreement.

In December 2018, the Company terminated the SRA with BIDMC due to the departure of key personnel from BIDMC.

Note 4 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 13, 2015, the Company entered a Founders Agreement with Fortress, which was amended and restated on May 17, 2016 and again on July 26, 2016 (the "Mustang Founders Agreement"). The Mustang Founders Agreement provides that, in exchange for the time and capital expended in the formation of Mustang and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Fortress loaned $2.0 million, representing the up-front fee required to acquire the Company's license agreement with COH. The Mustang Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Fortress and the Company or a Change in Control (as defined in the Mustang Founders Agreement) occurs. Concurrently with the second amendment on July 26, 2016, to the Mustang Founders Agreement, Fortress entered into an Exchange Agreement whereby Fortress exchanged its 7.25 million Class B Common shares for 7.0 million common shares and 250,000 Class A Preferred shares. Class A Preferred Stock is identical to common stock other than as to voting rights, conversion rights and the PIK Dividend right (as described below). Each share of Class A Preferred Stock will be entitled to vote the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding Mustang common stock and (B) the whole shares of Mustang common stock into which the shares of outstanding Class A Common Stock and Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Each share of Class A Preferred Stock is convertible, at Fortress' option, into one fully paid and nonassessable share of Mustang common stock, subject to certain adjustments. As holders of Class A Preferred Stock, Fortress will receive on each March 13 (each a "PIK Dividend Payment Date") until the date all outstanding Class A Preferred Stock is converted into common stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock ("PIK Dividends") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to two and one-half percent (2.5%) of Mustang's fully-diluted outstanding capitalization on the date that is one (1) business day prior to any PIK Dividend Payment Date.

As additional consideration under the Mustang Founders Agreement, Mustang will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Mustang that occurs after the effective date of the Mustang Founders Agreement and ending on the date when Fortress no longer has majority voting control in the Company's voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of the Company's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, the Company will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%) (see Note 7).

Effective as of March 13, 2015, the Company entered into a Management Services Agreement (the "MSA") with Fortress. Pursuant to the terms of the MSA, for a period of five years, Fortress will render advisory and consulting services to the Company. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of the Company's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). The Company is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of its actions or inactions based upon their advice. Fortress and its affiliates, including all members of the Company's Board of Directors, have been contractually exempt from fiduciary duties to the Company relating to corporate opportunities. In consideration for the Services, the Company will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which the Company has net assets in excess of $100 million at the beginning of the calendar year.

For the years ended December 31, 2018 and 2017, the Company recorded approximately $0.5 million and $0.5 million, respectively, as expense related to this agreement.

Payable and Accrued Expenses Related Party

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

National Securities Inc.

As of December 31, 2018, Fortress owned 32.1% of National Holdings Corporation ("NHLD"). National Securities Inc. ("NSC"), a subsidiary of NHLD, acted as placement agent for the Company's third-party financings. No fees were incurred for the year ended December 31, 2018 for any such financings. For the year ended December 31, 2017, the Company paid NSC placement agent fees of $5.6 million and issued to NSC 861,077 warrants to purchase the Company's common stock. The warrants have a five-year term and an exercise price of $8.50 per share. For the year ended December 31, 2016, the Company paid NSC placement agent fees of $4.0 million and issued to NSC 601,486 warrants to purchase the Company's common stock. The warrants have a five-year term and an exercise price of $8.50 per share.

Director Compensation

Dr. Rosenwald

Pursuant to the terms of the Director Compensation Plan, Dr. Rosenwald will receive a cash fee of $50,000 per year paid quarterly and an annual stock award of the greater of (i) a number of shares of common stock having a fair market value on the grant date of $50,000 or (ii) 10,000 shares of common stock, which shares shall vest and become non-forfeitable on the third anniversary of the grant date, subject to continued service on the Board on such date. For the year ended December 31, 2018, the Company recognized $84,000 in expense in its Statements of Operations related to the director compensation, including approximately $34,000 in expense related to an annual equity incentive grant of 20,000 restricted shares. For the year ended December 31, 2017, the Company recognized $25,052 in expense in its Statements of Operations related to the director compensation, including approximately $10,000 in expense related to an annual equity incentive grant of 10,000 restricted shares.

