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): **November 2, 2023**

Mustang Bio, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38191**	**47-3828760**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 Capital 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 8.01. Other Events.

On November 2, 2023, Mustang Bio, Inc. (the "Company" or "Mustang") issued a press release to announce that interim Phase 1/2 data from Mustang's multicenter clinical trial of MB-106, a CD20-targeted, autologous CAR-T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas and chronic lymphocytic leukemia have been selected for presentation at the 65th American Society of Hematology Annual Meeting, taking place December 9-12, 2023 in San Diego. A copy of the press release is filed herewith as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed herewith:

Exhibit Number	Description
99.1	Press release issued by Mustang Bio, Inc., dated November 2, 2023.
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.

Mustang Bio, Inc.
(Registrant)

Date: November 2, 2023

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

Exhibit 99.1

Mustang Bio Announces MB-106 CD20-Targeted CAR-T Data Selected for Presentation at 65th American Society of Hematology (ASH) Annual Meeting

Updated interim data from Mustang's multicenter Phase 1/2 clinical trial demonstrate favorable safety and efficacy profile of MB-106 in heavily pre-treated lymphoma patients

Worcester, MA – November 2, 2023 – 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 difficult-to-treat cancers and rare genetic diseases, today announced that interim Phase 1/2 data from Mustang's multicenter clinical trial of MB-106, a CD20-targeted, autologous CAR-T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas ("NHL") and chronic lymphocytic leukemia ("CLL"), have been selected for a poster presentation at the 65th American Society of Hematology ("ASH") Annual Meeting, taking place December 9-12, 2023 in San Diego. MB-106 is being developed in a collaboration between Mustang and Fred Hutchinson Cancer Center ("Fred Hutch").

The abstract posted today on the ASH Annual Meeting website reported on four patients who received MB-106 at dose level 1 ("DL1"), 3.3×10^6 cells/kg: two patients with follicular lymphoma ("FL") who achieved complete response as demonstrated by both PET-CT and bone marrow biopsy, one patient with Waldenstrom macroglobulinemia ("WM") who achieved a very good partial response ("VGPR"), and one patient with transfusion-dependent hairy cell leukemia variant ("HCL-v") who continued to have stable disease with decreased bone marrow disease and who achieved complete transfusion independence which is ongoing at 6 months. All patients displayed MB-106 expansion, with peak levels between 7-14 days post-infusion, and CAR-T cell persistence is ongoing at 6 months. From a safety perspective, 3 patients experienced Grade 1 cytokine release syndrome and no occurrences of immune effector cell-associated neurotoxicity syndrome were reported. Dose-limiting toxicities ("DLT") were monitored through day 28, and no DLTs were observed at DL1. Because of this favorable safety profile, MB-106 is infused in the outpatient setting if allowed by the institution, except for the first patient in each DL cohort, who is kept for overnight observation after MB-106 administration.

All four patients were heavily pre-treated, with a median of 5.5 prior lines of treatment. The WM patient in particular had nine prior treatments, including autologous stem cell transplant, and a high disease burden, and the patient's VGPR was notable for complete metabolic response by PET-CT, morphologic clearance of lymphoma in bone marrow and resolution of the immunoglobulin M paraprotein. Other high-risk features were observed in each of the two FL patients: progression of disease within 24 months of first-line treatment in one patient and prior CD19-targeted CAR-T therapy in the other. Finally, the HCL-v patient received non-conforming material following FDA authorization.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We're encouraged by the promising initial safety and efficacy data from our ongoing Phase 1/2 multicenter MB-106 clinical trial, which align with the data from the ongoing Phase 1/2 single-institution clinical trial at Fred Hutch. MB-106 continues

to demonstrate a favorable safety and efficacy profile, including complete responses from both trials in patients previously treated with CD19-targeted CAR-T cell therapy. In particular, we are excited about the very good partial response in WM, our lead indication for MB-106 and a disease where complete responses are extremely rare. We look forward to the upcoming presentation at the ASH Annual Meeting, during which we anticipate sharing additional data from the Phase 1 indolent NHL arm, including all patients treated at the second and final dose level, 1×10^7 cells/kg, who have had at least 28-day follow-up. Looking beyond this meeting, we expect to treat the first patient in the pivotal Phase 2 WM trial in mid-2024, which could enable disclosure of top-line data from this trial as early as mid-2026."

Details of the presentation are as follows:

Title: Efficacy and Safety of a Third Generation CD20 CAR-T (MB-106) for Treatment of Relapsed/Refractory Indolent B-Cell Non-Hodgkin Lymphoma: Phase-1 Results from a Multicenter Trial
Session Name: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I
Date and Time: Saturday, December 9, 2023, 5:30 pm - 7:30 pm PT
Location: San Diego Convention Center, Halls G-H
Abstract Number: 2102
Presenter: Mazyar Shadman, M.D., M.P.H., Study Chair, Innovators Network Endowed Chair at Fred Hutch, Associate Professor and physician at Fred Hutch and University of Washington

For more information, please visit the 65th ASH Annual Meeting and Exposition website at https://www.hematology.org/meetings/annual-meeting/abstracts.

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 difficult-to-treat cancers 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. The Company's forward-looking statements, 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, statements about the Company's expectations with respect to the consummation of the sale of its manufacturing facility, its entry into a manufacturing services agreement with the prospective purchaser of the facility and its ability to obtain its MB-106 drug product pursuant to such manufacturing services agreement and any other statements that are not historical facts. Actual events or results may differ materially from those described in this press release due to a number of risks and uncertainties. Risks and uncertainties include, among other things, risks related to the satisfaction of the conditions to closing the sale of the Company's manufacturing facility in the

anticipated timeframe or at all; whether the prospective purchaser of the Company's manufacturing facility is able to successfully perform its obligation to produce the Company's products under the manufacturing services agreement on a timely basis and to acceptable standards; disruption from the sale of the Company's manufacturing facility making it more difficult to maintain business and operational relationships; negative effects of the announcement or the consummation of the transaction on the market price of the Company's common stock; significant transaction costs; the development stage of the Company's primary product candidates, 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 30, 2023, 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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