
Section 1: 8-K (FORM 8-K)

**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 18, 2019**

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.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(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.

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 18, 2019, 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, 2018. 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:

Exhibit Number	Description
<u>99.1</u>	<u>Press release issued by Mustang Bio, Inc., dated March 18, 2019.</u>

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 18, 2019

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

[\(Back To Top\)](#)

Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1



Mustang Bio Reports Full-Year 2018 Financial Results and Recent Corporate Highlights

New York, NY – March 18, 2019 – Mustang Bio, Inc. (“Mustang”) (NASDAQ: MBIQ), 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, 2018.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “2018 was a transformational year for Mustang that positioned the company for further exciting advances in 2019. We enhanced our pipeline of therapies in August by adding a clinical-stage lentiviral gene therapy product candidate with curative potential for X-linked severe combined immunodeficiency (“XSCID”), for which we’re expecting compelling data to be published in a major medical journal this year. In June, we opened our cell processing facility in Worcester, Mass., which is now fully operational. We anticipate processing patients’ cells in the coming months under Mustang’s first IND—a significant milestone for the company. In December, the U.S. Food and Drug Administration (“FDA”) granted Orphan Drug Designation to MB-102 (CD123 CAR T) for the treatment of blastic plasmacytoid dendritic cell neoplasm (“BPDCN”), a rare and incurable blood cancer. Most recently, in February we licensed an oncolytic virus (C134) that we plan to combine with MB-101 (IL13R α 2-specific CAR) to potentially enhance efficacy in treating glioblastoma multiforme. With these achievements, Mustang has built a strong foundation for success in the coming year.”

Financial Results:

- As of December 31, 2018, Mustang’s consolidated cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash totaled \$34.6 million, compared to \$41.3 million as of September 30, 2018, and \$61.5 million as of December 31, 2017, a decrease of \$6.7 million for the fourth quarter and a decrease of \$26.9 million year-to-date.
- Research and development expenses were \$21.1 million for the year ended December 31, 2018. This compares to \$7.9 million for 2017. Non-cash, stock-based compensation expenses included in research and development were \$3.4 million for the year ended December 31, 2018, compared to \$0.7 million for 2017.
- Research and development expenses from license acquisitions totaled \$3.4 million for the year ended December 31, 2018, compared to \$12.4 million for 2017. Non-cash, stock-based compensation expenses included in research and development – licenses acquired were \$2.1 million for the year ended December 31, 2018, compared to \$9.6 million for 2017.
- General and administrative expenses were \$6.8 million for the year ended December 31, 2018. This compares to \$11.4 million for 2017. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$1.5 million for the year ended December 31, 2018, compared to \$2.6 million for 2017.
- Net loss attributable to common stockholders was \$30.7 million, or \$1.14 per share, for the year ended December 31, 2018, compared to a net loss attributable to common stockholders of \$31.3 million, or \$1.24 per share, for 2017.

2018 and Recent Corporate Highlights:

- In May 2018, Mustang 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 Mustang's IL13R α 2-specific CAR T MB-101 in glioblastoma.
-

- In June 2018, Mustang opened a proprietary CAR T cell therapy manufacturing facility at UMass Medicine Science Park in Worcester, Mass. The facility will support the clinical development and commercialization of Mustang's CAR T and gene therapy product candidates and enable proprietary cell therapy research.
- Also in June 2018, Mustang was added to the Russell 2000®, 3000® and Microcap® Indexes.
- In July 2018, Mustang completed a pre-Investigational New Drug ("pre-IND") meeting with the FDA for MB-102 (CD123 CAR T). Based on the meeting, Mustang expects to initiate a multicenter Phase 1/2 trial of MB-102 in acute myeloid leukemia ("AML"), BPDCN and high-risk myelodysplastic syndrome in the second half of 2019.
- In August 2018, Mustang announced that it entered into an exclusive worldwide license agreement with St. Jude Children's Research Hospital for the development of a potentially first-in-class *ex vivo* lentiviral gene therapy for the treatment of XSCID, also known as bubble boy disease. The therapy is currently being evaluated in a Phase 1/2 multicenter trial in infants under the age of two. This study is the world's first lentiviral gene therapy trial for infants with XSCID. The therapy is also being investigated in patients over the age of two in a second Phase 1/2 trial at the National Institutes of Health ("NIH"). The company believes these may be registration trials.
- In October 2018, Mustang announced that City of Hope initiated a first-of-its-kind Phase 1 clinical trial evaluating the safety and effectiveness of intraventricular delivery of CAR T cells to the brains of patients with HER2-positive breast cancer with brain metastases; the first patient was dosed in December 2018. In addition, Mustang announced that City of Hope dosed the first patient in a Phase 1 clinical trial of HER2-specific CAR T cells in treating recurrent or refractory grade III-IV glioma. The trial is evaluating the side effects and best dose of HER2-specific CAR T cells in treating patients with grade III-IV glioma that has come back or does not respond to treatment.
- In November 2018, Mustang 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.
- 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. Mustang intends to combine the oncolytic virus with MB-101 (IL13Rα2-specific CAR) to potentially enhance efficacy in treating glioblastoma multiforme.

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 and CRISPR/Cas9-enhanced 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.

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.

Company Contacts:

Jaclyn Jaffe and William Begien
Mustang Bio, Inc.
(781) 652-4500
ir@mustangbio.com

Investor Relations Contact:

Daniel Ferry
LifeSci Advisors, LLC
(617) 535-7746
daniel@lifesciadvisors.com

Media Relations Contact:

Tony Plohoros
6 Degrees
(908) 940-0135
tplohoros@6degreespr.com

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

	December 31,	
	2018	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

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	<u>31,223</u>	<u>31,785</u>
Loss from operations	<u>(31,223)</u>	<u>(31,785)</u>
Other income (expense)		
Interest income	569	505
Interest expense	(8)	(8)
Total other income (expense)	<u>561</u>	<u>497</u>
Net Loss	<u>\$ (30,662)</u>	<u>\$ (31,288)</u>
Net loss per common share outstanding, basic and diluted	<u>\$ (1.14)</u>	<u>\$ (1.24)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>26,949,374</u>	<u>25,252,832</u>

[\(Back To Top\)](#)