Mr. Weiss - Advisory Agreement with Caribe BioAdvisors, LLC

The Board of the Company by unanimous written consent approved and authorized the execution of an advisory agreement dated January 1, 2017 (the "Advisory Agreement"), with Caribe BioAdvisors, LLC (the "Advisor"), owned by Michael S. Weiss, the Chairman of the Board, to provide the board advisory services of Mr. Weiss as Chairman of the Board. Pursuant to the Advisory Agreement, the Advisor will be paid an annual cash fee of $60,000, paid quarterly and an annual stock award of the greater of (i) a number of shares of common stock having a fair market value on the grant date of $50,000 or (ii) 10,000 shares of common stock, which shares shall vest and become non-forfeitable on the third anniversary of the grant date, subject to continued service on the Board on such date. For year ended December 31, 2018, the Company recognized $84,000 in expense in its Statements of Operations related to the advisory agreement, including approximately $34,000 in expense related to an annual equity incentive grant of 20,000 restricted shares. For year ended December 31, 2017, the Company recognized $70,800 in expense in its Statements of Operations related to the advisory agreement, including approximately $10,800 in expense related to an annual equity incentive grant of 10,000 restricted shares.

Stock Awards Made to Fortress Employees

In April 2017, the Company made an option award to two employees of Fortress (see Note 7).

Note 5 - Property and Equipment

Mustang's property and equipment consisted of the following ($ in thousands):

	Estimated Useful Life (in years)	December 31, 2018	December 31, 2017
Computer equipment	3	$ 53	$ -
Furniture and fixtures	5	111	-
Machinery & equipment	5	3,143	142
Leasehold improvements	9	3,790	-
Construction in process	N/A	393	1,241
Total property and equipment		7,490	1,383
Less: accumulated depreciation		(632)	(2)
Property and equipment, net		$ 6,858	$ 1,381

Mustang's depreciation expense for the year ended December 2018 and 2017 was approximately $0.6 million and $2,000, respectively, and was recorded in research and development expense in the Statements of Operations.

Note 6 - Commitments and Contingencies

Leases

On October 27, 2017, Mustang entered into a lease agreement with WCS - 377 Plantation Street, Inc., a Massachusetts nonprofit corporation. Pursuant to the terms of the lease agreement, Mustang agreed to lease 27,043 sf from the Landlord, located at 377 Plantation Street in Worcester, MA, through November 2026, subject to additional extensions at Mustang's option. Base rent, net of abatements of $0.6 million over the lease term, totals approximately $3.6 million, on a triple-net basis.

The terms of the lease also require that Mustang post an initial security deposit of $0.8 million, in the form of $0.5 million letter of credit and $0.3 million in cash, which shall increase to $1.3 million ($1.0 million letter of credit, $0.3 million in cash) when the Facility is fully occupied by Mustang. After the fifth lease year, the letter of credit obligation is subject to reduction.

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

Total future minimum lease payments under the lease are:

($ in thousands)	
2019	$ 264
2020	448
2021	462
2022	476
2023	489
Beyond	1,458
Total minimum lease payments	$ 3,597

Litigation

On January 15, 2016, Dr. Winson Tang ("Plaintiff") filed a Complaint against the Company in the Superior Court of the State of California, County of Los Angeles. Winson Tang v. Lindsay Rosenwald et al., Case No. BC607346. As amended, the Complaint requested a declaration that Plaintiff was a 15% owner of the Company's outstanding shares and alleged two claims for breach of contract against other Defendants. On November 3, 2017, Plaintiff and Defendants entered into a Settlement Agreement. The Settlement Agreement did not require issuance of any new shares by us.

