

**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 16, 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 August 16, 2021, 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, 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
99.1	Press release issued by Mustang Bio, Inc., dated August 16, 2021.
104	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: August 16, 2021

Mustang Bio, Inc.
(Registrant)

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



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

Worcester, MA – August 16, 2021 – Mustang Bio, Inc. (“Mustang”) (NASDAQ: MBIQ), 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, 2021.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “In the first half of 2021, Mustang continued to progress the development of our CAR T therapies across multiple cancers, as well as our lentiviral gene therapies for the treatment of X-linked severe combined immunodeficiency (“XSCID”), also known as bubble boy disease. We are encouraged by the updated interim MB-106 CD20-targeted, autologous CAR T data presented at the European Hematology Association 2021 Virtual Congress (“EHA2021”) in June. The data presented showed a favorable safety profile and compelling clinical activity, with a 93% overall response rate and 67% complete response rate in patients with high-risk B-cell non-Hodgkin lymphomas (“B-NHL”) and chronic lymphocytic leukemia (“CLL”) who were treated with our modified cell manufacturing process. Additionally, the U.S. Food and Drug Administration (“FDA”) accepted Mustang’s Investigational New Drug (“IND”) application to initiate a multicenter Phase 1/2 clinical trial investigating the safety, tolerability and efficacy of MB-106 for relapsed or refractory B-NHL and CLL. We look forward to enrolling the first patient in the trial later this quarter and to further advancing MB-106 for patients with B-NHL and CLL.”

Dr. Litchman continued, “Last week, we announced an exclusive license agreement for a novel *in situ* CAR T technology that may be able to transform the administration of CAR T therapies, facilitating how the treatments are delivered to patients, with the potential to be used broadly as an off-the-shelf therapy. With this collaboration with the Mayo Clinic, we gain access to an innovative platform technology that we hope will become the discovery engine for a whole new generation of CAR T products at Mustang. We also announced that the first patient was dosed at City of Hope in a clinical trial to establish the safety and feasibility of administering MB-101 (autologous IL13R α 2-targeted CAR T cells) to patients with leptomeningeal brain tumors. On the regulatory front, we are delighted that the European Medicines Agency (“EMA”) recently granted Priority Medicines (“PRIME”) designation to MB-107, our lentiviral gene therapy for the treatment of XSCID in newly diagnosed infants. We anticipate enrolling the first patient in the pivotal Mustang-IND MB-107 trial for newborns with XSCID shortly and also expect to file an IND for a pivotal MB-207 trial in previously transplanted XSCID patients later this quarter. We look forward to continuing to provide updates on our CAR T and gene therapy clinical programs in the second half of the year.”

Recent Corporate Highlights:

- 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 for relapsed or refractory B-NHL and CLL.
- Also in May 2021, Mustang announced that the first patient was dosed at City of Hope in a clinical trial to establish the safety and feasibility of administering MB-101 (autologous IL13R α 2-directed CAR T cells) to patients with leptomeningeal brain tumors (e.g., glioblastoma, ependymoma or medulloblastoma).
- In June 2021, Mustang announced MB-106 CD20-targeted CAR T data were presented at EHA2021. Dr. Mazyar Shadman of Fred Hutchinson Cancer Research Center presented updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL, which showed a favorable safety profile and compelling clinical activity with a 93% overall response rate and 67% complete response rate in patients treated with the modified cell manufacturing process.

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- Also in June 2021, Mustang hosted a key opinion leader webinar featuring a presentation from Dr. Shadman, who discussed interim results from the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 CD20-targeted CAR T for B-NHL and CLL. A replay of the webinar can be found here: <https://lifesci.rampard.com/WebcastingAppv5/Events/Registration/registration.jsp?Y2lk=MTI0MA==>.
 - Additionally in June 2021, Mustang announced that it has been awarded a \$300,000 Massachusetts Life Sciences Center tax incentive based on a hiring commitment of 20 net new full-time equivalent employees for calendar year 2021 and retaining that headcount level through 2025.
 - Earlier this month, Mustang announced that the EMA granted PRIME designation to MB-107, its lentiviral gene therapy for the treatment of XSCID in newly diagnosed infants.
 - Last week, Mustang announced an exclusive license agreement with Mayo Clinic for a novel technology that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy.

