

---

---

**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): **May 11, 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).

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 May 11, 2020, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the first quarter ended March 31, 2020. 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="#">99.1</a>	<a href="#">Press release issued by Mustang Bio, Inc., dated May 11, 2020.</a>

---

**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.

Date: May 11, 2020

**Mustang Bio, Inc.**  
(Registrant)

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

---



### Mustang Bio Reports First Quarter 2020 Financial Results and Recent Corporate Highlights

**Worcester, MA – May 11, 2020** – 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 first quarter ended March 31, 2020.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “We were pleased to announce several important milestones in the first few months of 2020. Most notably, we were excited to submit our Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (“FDA”) for MB-107, our lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (“XSCID”), also known as bubble boy disease, and we look forward to commencing a multi-center Phase 2 clinical trial in newly diagnosed infants with XSCID under the age of two. We also anticipate filing a second IND in the third quarter of this year for a multi-center trial for the treatment of previously transplanted XSCID patients. Additionally, the European Medicines Agency (“EMA”) granted Advanced Therapy Medicinal Product (“ATMP”) classification to MB-107, which is an important step in establishing our path to market approval and commercialization in Europe.”

“Among our other first quarter accomplishments was the complete response achieved at the lowest dose level in the first subject treated following process optimization in our Phase 1/2 clinical trial of MB-106, our CD20-targeted, autologous CAR T cell therapy, for patients with relapsed or refractory B-cell non-Hodgkin lymphomas. This trial is ongoing, and we hope to announce additional interim data later this year. We are also very pleased to report that MB-105, a PSCA-directed CAR T currently under investigation in a Phase 1 trial at City of Hope, appeared to be active in the first patient to receive the therapy following a standard CAR T conditioning regimen. As we progress through 2020, we look forward to advancing our gene and CAR T cell therapies toward additional potentially value-creating regulatory and clinical milestones in the months ahead,” Dr. Litchman concluded.

#### Recent Corporate Highlights:

- In May 2020, Mustang submitted an IND application with the FDA to initiate a multi-center Phase 2 clinical trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two. The trial is expected to enroll 10 patients who, together with 15 patients enrolled in the current multicenter trial led by St. Jude Children’s Research Hospital, will be compared with 25 matched historical control patients who have undergone hematopoietic stem cell transplant (“HSCT”). The primary efficacy endpoint will be event-free survival. The initiation of this trial is currently on hold pending CMC clearance by the FDA. Mustang is targeting topline data from the trial in the second half of 2022.
  - Mustang further expects to file an IND in the third quarter of 2020 for a registrational multi-center Phase 2 clinical trial of its lentiviral gene therapy in previously transplanted XSCID patients. This product will be designated MB-207. Mustang anticipates enrolling 20 patients and comparing them to matched historical control patients who have undergone a second HSCT. Mustang is targeting topline data for this trial in the second half of 2022.
  - In the ongoing Phase 1 trial at City of Hope with MB-105, a PSCA-directed CAR T administered systemically to patients with PSCA-positive castration resistant prostate cancer, the first patient to receive the therapy following a standard CAR T conditioning regimen experienced a significant reduction in his prostate-specific antigen (“PSA”) at day 28. This PSA response was associated with radiographic improvement of the patient’s metastatic disease.
-

- In April 2020, Mustang announced that the EMA granted ATMP classification to MB-107 for the treatment of XSCID.
- 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 and Fred Hutchinson Cancer Research Center, 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.