In connection with the legal settlement, above, Fortress delivered 200,000 Mustang common shares, held by Fortress, to Plaintiff. During the year ended December 31, 2017, the Company recorded this transaction as a capital contribution from Fortress and a corresponding expense of approximately $2.0 million based upon the closing share price of Mustang shares as of the date of the Settlement Agreement. In addition to the share issuance the Company paid, in November 2017, a $0.2 million cash settlement to the plaintiff, such amount was recorded in general and administrative expenses on the Statements of Operations.

Note 7 - Stockholders' Equity

Common Stock

The Company, in accordance with its certificate of incorporation, as amended in July 2016, which was retroactively applied, is authorized to issue 50,000,000 common shares with a par value of $0.0001 per share, of which 1,000,000 shares are designated as "Class A Common Stock" and 15,000,000 shares are designated as "Class B Common Stock" see below Fortress Issuances and Note 4.

In connection with the Company's formation, Fortress subscribed for 7,000,000 shares of the Class B Common Stock and 2,000,000 shares of the Company's Common Stock, pursuant to the Founders Agreement. Fortress paid the par value of $900 in 2016. The fair value of the Company's common shares approximated par value as no licenses had been transferred at that time. Dividends, if and when declared, are to be distributed pro-rata to the Class A, B and Common Stock holders.

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

The Class B Common Stockholders are entitled, for each share of Class B Common Stock held, to a number of votes equal to 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 Stock and the Class B Common Stock are convertible and the denominator of which is the number of shares of outstanding Class B common shares.

Pursuant to the Founders Agreement, on March 13, 2016 the Company issued 250,000 shares of Class B Common Stock to Fortress, which equaled 2.5% of the fully diluted outstanding equity of Mustang at the time of issuance for the annual equity fee (see Note 4).

In February 2017, COH executed a waiver and acknowledgement agreement permitting issuance of the COH Anti-Dilution Shares in the form of Mustang common stock rather than Class A common shares as originally required, and such shares were issued. Therefore, in February 2017, the Company reclassed $1.7 million of common shares issuable liability to additional paid-in capital and issued 293,588 common shares to COH. As of December 31, 2017, COH owns 1,000,000 Class A common shares and 293,588 common shares. The shares were valued utilizing a weighted market model at approximately $5.73 per share or approximately $1.7 million.

On March 13, 2017, the Company issued to Fortress 767,264 shares of common stock at $5.73 per share representing the stock dividend payable in connection with Fortress' ownership of Class A Preferred Stock. Pursuant to this issuance, the Company recorded a $4.4 million decrease in common shares issuable and a corresponding increase in additional paid in capital to account for the issuance of the PIK Dividend.

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

In July 2018, the Company filed a shelf registration statement on Form S-3 (the "S-3"), which was declared effective in July 2018. Under the S-3, the Company may sell up to a total of $75 million of its securities. In connection with the S-3, the Company entered into an At-the-Market Issuance Sales Agreement (the "ATM") with B. Riley FBR, Inc., Cantor Fitzgerald & Co., National Securities Corporation, and Oppenheimer & Co. Inc. (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. No securities have been issued by the Company under the S-3 registration as of December 31, 2018.

Pursuant to the Founders Agreement, the Company issued 834,756 shares of common stock to Fortress for the Annual Stock Dividend, representing 2.5% of the fully diluted outstanding equity of the Company on March 12, 2018.

Offerings and Issuances of Common Stock and Warrants

On January 31, 2017, the Company closed the sixth round of financing totaling gross proceeds of $55.5 million, before expenses, in a private placement of shares and warrants for which NSC was the placement agent and received a fee of $5.5 million or approximately 10% of the gross proceeds. The Company issued 8,536,774 unregistered shares of common stock and 2,134,193 warrants in connection with this transaction. In addition, NSC received 853,677 warrants or approximately 10% of the shares issued.

