

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

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **March 16, 2020**

**Mustang Bio, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-38191**  
(Commission File Number)

**47-3828760**  
(IRS Employer Identification No.)

**377 Plantation Street  
Worcester, Massachusetts 01605**  
(Address of Principal Executive Offices)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

**Item 2.02 Results of Operations and Financial Condition.**

On March 16, 2020, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the fiscal year ended December 31, 2019. A copy of such press release is being furnished as Exhibit 99.1 to this report.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished herewith:

<b>Exhibit Number</b>	<b>Description</b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press release issued by Mustang Bio, Inc., dated March 16, 2020.</u></a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**MUSTANG BIO, INC.**  
(Registrant)

Date: March 16, 2020

By: /s/ Manuel Litchman, M.D.  
Name: Manuel Litchman, M.D.  
Title: President and Chief Executive Officer

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### Mustang Bio Reports Full-Year 2019 Financial Results and Recent Corporate Highlights

**New York, NY – March 16, 2019** – Mustang Bio, Inc. (“Mustang”) (NASDAQ: MBIO), 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, today announced financial results and recent corporate highlights for the full year ended December 31, 2019.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “We are delighted by Mustang’s numerous accomplishments in 2019. We started off the year by executing a worldwide license agreement with Nationwide Children’s Hospital to develop MB-108, oncolytic virus C134, for the treatment of glioblastoma multiforme. In April, we announced the exciting *New England Journal of Medicine* publication of positive Phase 1/2 data from our partner, St. Jude Children’s Research Hospital (“St. Jude”), which demonstrated the curative potential of MB-107, a lentiviral gene therapy for X-linked severe combined immunodeficiency (“XSCID”), also known as bubble boy disease. We plan to transfer the MB-107 Investigational New Drug (“IND”) application from St. Jude to Mustang shortly. In August, the FDA accepted our first IND application to initiate a multi-center Phase 1/2 clinical trial of MB-102 (CD123-targeted CAR T cell therapy) in acute myeloid leukemia (“AML”), blastic plasmacytoid dendritic cell neoplasm (“BPDCN”) and high-risk myelodysplastic syndrome. We look forward to dosing our first patient soon, using MB-102 processed at our own cell processing facility.”

Dr. Litchman continued, “In 2019, we were also pleased that the FDA granted prestigious designations to our drug candidates, including the Regenerative Medicine Advanced Therapy (“RMAT”) designation to MB-107 and Orphan Drug Designations to MB-108 for the treatment of malignant glioma and to MB-102 for the treatment of AML. In addition, several Phase 1 trials were initiated with our collaborators during the year, including the MB-104 (CS1-targeted CAR T cell therapy) trial at City of Hope for multiple myeloma, the MB-105 (PSCA-targeted CAR T cell therapy) trial at City of Hope for the treatment of prostate cancer, the MB-103 (HER2-targeted CAR T cell therapy) trial at City of Hope for the treatment of glioblastoma multiforme and of HER2-positive breast cancer with brain metastases, the MB-101 (IL13R $\alpha$ 2-targeted CAR T cell therapy) trial at City of Hope in combination with checkpoint inhibitors for the treatment of recurrent malignant glioma, and the MB-108, oncolytic virus C134, trial for the treatment of glioblastoma multiforme at the University of Alabama at Birmingham.”

Dr. Litchman concluded, “Mustang raised a total of \$69 million throughout 2019, which enables us to continue to advance our gene and CAR T cell therapy programs. We look forward to maintaining this positive momentum through 2020, including several important data readouts anticipated in the second half of the year.”

#### **Financial Results:**

- As of December 31, 2019, Mustang’s cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash totaled \$62.4 million, compared to \$73.3 million as of September 30, 2019, and \$34.6 million as of December 31, 2018, a decrease of \$10.9 million for the fourth quarter and an increase of \$27.8 million year-to-date.
  - Research and development expenses were \$30.0 million for the year ended December 31, 2019. This compares to \$21.1 million for 2018. Non-cash, stock-based compensation expenses included in research and development were \$0.9 million for the year ended December 31, 2019, compared to \$3.4 million for 2018.
  - Research and development expenses from license acquisitions totaled \$6.3 million for the year ended December 31, 2019, compared to \$3.4 million for 2018. Non-cash, stock-based compensation expenses included in research and development – licenses acquired were \$4.9 million for the year ended December 31, 2019, compared to \$2.1 million for 2018.
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- General and administrative expenses were \$9.6 million for the year ended December 31, 2019. This compares to \$6.8 million for 2018. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$3.4 million for the year ended December 31, 2019, compared to \$1.5 million for 2018.
- Net loss attributable to common stockholders was \$46.4 million, or \$1.29 per share, for the year ended December 31, 2019, compared to a net loss attributable to common stockholders of \$30.7 million, or \$1.14 per share, for 2018.

