
**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 14, 2021**

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 (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 14, 2021, 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, 2021. 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> 104	<u>Press release issued by Mustang Bio, Inc., dated May 14, 2021.</u> Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

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 14, 2021

Mustang Bio, Inc.
(Registrant)

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



Mustang Bio Reports First Quarter 2021 Financial Results and Recent Corporate Highlights

Worcester, MA– May 14, 2021 – 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, 2021.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “In the first quarter of 2021, we successfully executed our clinical and regulatory strategies and achieved milestones that we believe will drive Mustang’s continued progress. We announced encouraging MB-107 and MB-207 clinical updates from our investigator-IND trials for X-Linked Severe Combined Immunodeficiency (“XSCID”), as well as additional consistent safety and efficacy data pertaining to our lentiviral vector gene therapies that we have seen over the more than eight years since the first patient was treated in 2012. In January, the U.S. Food and Drug Administration (“FDA”) lifted a Chemistry, Manufacturing and Controls (“CMC”) hold on the MB-107 Investigational New Drug (“IND”) application for newly diagnosed infants under the age of two and we expect to dose the first infant in the multicenter trial soon. We also plan to file an IND for our MB-207 clinical trial for patients with XSCID who have been previously treated with hematopoietic stem cell transplantation (“HSCT”) and for whom re-treatment is indicated.”

Dr. Litchman continued, “Notably, we are thrilled with the progress of our MB-106 CD20-targeted CAR T cell therapy program for relapsed or refractory CD20+ B-cell non-Hodgkin lymphomas (“B-NHL”) and chronic lymphocytic leukemia (“CLL”). Earlier this month, we announced that the FDA approved Mustang’s IND to initiate a multicenter Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 for relapsed or refractory CD20+ B-NHL and CLL. Also, we look forward to the Fred Hutchinson Cancer Research Center presentation at the European Hematology Association 2021 (“EHA2021”) Virtual Congress next month, where Dr. Mazyar Shadman will present updated interim data from their ongoing CD20-targeted CAR T clinical trial. We are very pleased to have three active Mustang-sponsored INDs, and we anticipate having four active Mustang-sponsored INDs by the end of the year.”

Financial Results:

- As of March 31, 2021, Mustang’s cash and cash equivalents and restricted cash totaled \$130.4 million, compared to \$98.8 million as of December 31, 2020, an increase of \$31.6 million year-to-date.
- Research and development expenses including license acquisitions were \$11.6 million for the first quarter of 2021, compared to \$9.6 million for the first quarter of 2020. Non-cash, stock-based expenses included in research and development were \$0.7 million for the first quarter of 2021, compared to \$0.4 million for the first quarter of 2020.
- General and administrative expenses were \$3.5 million for the first quarter of 2021, compared to \$2.0 million for the first quarter of 2020. Non-cash, stock-based expenses included in general and administrative expenses were \$1.5 million for the first quarter of 2021, compared to \$0.5 million for the first quarter of 2020.
- Net loss attributable to common stockholders was \$15.0 million, or \$0.19 per share, for the first quarter of 2021, compared to a net loss attributable to common stockholders of \$11.9 million, or \$0.28 per share, for the first quarter of 2020.

Recent Corporate Highlights:

- In February 2021, Mustang announced encouraging MB-107 and MB-207 clinical updates from its investigator-IND XSCID trials, as well as additional consistent safety and efficacy data. On January 28, 2021, the FDA removed a CMC hold on the MB-107 Phase 2 clinical trial IND after reviewing a comprehensive CMC package that was submitted by Mustang in late December 2020. The company expects to enroll the first patient in this pivotal multicenter trial in the second quarter of 2021 and is targeting topline data from the trial in the second half of 2022. The company also expects to file an IND in the second quarter of 2021 for its pivotal multicenter Phase 2 clinical trial of MB-207.
- In May 2021, Mustang announced that the FDA approved its IND application to initiate a multicenter Phase 1/2 clinical trial investigating the safety and efficacy of MB-106, a CD20-targeted CAR T therapy for high-risk B-NHL and CLL.
- Also in May 2021, Mustang announced that CD20-targeted CAR T therapy data were selected for presentation at the EHA2021 Virtual Congress scheduled to take place in June. Dr. Mazyar Shadman of Fred Hutch will present updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL. A copy of the abstract can be viewed online through the EHA2021 website [here](#).

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.

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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Company Contacts:

Jaelyn 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) 591-2839
tplohoros@6degreespr.com

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

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 129,371	\$ 97,804
Other receivables - related party	17	15
Prepaid expenses and other current assets	1,581	1,715
Total current assets	130,969	99,534
Property, plant and equipment, net	7,080	7,529
Fixed assets - construction in process	1,458	499
Restricted cash	1,000	1,000
Other assets	255	250
Operating lease right-of-use asset, net	1,060	1,088
Total Assets	\$ 141,822	\$ 109,900
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,959	\$ 8,747
Payables and accrued expenses - related party	343	490
Operating lease liabilities - short-term	284	278
Total current liabilities	6,586	9,515
Operating lease liabilities - long-term	1,875	1,950
Total Liabilities	8,461	11,465
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 March 31, 2021 and December 31, 2020, respectively	—	—
Common Stock (\$0.0001 par value), 125,000,000 shares authorized		
Class A common shares, 845,385 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	—	—
Common shares, 85,043,153 and 70,920,693 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	8	7
Common stock issuable, 63,688 and 2,103,122 shares as of March 31, 2021 and December 31, 2020, respectively	218	7,939
Additional paid-in capital	333,566	275,963
Accumulated deficit	(200,431)	(185,474)
Total Stockholders' Equity	133,361	98,435
Total Liabilities and Stockholders' Equity	\$ 141,822	\$ 109,900

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

	For the three months ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 11,618	\$ 9,314
Research and development – licenses acquired	—	250
General and administrative	3,469	1,956
Total operating expenses	<u>15,087</u>	<u>11,520</u>
Loss from operations	<u>(15,087)</u>	<u>(11,520)</u>
Other income (expense)		
Interest income	134	263
Interest expense	(4)	(600)
Total other income (expense)	<u>130</u>	<u>(337)</u>
Net Loss	<u>\$ (14,957)</u>	<u>\$ (11,857)</u>
Net loss per common share outstanding, basic and diluted	<u>\$ (0.19)</u>	<u>\$ (0.28)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>80,466,049</u>	<u>41,971,316</u>