On March 31, 2017, the Company closed the seventh round of financing totaling gross proceeds of $0.4 million, before expenses, in a private placement of shares and warrants for which NSC was the placement agent and received a fee of approximately $42,000 or approximately 10% of the gross proceeds. The Company issued 64,000 unregistered shares of common stock and 16,000 warrants in connection with this transaction. In addition, NSC received 6,400 warrants or approximately 10% of the shares issued.

On August 3, 2017, the Company closed the final round of financing totaling gross proceeds of $65,000. The Company issued 10,000 unregistered shares of common stock and 2,500 warrants in connection with this transaction. In addition, NSC received 1,000 warrants or approximately 10% of the shares issued.

Pursuant to the Founders Agreement, the Company issued 982,533 shares to Fortress, representing 2.5% of the aggregate number of shares of common stock issued in the offerings noted above. For the year ended December 31, 2017, the Company recorded expense of approximately $1.2 million, related to this issuance (based upon the fair value of common shares on the date of issuance), which is included in general and administrative expenses in the Company's Statements of Operations. For the year ended December 31, 2017, the Company recorded in research and development license acquired expenses on the Statement of Operations of $9.6 million or 834,756 shares of common stock issuable to Fortress on the anniversary of the A&R Founders Agreement, representing 2.5% of the Company's outstanding shares at March 12, 2018, at $11.45 per share (fair value of common shares on March 12, 2018).

In July 2018, the Company filed a shelf registration statement on Form S-3 (the "S-3"), which was declared effective in July 2018. Under the S-3, the Company may sell up to a total of $75 million of its securities. In connection with the S-3, the Company entered into an At-the-Market Issuance Sales Agreement (the "ATM") with B. Riley FBR, Inc., Cantor Fitzgerald & Co., National Securities Corporation, and Oppenheimer & Co. Inc. (each an "Agent" and collectively, the "Agents"), relating to the sale of shares of common stock. Under the ATM, the Company pays the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock. No securities have been issued by the Company under the S-3 registration as of December 31, 2018.

Stock Issuances to Fortress

Pursuant to the Company's Second Amended and Restated Certificate of Incorporation, on March 13, 2017, the Company issued 767,264 shares of common stock to Fortress, which equaled to 2.5% of the fully diluted outstanding equity of the Company at the time of issuance, for the annual stock dividend. The Company recorded an expense of approximately $4.4 million in research and development licenses-acquired related to this stock grant during the year ended December 31, 2016.

Pursuant to the Company's Second Amended and Restated Certificate of Incorporation, on March 13, 2018, the Company issued 834,756 shares of common stock to Fortress, which equaled to 2.5% of the fully diluted outstanding equity of the Company at the time of issuance, for the annual stock dividend. The Company recorded an expense of approximately $9.6 million in research and development licenses-acquired related to these issuable shares during the year ended December 31, 2017.

In connection with the Mustang Founders Agreement, the Company issued 365,639 shares of common stock to Fortress representing 2.5% of the total shares issued in it's Offering which commenced September 16, 2016 and ended in August 2017. See description of Offering above.

Pursuant to the Company's Second Amended and Restated Certificate of Incorporation, on January 1, 2019, the Company issued 709,314 shares of common stock to Fortress, which equaled 2.0%, on a pro rata basis, of the fully diluted outstanding equity of the Company at the time of issuance, for the annual stock dividend. The Company recorded an expense of approximately $2.1 million in research and development licenses-acquired related to these issuable shares during the year ended December 31, 2018.

Stock Awards

Stock Options

The Company has in effect the 2016 Incentive Plan (the "Incentive Plan"). The Incentive Plan was adopted in 2016 by our stockholders and the compensation committee of the Company's board of directors and is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan initially authorized grants to issue up to 2,000,000 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant. In June 2018, the Company's stockholders approved an amendment to the Incentive Plan to increase the number of authorized shares issuable by 3,000,000 shares, for a total of 5,000,000 shares. Total shares available for the issuance of stock-based awards under the Incentive Plan was 2,049,689 shares at December 31, 2018.

