
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): **November 13, 2018**

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 November 13, 2018, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 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 November 13, 2018.</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: November 14, 2018

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

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

Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1



Mustang Bio Reports Third Quarter 2018 Financial Results and Recent Corporate Highlights

New York, NY – November 13, 2018 – Mustang Bio, Inc. (“Mustang”) (NASDAQ: MBIO), a company focused on the development of novel immunotherapies based on proprietary chimeric antigen receptor engineered T cell (“CAR T”) technology and gene therapies for rare diseases, today announced financial results and recent corporate highlights for the third quarter ended September 30, 2018.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “The third quarter of 2018 and recent months have been marked by clinical progress and a key addition to our management team with the appointment of Martina A. Sersch, M.D., Ph.D., as Chief Medical Officer. Notably, we expanded our pipeline into gene therapy by securing an exclusive worldwide license agreement with St. Jude Children’s Research Hospital (“St. Jude”) for the development of a first-in-class, *ex vivo*, clinical-stage lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (“X-SCID”). Data from a multicenter Phase 1/2 trial led by St. Jude in infants under the age of two years old are extremely encouraging. Eight patients under the age of two with X-SCID have been treated to date, with results presented at the 21st Annual Meeting of the American Society of Gene & Cell Therapy in May 2018. The therapy was well tolerated. In addition, six patients achieved reconstituted immune systems within three to four months following treatment, with the remaining two patients continuing to progress favorably in earlier stages of recovery. Four of these six patients have discontinued monthly infusions of intravenous immunoglobulin, and the remaining patients, at earlier stages of recovery, continue to progress favorably. In three patients who had disseminated infections prior to therapy, all infections resolved completely. In addition, the therapy is being investigated in patients over the age of two in a second Phase 1/2 trial at the National Institutes of Health (“NIH”), with equally encouraging data and an excellent safety profile to date. The two patients with the longest follow-up have seen sustained restoration of antibody production after immunization, and all five patients treated experienced a decrease in viral infections and overall clinical improvement.”

Dr. Litchman continued, “We also recently announced updates on two Phase 1 clinical trials at City of Hope using our HER2-specific CAR T cell therapy, including a first-of-its-kind trial using intraventricular delivery of CAR T cells to brains of patients with HER2-positive breast cancer with brain metastases. As we look ahead to the fourth quarter of 2018, we look forward to filing our first Investigational New Drug (IND) application to support a Phase 1/2 trial of MB-102 in acute myeloid leukemia (“AML”), blastic plasmacytoid dendritic cell neoplasm and high-risk myelodysplastic syndrome.”

Recent Corporate Highlights:

- In July 2018, Mustang completed a pre-IND meeting with the U.S. Food and Drug Administration (“FDA”) for MB-102 (CD123 CAR T). Based on the meeting, Mustang expects to file an IND in the fourth quarter of 2018 to support a Phase 1/2 trial of MB-102 in AML, blastic plasmacytoid dendritic cell neoplasm and high-risk myelodysplastic syndrome.

- In August 2018, Mustang announced that it 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 X-SCID, 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 X-SCID. 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").
 - In October 2018, Mustang appointed Martina A. Sersch, M.D., Ph.D., as Chief Medical Officer.
 - Also in October 2018, Mustang announced that 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 has been initiated at City of Hope. 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 will evaluate 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.
-

Financial Results:

- As of September 30, 2018, Mustang's consolidated cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash totaled \$41.3 million, compared to \$47.2 million as of June 30, 2018, and \$61.5 million as of December 31, 2017, a decrease of \$5.9 million for the quarter and a decrease of \$20.2 million year-to-date.
- Research and development expenses were \$5.3 million for the third quarter of 2018, compared to \$2.2 million for the third quarter of 2017. Non-cash, stock-based compensation expenses included in research and development were \$0.7 million for third quarter of 2018, compared to \$0.3 million for the third quarter of 2017.
- Research and development expenses from license acquisitions were \$1.0 million for the third quarter of 2018, compared to \$0.3 million for the third quarter of 2017.
- General and administrative expenses were \$1.3 million for the third quarter of 2018, compared to \$4.6 million for the third quarter of 2017. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$0.2 million for the third quarter of 2018, compared to \$0.5 million for the third quarter of 2017.
- Net loss attributable to common stockholders was \$7.5 million, or \$0.28 per share, for the third quarter of 2018, compared to \$6.9 million, or \$0.27 per share, for the third quarter of 2017. Net loss attributable to common stockholders was \$18.9 million, or \$0.70 per share, for the first nine months of 2018, compared to \$15.7 million, or \$0.63 per share, for the first nine months of 2017.

About Mustang Bio

Mustang Bio, Inc. ("Mustang") is a clinical-stage biopharmaceutical company focused on the development and commercialization of a broad range of proprietary chimeric antigen receptor engineered T cell (CAR T) immunotherapies and gene therapies in areas of unmet need. 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 X-SCID. Mustang is registered under the Securities Exchange Act of 1934, as amended, and files periodic reports with the U.S. Securities and Exchange Commission. 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 Contact:

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

Investor Relations Contact:

Jeremy Feffer
Managing Director, LifeSci Advisors, LLC
(212) 915-2568
jeremy@lifesciadvisors.com

Media Relations Contact:

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

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

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
	<u>(Unaudited)</u>	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 18,296	\$ 34,975
Short-term investments (certificates of deposit)	22,538	26,002
Interest receivable on short-term investments (certificates of deposit)	69	106
Other receivables - related party	50	-
Prepaid expenses	872	278
Total current assets	41,825	61,361
Property, plant and equipment, net	6,760	140
Fixed assets - construction in process	33	1,241
Restricted cash	500	500
Other assets	394	251
Total Assets	\$ 49,512	\$ 63,493
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 3,777	\$ 3,474
Payables and accrued expenses - related party	275	137
Total current Liabilities	4,052	3,611
Deferred Rent Payable	470	50
Total Liabilities	4,522	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 September 30, 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 September 30, 2018 and December 31, 2017	-	-
Common shares, 26,263,631 and 25,236,255 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	3	3
Common stock issuable, 0 and 834,756 shares as of September 30, 2018 and December 31, 2017, respectively	-	9,558
Additional paid-in capital	112,287	98,679
Accumulated deficit	(67,300)	(48,408)
Total Stockholders' Equity	44,990	59,832
Total Liabilities and Stockholders' Equity	\$ 49,512	\$ 63,493

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

	<u>For the three months ended September 30,</u>		<u>For the nine months ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenue - related party	\$ -	\$ -	\$ 50	\$ -
Operating expenses:				
Research and development	5,316	2,188	13,165	5,388
Research and development – licenses acquired	1,000	300	1,075	2,375
General and administrative	1,340	4,596	5,133	8,293
Total operating expenses	<u>7,656</u>	<u>7,084</u>	<u>19,373</u>	<u>16,056</u>
Loss from operations	<u>(7,656)</u>	<u>(7,084)</u>	<u>(19,323)</u>	<u>(16,056)</u>
Interest income	138	144	431	369
Net Loss	<u>\$ (7,518)</u>	<u>\$ (6,940)</u>	<u>\$ (18,892)</u>	<u>\$ (15,687)</u>
Net loss per common share outstanding, basic and diluted	<u>\$ (0.28)</u>	<u>\$ (0.27)</u>	<u>\$ (0.70)</u>	<u>\$ (0.63)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>27,146,721</u>	<u>26,186,924</u>	<u>26,871,505</u>	<u>24,936,626</u>

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