#### **Financial Results:**

- As of March 31, 2020, Mustang's cash, cash equivalents and restricted cash totaled \$56.8 million, compared to \$62.4 million as of December 31, 2019, a decrease of \$5.6 million for the first quarter.
- Research and development expenses were \$9.3 million for the first quarter of 2020. This compares to \$7.0 million for the first quarter of 2019. Non-cash, stock-based compensation expenses included in research and development were \$0.4 million for the first quarter of 2020, compared to \$0.1 million for the first quarter of 2019.
- Research and development expenses from license acquisitions totaled \$0.3 million for the first quarter of 2020, compared to \$0.5 million for the first quarter of 2019.
- General and administrative expenses were \$2.0 million for the first quarter of 2020. This compares to \$2.3 million for the first quarter of 2019. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$0.4 million for the first quarter of 2020, compared to \$0.7 million for the first quarter of 2019.
- Net loss attributable to common stockholders was \$11.9 million, or \$0.28 per share, for the first quarter of 2020, compared to a net loss attributable to common stockholders of \$9.6 million, or \$0.34 per share, for the first quarter of 2019.

#### **About Mustang Bio**

Mustang Bio, Inc. 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 ("SEC"). 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.

---

**Company Contacts:**

Jaelyn Jaffe and William Begien  
Mustang Bio, Inc.  
(781) 652-4500  
[ir@mustangbio.com](mailto:ir@mustangbio.com)

**Investor Relations Contact:**

Daniel Ferry  
LifeSci Advisors, LLC  
(617) 430-7576  
[daniel@lifesciadvisors.com](mailto:daniel@lifesciadvisors.com)

**Media Relations Contact:**

Tony Plohoros  
6 Degrees  
(908) 591-2839  
[tplohoros@6degreespr.com](mailto:tplohoros@6degreespr.com)

---

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

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	(Unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 55,814	\$ 61,413
Other receivables - related party	14	19
Prepaid expenses and other current assets	1,877	1,631
Total current assets	<u>57,705</u>	<u>63,063</u>
Property, plant and equipment, net	7,729	6,779
Fixed assets - construction in process	712	1,157
Restricted cash	1,000	1,000
Other assets	250	250
Operating lease right-of-use asset, net	1,165	1,196
<b>Total Assets</b>	<b><u>\$ 68,561</u></b>	<b><u>\$ 73,445</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Short-term notes payable	\$ 3,125	\$ 1,250
Accounts payable and accrued expenses	6,107	5,668
Payables and accrued expenses - related party	546	596
Operating lease liabilities - short-term	257	257
Total current liabilities	<u>10,035</u>	<u>7,771</u>
Notes payable	10,563	12,179
Operating lease liabilities - long-term	2,159	1,843
<b>Total Liabilities</b>	<b><u>22,757</u></b>	<b><u>21,793</u></b>
<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 March 31, 2020 and December 31, 2019	-	-
Common Stock (\$0.0001 par value), 85,000,000 shares authorized	-	-
Class A common shares, 845,385 shares issued and outstanding as of March 31, 2020 and December 31, 2019	-	-
Common shares, 42,076,840 and 39,403,519 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	4	4
Common stock issuable, 0 and 1,206,667 shares as of March 31, 2020 and December 31, 2019, respectively	-	4,923
Additional paid-in capital	183,116	172,184
Accumulated deficit	(137,316)	(125,459)
<b>Total Stockholders' Equity</b>	<b><u>45,804</u></b>	<b><u>51,652</u></b>
<b>Total Liabilities and Stockholders' Equity</b>	<b><u>\$ 68,561</u></b>	<b><u>\$ 73,445</u></b>

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

	<u>For the three months ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
Operating expenses:		
Research and development	\$ 9,314	\$ 6,960
Research and development – licenses acquired	250	450
General and administrative	1,956	2,344
Total operating expenses	<u>11,520</u>	<u>9,754</u>
Loss from operations	<u>(11,520)</u>	<u>(9,754)</u>
Other income (expense)		
Interest income	263	152
Interest expense	(600)	(11)
Total other (expense) income	<u>(337)</u>	<u>141</u>
<b>Net Loss</b>	<b><u>\$ (11,857)</u></b>	<b><u>\$ (9,613)</u></b>
Net loss per common share outstanding, basic and diluted	<u>\$ (0.28)</u>	<u>\$ (0.34)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>41,971,316</u>	<u>27,945,802</u>