On April 24, 2017, the Company announced that Manuel Litchman, M.D., had been appointed President and Chief Executive Officer. Dr. Litchman was also appointed to the Company's Board of Directors.

The employment agreement grants Dr. Litchman an option to purchase 1,041,675 shares of the Company's common stock (the "Option"). The Option has an exercise price per share equal to the fair market value of a share the Company's common stock, $5.73 on the date of the grant of the stock option, subject to the conditions and vesting schedule set forth in his Employment Agreement.

On April 7, 2017, the Company granted 200,000 options to two employees of Fortress, who provide services to the Company in connection with our research and development. These options have an exercise price of $5.73, representing the fair market value of a share the Company's common stock on the date of the grant of the stock option.

Both grants have the following vesting schedule: 50% of the options vest over-time ("Time Based Option") with 25% vesting over 12 months of continued service and the remaining shares vesting in 12 equal quarterly installments thereafter, subject to continued employment. The remaining 50% (the "Performance Options") vest and become exercisable upon the occurrence of the following milestones being achieved: (i) 25% of the Performance Options vest upon the dosing of the first patient in the first Phase 2 clinical trial of any Company product candidate, (ii) 25% of the Performance Options vest upon the dosing of the first patient in the first Phase 2 clinical trial of a second Company product candidate, (iii) 25% of the Performance Options vest upon the Company's achievement of a fully-diluted market capitalization of $500,000,000 and (iv) 25% of the Performance Options vest upon the Company's achievement of a fully-diluted market capitalization of $1,000,000,000.

The value of the stock options granted approximated $5.5 million and was determined on the grant date using assumptions for risk free interest rate, the expected term, expected volatility, expected dividend yield, and an exercise price of $5.73. Mustang does not expect to pay dividends in the foreseeable future. As a result, the expected dividend yield is 0%. The fair value associated with the market award vesting was determined utilizing a binomial valuation methodology and the following assumptions:

	December 31, 2017
Risk-free interest rate	1.81% - 2.38%
Exercise price	$5.73
Expected dividend yield	0%
Expected term in years	5.5 - 10.0
Expected volatility	77.30% - 96.65%

The following table summarizes stock option activities for the year ended December 31, 2018 and 2017:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding at December 31, 2016	-	$ -	-
Options granted	1,241,675	5.73	9.31
Outstanding at December 31, 2017	1,241,675	5.73	9.31
Options granted	-	-	
Outstanding at December 31, 2018	1,241,675	5.73	8.31
Options vested and exercisable at December 31, 2018	232,813	$ 5.73	8.31

As of December 31, 2018, the Company had unrecognized stock-based compensation expense related to options of $1.1 million, which is expected to be recognized over a weighted average period of approximately 2.0 years . Effective on January 1, 2017, the Company elected to account for forfeited awards as they occur as permitted by ASU 2016-09. Ultimately, the actual expenses recognized over the vesting period will be for those shares that vested. Prior to making this election, the Company estimated a forfeiture rate for awards at 0%, as the Company did not have a significant history of forfeitures.

Restricted Stock

Certain employees and directors have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted stock award activities for the year ended December 31, 2018 and 2017:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2016	-	$ -
Granted	180,000	5.73
Nonvested at December 31, 2017	180,000	$ 5.73
Granted	322,636	5.78
Nonvested at December 31, 2018	502,636	$ 5.76

As of December 31, 2018, the Company had unrecognized stock-based compensation expense related to restricted stock of $1.9 million, which is expected to be recognized over a weighted average period of approximately 2.5 years. This amount does not include, as of December 31, 2018, 68,158 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation expense for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Restricted Stock Units

The following table summarizes restricted stock units activities for the year ended December 31, 2018 and 2017:

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2016	-	$ -
Granted	134,000	6.53
Nonvested at December 31, 2017	134,000	$ 6.53
Granted	1,072,000	8.16
Vested	(173,916)	9.25
Nonvested at December 31, 2018	1,032,084	$ 7.77

As of December 31, 2018, the Company had unrecognized stock-based compensation expense related to restricted stock units of approximately $4.2 million, which is expected to be recognized over a weighted average period of approximately 2.2 years. This amount does not include, as of December 31, 2018, 230,000 shares of restricted stock units outstanding issued to non-employees, the expense for which is determined each reporting period at the measurement date. The expense is recognized over the vesting period of the award.