#### **2019 and Recent Corporate Highlights:**

- In February 2019, Mustang announced that it entered into an exclusive worldwide license agreement with Nationwide Children's Hospital to develop oncolytic virus C134 (MB-108) for the treatment of glioblastoma multiforme. Mustang intends to combine the oncolytic virus with MB-101 (IL13R $\alpha$ 2-specific CAR T cell therapy) to potentially enhance efficacy in treating glioblastoma multiforme.
  - In April 2019, Mustang announced that it had entered into a \$20 million debt financing agreement with Horizon Technology Finance Corporation. Fifteen million of the \$20 million loan was funded upon closing. The remaining \$5 million may be funded upon Mustang's achievement of certain predetermined milestones. In connection with the debt financing, Mustang issued Horizon warrants to purchase up to 288,184 shares of its common stock at an exercise price of \$3.47 per share.
  - Also in April 2019, the *New England Journal of Medicine* published St. Jude data from a Phase 1/2 clinical trial of MB-107, a lentiviral gene therapy, for the treatment of newly diagnosed infants under two years old with XSCID. Data demonstrated that the lentiviral gene therapy achieved normalization of T-cell numbers in all eight newly diagnosed infants to date and that disseminated infections resolved completely in all affected infants. Seven of the eight infants treated have developed normal IgM levels to date. Four of those seven infants have discontinued monthly infusions of intravenous immunoglobulin (IVIG) therapy to date. Three of those four infants who discontinued monthly IVIG infusions have responded to vaccines to date.
  - In May 2019, Mustang completed an underwritten public offering, including the full exercise of the over-allotment option by the underwriters, that raised gross proceeds of \$31.6 million, excluding underwriting discounts, commissions and other offering-related expenses.
  - In May 2019, Mustang announced that City of Hope began enrolling patients with relapsed or treatment-resistant multiple myeloma in an innovative CS1-targeted CAR T cell therapy (MB-104) trial.
  - Also in May 2019, the FDA granted Orphan Drug Designation to MB-108 (oncolytic virus C134) for the treatment of malignant glioma, a type of brain cancer with a median survival of less than 18 months.
  - In July 2019, the FDA granted Orphan Drug Designation to MB-102 (CD123-targeted CAR T cell therapy) for the treatment of AML.
  - In August 2019, Mustang announced that the FDA approved its IND application to initiate a multi-center Phase 1/2 clinical trial of MB-102 in AML, BPDCN and high-risk myelodysplastic syndrome.
  - In August 2019, MB-107 was granted the RMAT designation by the FDA.
  - Also in August 2019, Mustang entered into a license agreement with CSL Behring for the Cytegrity™ stable producer cell line, which will be used to produce the viral vector for the MB-107 lentiviral gene therapy program.
  - Additionally in August 2019, the California Institute for Regenerative Medicine (CIRM) granted City of Hope \$9.28 million to fund an ongoing Phase 1 clinical trial of MB-103 (HER2-targeted CAR T cell therapy) for the treatment of HER2-positive breast cancer with brain metastases.
  - In September 2019, Mustang announced that City of Hope opened and initiated patient treatments in a Phase 1 clinical trial of MB-105 (PSCA-targeted CAR T cell therapy) for the treatment of prostate cancer.
  - In October 2019, Mustang announced that City of Hope received \$4.1 million in grant awards to initiate a clinical trial of MB-101 (IL13R $\alpha$ 2-targeted CAR T cell therapy) in combination with nivolumab (commercial name: Opdivo®) and ipilimumab (commercial name: Yervoy®) in patients with recurrent malignant glioma. The trial, which is now enrolling patients, is the first human study to combine IL13R $\alpha$ 2-targeted CAR T cell therapy with checkpoint inhibitors, as well as the first to locally deliver CAR T cells with combination treatment with systemic nivolumab treatment.
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- Also in October 2019, Mustang announced that the first patient was dosed in a Phase 1 clinical trial to determine the safety and efficacy of MB-108 (oncolytic virus C134), an attenuated herpes simplex virus type 1, in recurrent glioblastoma multiforme.
- Updated Phase 1/2 clinical data for MB-107 were selected for oral and poster presentations at the 61st American Society of Hematology (“ASH”) Annual Meeting, which was held in December 2019. Data demonstrated that MB-107 preceded by low-dose busulfan conditioning continued to be well tolerated and resulted in the development of a functional immune system both in newly diagnosed infants with XSCID, as well as in older patients with XSCID who had received prior hematopoietic stem cell transplantation (HSCT). Also, the enhanced transduction procedure demonstrated more rapid recovery of NK cells and more rapid improvement in chronic norovirus infections vis-à-vis the original transduction procedure in older patients with XSCID who had received prior HSCT.
- Also at the 61st ASH Annual Meeting, Mustang’s collaborator Fred Hutchinson Cancer Research Center (“Fred Hutch”) presented a poster about the design of the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 (CD20-targeted CAR T cell therapy) for high-risk B-cell non-Hodgkin lymphomas.
- In February 2020, Mustang announced that the first subject treated with the optimized MB-106 (CD20-targeted, autologous CAR T cell therapy) manufacturing process, developed in collaboration between Mustang Bio and Fred Hutch, achieved a complete response at the lowest starting dose in an ongoing Phase 1/2 clinical trial. The trial is evaluating the safety and efficacy of MB-106 in subjects with relapsed or refractory B-cell non-Hodgkin lymphomas.

