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 12, 2019**

Mustang Bio, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38191**	**47-3828760**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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.

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). ☒

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 12, 2019, 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, 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:

Exhibit Number	Description
99.1	Press release issued by Mustang Bio, Inc., dated November 12, 2019.

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 12, 2019

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 2019 Financial Results and Recent Corporate Highlights

New York, NY – November 12, 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 third quarter ended September 30, 2019.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We continue to be pleased with the progress of our gene therapy and CAR T programs. In the third quarter, MB-107 (lentiviral gene therapy) was granted the Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration (FDA), which we hope will translate into expedited development and approval of this very important and potentially curative lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (XSCID), also known as bubble boy disease. We look forward to a strong presence at the upcoming 61st American Society of Hematology (ASH) Annual Meeting, where additional data pertaining to MB-107 (lentiviral gene therapy) and information pertaining to MB-106 (CD20-targeted CAR T cell therapy) will be presented. With a strong balance sheet and the continued advancement of our gene therapy and CAR T programs, we are well positioned to execute on our goals for the rest of 2019 and into 2020."

Financial Results:

- As of September 30, 2019, Mustang's cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash totaled $73.3 million, compared to $83.1 million as of June 30, 2019 and $34.6 million as of December 31, 2018, a decrease of $9.8 million for the quarter and an increase of $38.7 million year-to-date.
- Research and development expenses were $7.3 million for the third quarter of 2019, compared to $5.3 million for the third quarter of 2018. Non-cash, stock-based compensation expenses included in research and development were $0.7 million for third quarter of 2019, compared to $0.7 million for the third quarter of 2018.
- Research and development expenses from license acquisitions totaled $0.7 million for the third quarter of 2019, compared to $1.0 million for the third quarter of 2018.
- General and administrative expenses were $2.0 million for the third quarter of 2019, compared to $1.3 million for the third quarter of 2018. Non-cash, stock-based compensation expenses included in general and administrative expenses were $0.4 million for the third quarter of 2019, compared to $0.2 million for the third quarter of 2018.
- Net loss attributable to common stockholders was $10.2 million, or $0.25 per share, for the third quarter of 2019, compared to $7.5 million, or $0.28 per share, for the third quarter of 2018.

Recent Corporate Highlights:

- In July 2019, the FDA granted Orphan Drug Designation to MB-102 (CD123-targeted CAR T cell therapy) for the treatment of acute

myeloid leukemia (AML).

- In August 2019, Mustang announced that the FDA approved its Investigational New Drug (IND) application to initiate a multi-center Phase 1/2 clinical trial of MB-102 in AML, blastic plasmacytoid dendritic cell neoplasm and high-risk myelodysplastic syndrome.
- In August 2019, MB-107, a lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (XSCID), also known as bubble boy disease, 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 for the treatment of XSCID

- 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 has 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 for a clinical trial of MB-101 (IL13Rα2-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 IL13Rα2-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.
- Also in October 2019, Mustang announced that the first participant 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.
- In November 2019, Mustang announced that MB-107 lentiviral gene therapy for XSCID clinical data were accepted for oral and poster presentations at the 61st ASH Annual Meeting in December 2019. In addition, Mustang's collaborator Fred Hutchinson Cancer Research Center will present 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.

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) 430-7576
daniel@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)

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 72,794	$ 16,469
Short-term investments (certificates of deposit)	-	17,604
Other receivables - related party	55	-
Prepaid expenses and other current assets	1,513	1,052
Total current assets	74,362	35,125
Property, plant and equipment, net	6,486	6,465
Fixed assets - construction in process	1,011	393
Restricted cash	500	500
Other assets	250	271
Operating lease right-of-use asset, net	1,226	-
Total Assets	**$ 83,835**	**$ 42,754**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,770	$ 5,381
Payables and accrued expenses - related party	284	236
Operating lease liabilities - short-term	239	-
Total current liabilities	6,293	5,617
Deferred rent payable	-	741
Notes payable	13,185	-
Operating lease liabilities - long-term	1,909	-
Total Liabilities	**21,387**	**6,358**
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, 2019 and December 31, 2018	-	-
Common Stock ($0.0001 par value), 85,000,000 shares authorized		
Class A common shares, 862,392 and 1,000,000 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	-	-
Common shares, 39,578,371 and 26,610,183 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	4	3
Common stock issuable, 0 and 709,314 shares as of September 30, 2019 and December 31, 2018, respectively	-	2,085
Additional paid-in capital	171,694	113,378
Accumulated deficit	(109,250)	(79,070)
Total Stockholders' Equity	**62,448**	**36,396**
Total Liabilities and Stockholders' Equity	**$ 83,835**	**$ 42,754**

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue - related party	$ -	$ -	$ -	$ 50
Operating expenses:				
Research and development	7,309	5,316	21,092	13,165
Research and development – licenses acquired	700	1,000	1,350	1,075
General and administrative	1,987	1,340	7,520	5,133
Total operating expenses	9,996	7,656	29,962	19,373
Loss from operations	(9,996)	(7,656)	(29,962)	(19,323)
Other income (expense)				
Interest income	406	138	945	431
Interest expense	(578)	-	(1,163)	-
Total other income (expense)	(172)	138	(218)	431
Net Loss	**$ (10,168)**	**$ (7,518)**	**$ (30,180)**	**$ (18,892)**
Net loss per common share outstanding, basic and diluted	$ (0.25)	$ (0.28)	$ (0.87)	$ (0.70)
Weighted average number of common shares outstanding, basic and diluted	39,875,209	27,146,721	34,752,938	26,871,505

(Back To Top)