Financial Results:

- As of June 30, 2021, Mustang’s cash and cash equivalents and restricted cash totaled \$130.9 million, compared to \$130.4 million at March 31, 2021 and \$98.8 million as of December 31, 2020, an increase of \$0.5 million for the quarter and an increase of \$32.1 million year-to-date.
- Research and development expenses including license acquisitions were \$11.9 million for the second quarter of 2021, compared to \$11.1 million for the second quarter of 2020. Non-cash, stock-based expenses included in research and development were \$0.3 million for the second quarter of 2021, compared to \$0.4 million for the second quarter of 2020.
- General and administrative expenses were \$2.5 million for the second quarter of 2021, compared to \$3.0 million for the second quarter of 2020. Non-cash, stock-based expenses included in general and administrative expenses were \$0.6 million for the second quarter of 2021, compared to \$1.5 million for the second quarter of 2020.
- Net loss attributable to common stockholders was \$14.4 million, or \$0.16 per share, for the second quarter of 2021, compared to a net loss attributable to common stockholders of \$14.6 million, or \$0.32 per share, for the second quarter of 2020.

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.

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

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
	<u>(Unaudited)</u>	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 129,923	\$ 97,804
Other receivables - related party	32	15
Prepaid expenses and other current assets	1,386	1,715
Total current assets	<u>131,341</u>	<u>99,534</u>
Property, plant and equipment, net	7,155	7,529
Fixed assets - construction in process	2,355	499
Restricted cash	1,000	1,000
Other assets	255	250
Operating lease right-of-use asset, net	1,101	1,088
Total Assets	<u>\$ 143,207</u>	<u>\$ 109,900</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,766	\$ 8,747
Payables and accrued expenses - related party	249	490
Operating lease liabilities - short-term	346	278
Total current liabilities	<u>6,361</u>	<u>9,515</u>
Operating lease liabilities - long-term	1,821	1,950
Total Liabilities	<u>8,182</u>	<u>11,465</u>
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, 2021 and December 31, 2020, respectively	—	—
Common Stock (\$0.0001 par value), 150,000,000 and 125,000,000 shares authorized as of June 30, 2021 and December 31, 2020, respectively		
Class A common shares, 845,385 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	—	—
Common shares, 89,936,162 and 70,920,693 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	9	7
Common stock issuable, 52,019 and 2,103,122 shares as of June 30, 2021 and December 31, 2020, respectively	185	7,939

Additional paid-in capital	349,621	275,963
Accumulated deficit	(214,790)	(185,474)
Total Stockholders' Equity	135,025	98,435
Total Liabilities and Stockholders' Equity	\$ 143,207	\$ 109,900

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

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 10,902	\$ 9,830	\$ 22,520	\$ 19,144
Research and development – licenses acquired	1,000	1,300	1,000	1,550
General and administrative	2,538	2,991	6,007	4,947
Total operating expenses	<u>14,440</u>	<u>14,121</u>	<u>29,527</u>	<u>25,641</u>
Loss from operations	<u>(14,440)</u>	<u>(14,121)</u>	<u>(29,527)</u>	<u>(25,641)</u>
Other income (expense)				
Interest income	85	142	219	405
Interest expense	(4)	(619)	(8)	(1,219)
Total other income (expense)	<u>81</u>	<u>(477)</u>	<u>211</u>	<u>(814)</u>
Net Loss	\$ (14,359)	\$ (14,598)	\$ (29,316)	\$ (26,455)
Net loss per common share outstanding, basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.32)</u>	<u>\$ (0.35)</u>	<u>\$ (0.61)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>87,561,764</u>	<u>45,023,030</u>	<u>84,033,508</u>	<u>43,497,173</u>