The following table summarizes stock-based compensation expense for the years ended December 31, 2018 and 2017 (in thousands).

	For the year ended December 31,	
	2018	2017
Employee	$ 3,664	$ 1,486
Non-employee	1,296	526
Total stock-based compensation expense	$ 4,960	$ 2,012

For the years ended December 31, 2018 and 2017, the Company recognized stock-based compensation of $5.0 million and $2.0 million, respectively.

Warrants

In connection with the Company's offering of shares of common stock in a private placement, each investor received a warrant equal to 25% of the common shares purchased in connection with the offering. Further, NSC received Placement Agent Warrants.

A summary of warrant activities for years ended December 31, 2018 and 2017 is presented below:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2016	2,243,664	$ 7.98	5.16
Granted	3,013,770	8.50	4.09
Exercised	(4,116)	-	-
Outstanding as of December 31, 2017	5,253,318	$ 8.28	3.89
Granted	-	-	-
Exercised	(42,620)	4.25	-
Outstanding as of December 31, 2018	5,210,698	$ 8.32	3.10

Upon the exercise of warrants, the Company will issue new shares of Common Stock.

Note 8 - Income Taxes

For financial reporting purposes, the Company calculated income tax provision and deferred income tax balances as if it was a separate entity and had filed its own separate tax return under Sub-Chapter C of the Internal Revenue Code.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	For the year ended December 31,	
	2018	2017
Statutory federal income tax rate	21%	35%
State taxes, net of federal tax benefit	7%	9%
Non-deductible items	-	(2)%
Credits	3%	-
Federal tax rate change	-	(18)%
State tax rate change	(2)%	(1)%
Other	(1)%	(1)%
Change in valuation allowance	(28)%	(22)%
Income taxes provision (benefit)	-	-

The components of the net deferred tax asset as of December 31, 2018 and 2017 are the following ($ in thousands):

	For the year ended December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryovers	$ 14,305	$ 7,236
Stock compensation and other	1,427	697
Change in warrant liability	45	50
Amortization of license	6,258	6,424
Accruals and reserves	237	22
Startup costs	6	8
Tax credits	1,070	178
Total deferred tax assets	$ 23,348	$ 14,615
Less valuation allowance	(23,348)	(14,615)
Deferred tax assets, net of allowance	$ -	$ -

On December 22, 2017, "H.R.1", formerly known as the "Tax Cuts and Jobs Act", was signed into law. Among other items, H.R.1 reduces the federal corporate tax rate to 21% from the existing maximum rate of 35%, effective January 1, 2018. As a result, the Company has recorded a decrease related to deferred tax assets of $5.7 million, with a corresponding net adjustment to deferred income tax expense of $5.7 million for the year ended December 31, 2017.

The SEC staff issued Staff Accounting Bulletin 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Act and allows the registrant to record provisional amounts during the measurement period. The Company is in the process of analyzing the impact of the various provisions of the Tax Act. The Company expects to complete its analysis within the measurement period in accordance with SAB 118.

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax asset. A valuation allowance of approximately $23.3 million and $14.6 million, respectively, was recorded for the year ended December 31, 2018 and 2017.

As of December 31, 2018, the Company had federal and state net operating loss carryforwards of approximately $48.2 million and $63.6 million, respectively. The federal and state net operating loss carryforwards will begin to expire, if not utilized, by 2035 and 2035, respectively. Utilization of the net operating loss carryforward may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended and similar state provisions.

There are no significant items determined to be unrecognized tax benefits taken or expected to be taken in a tax return, in accordance with ASC 740 "Income Taxes" ("ASC 740"), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements, that have been recorded on the Company's financial statements for the period ended December 31, 2018. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

Additionally, ASC 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for the period ended December 31, 2018.

