
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 11, 2022**

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-2b 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 11, 2022, 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, 2022. A copy of such press release is being furnished as Exhibit 99.1 to this report.

The information, including Exhibit 99.1, in this Form 8-K is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
99.1	Press release issued by Mustang Bio, Inc., dated August 11, 2022.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, 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 11, 2022

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



Mustang Bio Reports Second Quarter 2022 Financial Results and Recent Corporate Highlights

Worcester, MA– August 11, 2022– 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, 2022.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “We are very pleased with the significant clinical and regulatory milestones achieved in the first half of 2022 for our portfolio of cell and gene therapies. Interim Phase 1/2 data on MB-106, our CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas (“B-NHLs”) and chronic lymphocytic leukemia (“CLL”), were presented at several prestigious medical meetings. MB-106 continues to demonstrate high efficacy and a favorable safety profile across all patients with a wide range of hematologic malignancies including follicular lymphoma (“FL”), CLL, diffuse large B-cell lymphoma (“DLBCL”) and Waldenstrom macroglobulinemia (“WM”), with no cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome greater than grade 2. Additionally, the U.S. Food and Drug Administration (“FDA”) granted Orphan Drug Designation to MB-106 for WM, a rare type of B-NHL. We are excited by the continued progress of MB-106 and anticipate dosing the first patient shortly in a multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL under Mustang’s Investigational New Drug application (“IND”). Furthermore, we expect to enroll 3 to 6 patients in this trial by the end of 2022 and to disclose data from both the single-center Fred Hutch trial and the multicenter Mustang trial in the fourth quarter of this year. We also continued to advance our recurrent glioblastoma (“rGBM”) clinical program. Data presented at the American Association for Cancer Research (“AACR”) Annual Meeting 2022 support the safety of administering our two clinical candidates, MB-108 (Nationwide Children’s herpes simplex virus type 1 oncolytic virus) and MB-101 (City of Hope’s IL13R α 2-targeted CAR T cell therapy), sequentially to optimize treatment in a regimen designated as MB-109, for which we plan to file an IND in 2023.”

“Mustang is pleased to be a leader in the development of gene therapy treatments for severe combined immunodeficiency (“SCID”) patients. Interim Phase 1/2 data on treatment with the same lentiviral vector used in MB-107, our *ex vivo* lentiviral gene therapy for X-linked SCID (“XSCID”) in newly diagnosed infants under the age of two, presented at the American Society of Gene & Cell Therapy (“ASGCT”) 25th Annual Meeting showed all 23 treated patients were alive at 2.6-year median follow-up without evidence of malignant transformation, and the treatment established a stable, functioning immune system in patients. We also announced that the first patient successfully received LV-RAG1 *ex vivo* lentiviral gene therapy to treat recombina-activating gene-1 (“RAG1”) SCID (“RAG1-SCID”), in an ongoing Phase 1/2 multicenter clinical trial taking place in Europe. Mustang has exclusively licensed LV-RAG1 for the development of MB-110, a first-in-class *ex vivo* lentiviral gene therapy for RAG1-SCID. XSCID and RAG1-SCID make up almost 60% of all SCID

cases combined. We look forward to the continued advancement of our SCID clinical program, including our anticipated initiation in 2023 under Mustang's IND of multicenter pivotal Phase 2 trials for both MB-107 in newborn XSCID patients and MB-207 in previously transplanted XSCID patients."