#### **About Mustang Bio**

Mustang Bio, Inc. (“Mustang”) 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. Mustang aims to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, to fund research and development, and to outlicense or bring the technologies to market. Mustang has partnered with top medical institutions to advance the development of CAR T therapies across multiple cancers, as well as a lentiviral gene therapy for XSCID. Mustang is registered under the Securities Exchange Act of 1934, as amended, and files periodic reports with the U.S. Securities and Exchange Commission. Mustang was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit [www.mustangbio.com](http://www.mustangbio.com).

#### **Forward-Looking Statements**

This press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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**MUSTANG BIO, INC.**  
**Balance Sheets**  
(\$ in thousands, except for share and per share amounts)

	<u>December 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 61,413	\$ 16,469
Short-term investments (certificates of deposit)	-	17,604
Other receivables - related party	19	-
Prepaid expenses and other current assets	1,631	1,052
<b>Total current assets</b>	<u>63,063</u>	<u>35,125</u>
Property, plant and equipment, net	6,779	6,465
Fixed assets - construction in process	1,157	393
Restricted cash	1,000	500
Other assets	250	271
Operating lease right-of-use asset, net	1,196	-
<b>Total Assets</b>	<u>\$ 73,445</u>	<u>\$ 42,754</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Short-term notes payable	\$ 1,250	\$ -
Accounts payable and accrued expenses	5,668	5,381
Payables and accrued expenses - related party	596	236
Operating lease liabilities - short-term	257	-
<b>Total current liabilities</b>	<u>7,771</u>	<u>5,617</u>
Deferred rent payable	-	741
Notes payable	12,179	-
Operating lease liabilities - long-term	1,843	-
<b>Total Liabilities</b>	<u>21,793</u>	<u>6,358</u>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Preferred stock (\$0.0001 par value), 2,000,000 shares authorized, 250,000 shares of Class A preferred stock issued and outstanding as of December 31, 2019 and 2018, respectively	-	-
Common Stock (\$0.0001 par value), 85,000,000 shares authorized		
Class A common shares, 845,385 and 1,000,000 shares issued and outstanding as of December 31, 2019 and 2018, respectively	-	-
Common shares, 39,403,519 and 26,610,183 shares issued and outstanding as of December 31, 2019 and 2018, respectively	4	3
Common stock issuable, 1,206,667 and 709,314 shares as of December 31, 2019 and 2018, respectively	4,923	2,085
Additional paid-in capital	172,184	113,378
Accumulated deficit	(125,459)	(79,070)
<b>Total Stockholders' Equity</b>	<u>51,652</u>	<u>36,396</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 73,445</u>	<u>\$ 42,754</u>



**MUSTANG BIO, INC.**  
**Statements of Operations**  
(\$ in thousands, except for share and per share amounts)

	<b>For the year ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Operating expenses:		
Research and development	\$ 30,042	\$ 21,104
Research and development – licenses acquired	6,273	3,360
General and administrative	9,570	6,759
Total operating expenses	<u>45,885</u>	<u>31,223</u>
Loss from operations	<u>(45,885)</u>	<u>(31,223)</u>
Other income (expense)		
Interest income	1,263	569
Interest expense	(1,767)	(8)
Total other income (expense)	<u>(504)</u>	<u>561</u>
<b>Net Loss</b>	<b><u>\$ (46,389)</u></b>	<b><u>\$ (30,662)</u></b>
Net loss per common share outstanding, basic and diluted	<u>\$ (1.29)</u>	<u>\$ (1.14)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>36,061,811</u>	<u>26,949,374</u>