The federal and state tax returns for the years ended December 31, 2017, 2016, and 2015 are currently open for examination under the applicable federal and state income tax statues of limitations.

Note 9 - Quarterly Financial Information (unaudited)

(in thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2018				
Total Revenue	$ 50	$ -	$ -	$ (50)
Operating expenses	$ 6,477	$ 5,240	$ 7,656	$ 11,850
Other income	$ 146	$ 147	$ 138	$ 130
Net loss	$ (6,281)	$ (5,093)	$ (7,518)	$ (11,770)
Basic and diluted net loss per common share	$ (0.24)	$ (0.19)	$ (0.28)	$ (0.43)
2017				
Total Revenue	$ -	$ -	$ -	$ -
Operating expenses	$ 3,306	$ 5,665	$ 7,084	$ 15,730
Other income	$ 88	$ 136	$ 144	$ 129
Net loss	$ (3,218)	$ (5,529)	$ (6,940)	$ (15,601)
Basic and diluted net loss per common share	$ (0.14)	$ (0.21)	$ (0.27)	$ (0.61)

Note 10 - Subsequent Events

In February 2019, Mustang announced that it partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital to develop an oncolytic virus (C134) for the treatment of glioblastoma multiforme ("GBM"). Mustang intends to combine the oncolytic virus with MB-101 (IL13Rα2-specific CAR) to potentially enhance efficacy in treating GBM.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Mustang Bio, Inc.

By: /s/ Manuel Litchman
Name: Manuel Litchman
Title: President and Chief Executive Officer

March 18, 2019

POWER OF ATTORNEY

We, the undersigned directors and/or executive officers of Mustang Bio, Inc., hereby severally constitute and appoint Manuel Litchman, acting singly, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign this Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or appropriate to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Michael S. Weiss Michael S. Weiss	Executive Chairman of the Board	March 18, 2019
/s/ Manuel Litchman Manuel Litchman, M.D.	President and Chief Executive Officer	March 18, 2019
/s/ Lindsay A. Rosenwald Lindsay A. Rosenwald, M.D.	Director	March 18, 2019
/s/ Neil Herskowitz Neil Herskowitz	Director	March 18, 2019
/s/ Adam Chill Adam Chill	Director	March 18, 2019
/s/ Michael Zelefsky Michael Zelefsky, M.D.	Director	March 18, 2019
/s/ Brian Achenbach Brian Achenbach	Vice President of Finance & Corporate Controller	March 18, 2019

Exhibit 23.1

Mustang Bio, Inc.
New York, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-226175) and Form S-8 (Nos. 333-221819) of Mustang Bio, Inc. of our report dated March 18, 2019 relating to the financial statements appearing in this Form 10-K.

/s/ BDO USA, LLP

Boston, Massachusetts
March 18, 2019

EXHIBIT 31.1

CERTIFICATION PURSUANT TO

SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2018 of Mustang Bio, Inc. (the registrant);

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Dated: March 18, 2019

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

EXHIBIT 31.2

CERTIFICATION PURSUANT TO

SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Achenbach, Vice President of Finance & Corporate Controller (Principal Financial Officer), certify that:

(1) I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2018 of Mustang Bio, Inc. (the registrant);

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Dated: March 18, 2019

By: /s/ Brian Achenbach
Brian Achenbach
Vice President of Finance & Corporate Controller
(Principal Financial Officer)

EXHIBIT 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Mustang Bio, Inc. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Manuel Litchman, M.D., President and Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

Dated: March 18, 2019

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

EXHIBIT 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Mustang Bio, Inc. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Achenbach, Vice President Finance & Corporate Controller, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company, as of, and for, the periods presented in the Report.

Dated: March 18, 2019

By: /s/ Brian Achenbach
Brian Achenbach
Vice President of Finance & Corporate Controller
(Principal Financial Officer)