Recent Corporate Highlights:

- In April 2022, Mustang announced that interim Phase 1/2 clinical trial data on MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell NHL and CLL, were presented at the 2022 Tandem Meetings | Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy and Center for International Blood & Marrow Transplant Research. Data demonstrated high efficacy and a favorable safety profile in all patients (n=25). Five dose levels were used during the study, and CRs were observed at all dose levels. Durable responses were observed in a wide range of hematologic malignancies including FL, CLL, DLBCL, and WM. An overall response rate ("ORR") of 96% and a complete response rate ("CR") of 72% were observed in all patients across all dose levels. Within the next 60 days, Mustang expects to dose the first patient in a multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL, and further expects to enroll 3 to 6 patients in this trial by the end of 2022.
 - Also in April 2022, MB-106 data focused on CLL were presented at the 4th International Workshop on CAR-T and Immunotherapies.
 - Additionally, in April 2022, Mustang announced interim data from two ongoing investigator-sponsored Phase 1 clinical trials evaluating two clinical candidates, MB-101 (IL13R α 2-targeted CAR T cell therapy licensed from City of Hope) and MB-108 (herpes simplex virus type 1 oncolytic virus licensed from Nationwide Children's Hospital) for the treatment of recurrent glioblastoma ("rGBM"). The data were from a late-breaking poster presented at the AACR Annual Meeting 2022. Preclinical data also presented support the safety of administering these two therapies sequentially to optimize treatment in a regimen designated as MB-109. Mustang expects to file an IND in 2023 to initiate an MB-109 Phase 1 clinical trial.
 - In May 2022, interim Phase 1/2 data on treatment with the same lentiviral vector used in MB-107, Mustang's lentiviral gene therapy for XSCID, also known as bubble boy disease, in newly diagnosed infants under the age of two, were presented in an oral presentation during the Clinical Trials Spotlight Symposium at the ASGCT 25th Annual Meeting. The presentation included updated data from a multicenter Phase 1/2 clinical trial for XSCID in newly diagnosed infants under the age of two at St. Jude Children's Research Hospital, UCSF Benioff Children's Hospital in San Francisco and Seattle Children's Hospital. All 23 treated patients were alive at 2.6-year median follow-up without evidence of malignant transformation.
 - In June 2022, MB-106 CD20-targeted autologous CAR T cell therapy data were presented in an oral session at the European Hematology Association 2022 Hybrid Congress. Mazyar Shadman, M.D., M.P.H., Associate Professor and physician at Fred Hutchinson Cancer Center and University of Washington presented updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL. Data presented included a 94% ORR and 78% CR in 18 patients with FL. Overall, for the 26 patients treated on the trial, there was a 96% ORR and 73% CR, including complete responses in both DLBCL patients, both WM patients, and both patients previously treated with CD19-targeted CAR-T therapy (1 DLBCL patient and 1 FL patient).
 - Also in June 2022, the FDA granted Orphan Drug Designation to MB-106 CD20-targeted autologous CAR T cell therapy for the treatment of WM, a rare type of B-NHL.
 - In July 2022, Mustang announced that the first patient successfully received LV-RAG1 *ex vivo* lentiviral gene therapy to treat RAG1-SCID, in an ongoing Phase 1/2 multicenter clinical trial taking place in Europe. LV-RAG1 is exclusively licensed by Mustang for the development of MB-110, a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID.
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- In 2023, Mustang expects to enroll the first patient in a pivotal multicenter Phase 2 clinical trial under Mustang's IND to evaluate MB-107, a lentiviral gene therapy for the treatment of infants under the age of two with XSCID.
- Mustang filed an IND application in December 2021 for its pivotal multicenter Phase 2 clinical trial of MB-207, a lentiviral gene therapy for the treatment of patients with XSCID who have been previously treated with hematopoietic stem cell transplantation ("HSCT") and for whom re-treatment is indicated. The trial is currently on hold pending CMC clearance from the FDA and, based on feedback from the Agency, Mustang expects to enroll the first patient in a pivotal multicenter Phase 2 clinical trial in 2023.

