

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): **August 9, 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.

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 August 9, 2019, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the second quarter ended June 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
<u>99.1</u>	<u>Press release issued by Mustang Bio, Inc., dated August 9, 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: August 9, 2019

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

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Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1



Mustang Bio Reports Second Quarter 2019 Financial Results and Recent Corporate Highlights

New York, NY – August 9, 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 second quarter ended June 30, 2019.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “The second quarter of 2019 marked 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). We look forward to transferring the MB-107 IND from St. Jude to Mustang in the fourth quarter of this year. Additionally, we are delighted that the U.S. Food and Drug Administration (FDA) accepted our first Investigational New Drug (IND) application to initiate a multi-center Phase 1/2 clinical trial of MB-102 (CD123 CAR T) in acute myeloid leukemia (AML), blastic plasmacytoid dendritic cell neoplasm (BPDCN) and high-risk myelodysplastic syndrome (MDS).”

Dr. Litchman continued, “Having raised a total of \$69 million in the first half of 2019, we look forward to continuing to advance the development of our gene and CAR T cell therapy product candidates in the second half of 2019 and potentially reporting additional CAR T data in the fourth quarter.”

Financial Results:

- As of June 30, 2019, Mustang’s cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash totaled \$83.1 million, compared to \$41.1 million as of March 31, 2019 and \$34.6 million as of December 31, 2018, an increase of \$42.0 million for the quarter and an increase of \$48.5 million year-to-date.
- Research and development expenses were \$6.8 million for the second quarter of 2019, compared to \$3.6 million for the second quarter of 2018. Non-cash, stock-based compensation expenses included in research and development were \$0.3 million for second quarter of 2019, compared to \$0.6 million for the second quarter of 2018.
- Research and development expenses from license acquisitions totaled \$0.2 million for the second quarter of 2019, compared to \$0 million for the second quarter of 2018.
- General and administrative expenses were \$3.2 million for the second quarter of 2019, compared to \$1.7 million for the second quarter of 2018. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$1.6 million for the second quarter of 2019, compared to \$0.4 million for the second quarter of 2018.
- Net loss attributable to common stockholders was \$10.4 million, or \$0.29 per share, for the second quarter of 2019, compared to \$5.1 million, or \$0.19 per share, for the second quarter of 2018.

Recent Corporate Highlights:

- 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 achieving 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.
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- Also in April 2019, the *New England Journal of Medicine* published St. Jude data from a Phase 1/2 clinical trial of 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 with XSCID to date and 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 a full over-allotment option exercise, that raised gross proceeds of \$31.6 million, excluding underwriting discounts, commissions and other offering-related expenses.
- 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 CAR T) for the treatment of AML.
- In August 2019, Mustang announced that the FDA had approved its IND application to initiate a multi-center Phase 1/2 clinical trial of MB-102 (CD123 CAR T) in AML, BPDCN and high-risk MDS .

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.

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

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 82,634	\$ 16,469
Short-term investments (certificates of deposit)	-	17,604
Other receivables - related party	128	-
Prepaid expenses and other current assets	660	1,052
Total current assets	83,422	35,125
Property, plant and equipment, net	6,513	6,465
Fixed assets - construction in process	699	393
Restricted cash	500	500
Other assets	250	271
Operating lease right-of-use asset, net	1,241	-
Total Assets	\$ 92,625	\$ 42,754
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,452	\$ 5,381
Payables and accrued expenses - related party	759	236
Operating lease liabilities - short-term	157	-
Total current liabilities	6,368	5,617
Deferred rent payable	-	741
Notes payable	12,951	-
Operating lease liabilities - long-term	1,862	-
Total Liabilities	21,181	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 June 30, 2019 and December 31, 2018	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Class A common shares, 862,392 and 1,000,000 shares issued and outstanding as of June 30, 2019, and December 31, 2018, respectively	-	-
Common shares, 39,454,316 and 26,610,183 shares issued and outstanding as of June 30, 2019, and December 31, 2018, respectively	4	3
Common stock issuable, 0 and 709,314 shares as of June 30, 2019, and December 31, 2018, respectively	-	2,085
Additional paid-in capital	170,522	113,378
Accumulated deficit	(99,082)	(79,070)
Total Stockholders' Equity	71,444	36,396
Total Liabilities and Stockholders' Equity	\$ 92,625	\$ 42,754

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

	<u>For the three months ended June 30,</u>		<u>For the six months ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenue - related party	\$ -	\$ -	\$ -	\$ 50
Operating expenses:				
Research and development	6,823	3,557	13,783	7,849
Research and development – licenses acquired	200	-	650	75
General and administrative	3,189	1,683	5,533	3,793
Total operating expenses	<u>10,212</u>	<u>5,240</u>	<u>19,966</u>	<u>11,717</u>
Loss from operations	<u>(10,212)</u>	<u>(5,240)</u>	<u>(19,966)</u>	<u>(11,667)</u>
Other income (expense)				
Interest income	387	147	539	293
Interest expense	(574)	-	(585)	-
Total other income (expense)	<u>(187)</u>	<u>147</u>	<u>(46)</u>	<u>293</u>
Net Loss	<u>\$ (10,399)</u>	<u>\$ (5,093)</u>	<u>\$ (20,012)</u>	<u>\$ (11,374)</u>
Net loss per common share outstanding, basic and diluted	<u>\$ (0.29)</u>	<u>\$ (0.19)</u>	<u>\$ (0.62)</u>	<u>\$ (0.43)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>36,306,710</u>	<u>27,087,918</u>	<u>32,149,352</u>	<u>26,731,616</u>

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