Financial Results:

- As of June 30, 2022, Mustang's cash and cash equivalents and restricted cash totaled \$108.4 million, compared to \$123.2 million at March 31, 2022 and \$110.6 million as of December 31, 2021, a decrease of \$14.8 million for the quarter and a decrease of \$2.2 million year-to-date.
- Research and development expenses were \$15.2 million for the second quarter of 2022, compared to \$11.9 million for the second quarter of 2021. Non-cash, stock-based expenses included in research and development were \$0.4 million for the second quarter of 2022, compared to \$0.3 million for the second quarter of 2021.
- General and administrative expenses were \$3.1 million for the second quarter of 2022, compared to \$2.5 million for the second quarter of 2021. Non-cash, stock-based expenses included in general and administrative expenses were \$0.2 million for the second quarter of 2022, compared to \$0.2 million for the second quarter of 2021.
- Net loss attributable to common stockholders was \$19.1 million, or \$0.19 per share, for the second quarter of 2022, compared to a net loss attributable to common stockholders of \$14.4 million, or \$0.16 per share, for the second quarter of 2021.

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 lentiviral gene therapies for severe combined immunodeficiency. Mustang's common stock is registered under the Securities Exchange Act of 1934, as amended, and Mustang 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 contains "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, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions, include, but are not limited to, any statements relating to our growth strategy and product development programs, including the timing of and our ability to make regulatory filings such as INDs and other applications and to obtain regulatory approvals for our product candidates, statements concerning the potential of therapies and product candidates, 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 Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K filed on March 23, 2022, subsequent Reports on Form 10-Q, and our other filings we make with the SEC. 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.
Balance Sheets (Unaudited)
(in thousands, except share and per share amounts)

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 107,369	\$ 109,618
Other receivables - related party	33	50
Prepaid expenses and other current assets	1,974	2,038
Total current assets	<u>109,376</u>	<u>111,706</u>
Property, plant and equipment, net	8,663	9,025
Fixed assets - construction in process	1,537	2,027
Restricted cash	1,000	1,000
Other assets	359	362
Operating lease right-of-use asset, net	970	1,050
Total Assets	<u>\$ 121,905</u>	<u>\$ 125,170</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 10,165	\$ 9,744
Payables and accrued expenses - related party	448	723
Operating lease liabilities - short-term	368	348
Total current liabilities	<u>10,981</u>	<u>10,815</u>
Deferred income	270	270
Note payable, long-term, net	27,150	—
Operating lease liabilities - long-term	1,496	1,685
Total Liabilities	<u>39,897</u>	<u>12,770</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, 2022 and December 31, 2021, respectively	—	—
Common stock (\$0.0001 par value), 200,000,000 and 150,000,000 shares authorized as of June 30, 2022 and December 31, 2021, respectively		
Class A common shares, 845,385 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	—	—
Common shares, 104,511,195 and 93,582,991 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	10	9
Common stock issuable, 41,652 and 2,536,607 shares as of June 30, 2022 and December 31, 2021, respectively	28	4,329
Additional paid-in capital	372,708	359,906
Accumulated deficit	(290,738)	(251,844)
Total Stockholders' Equity	<u>82,008</u>	<u>112,400</u>
Total Liabilities and Stockholders' Equity	<u>\$ 121,905</u>	<u>\$ 125,170</u>

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

	<u>For the three months ended June 30,</u>		<u>For the six months ended June 30,</u>	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 15,164	\$ 10,902	\$ 31,453	\$ 22,520
Research and development – licenses acquired	—	1,000	—	1,000
General and administrative	3,077	2,538	6,426	6,007
Total operating expenses	18,241	14,440	37,879	29,527
Loss from operations	(18,241)	(14,440)	(37,879)	(29,527)
Other income (expense)				
Interest income	77	85	150	219
Interest expense	(935)	(4)	(1,165)	(8)
Total other income (expense)	(858)	81	(1,015)	211
Net Loss	\$ (19,099)	\$ (14,359)	\$ (38,894)	\$ (29,316)
Net loss per common share outstanding, basic and diluted	\$ (0.19)	\$ (0.16)	\$ (0.39)	\$ (0.35)
Weighted average number of common shares outstanding, basic and diluted	102,947,158	87,561,764	100,444,938	84,033,508