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): **October 26, 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 October 26, 2023, Mustang Bio, Inc. (the "Company") issued a press release to announce the U.S. Food and Drug Administration's acceptance of the Company's Investigational New Drug Application of MB-109 for the treatment of recurrent glioblastoma and high-grade astrocytoma, within 30 days of initial submission. 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 October 26, 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: October 26, 2023

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

Exhibit 99.1

Mustang Bio Announces FDA Acceptance of IND Application for MB-109, a Novel Combination of MB-101 (IL13Rα2-targeted CAR-T cell therapy) and MB-108 (HSV-1 oncolytic virus), for the Treatment of Recurrent Glioblastoma and High-Grade Astrocytoma

MB-101 (IL13Rα2-targeted CAR-T cell therapy) and MB-108 (HSV-1 oncolytic virus) are separately well tolerated in patients with recurrent GBM in ongoing Phase 1 clinical trials; preclinical data support potential of MB-109 to optimize clinical results

The Phase 1 study will assess the safety, tolerability and efficacy of MB-109 in patients with recurrent glioblastoma and high-grade astrocytoma and is expected to begin enrolling patients in 2024

Worcester, MA– October 26, 2023 – Mustang Bio, Inc. ("Mustang" or the "Company") (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 the U.S. Food and Drug Administration ("FDA") has accepted the Company's Investigational New Drug ("IND") application of MB-109 for the treatment of recurrent glioblastoma ("GBM") and high-grade astrocytoma. Mustang is planning to initiate a Phase 1 multicenter clinical trial at City of Hope ("COH") and the University of Alabama at Birmingham ("UAB") to assess the safety, tolerability and efficacy of MB-109, a novel combination of MB-101 (COH-developed IL13Rα2-targeted CAR-T cell therapy) and MB-108 [Nationwide Children's Hospital- ("Nationwide") developed HSV-1 oncolytic virus] in adult patients with recurrent GBM and high-grade astrocytomas that express IL13Rα2 on the surface of the tumor cells.

As previously reported, preclinical data presented at the American Association for Cancer Research ("AACR") Annual Meeting in 2022 supported this combination therapy to potentially optimize results to treat recurrent GBM. The combination leverages MB-108 to reshape the tumor microenvironment ("TME") and make cold tumors "hot," thereby potentially improving the efficacy of MB-101 CAR-T cell therapy. Data presented separately on MB-101 and MB-108 showed that administration of these therapies was well tolerated in recurrent GBM patients. Two patients treated solely with MB-101 who had high levels of intratumoral CD3+ T cells pre-therapy (i.e., "hot" tumors) achieved complete responses lasting 7.5 and 31+ months, respectively. Importantly, of the 53 COH Phase 1 patients disclosed at AACR in 2022, these 2 complete responses were observed in the 2 patients with the "hottest" tumors prior to treatment with MB-101. Phase 1 clinical trials of MB-101 at COH and of MB-108 at UAB continue to enroll patients.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We are very pleased with the FDA's acceptance of our IND application for MB-109, which allows Mustang to initiate a Phase 1 clinical trial to further evaluate combining MB-108 and MB-101, an attractive strategy for improving outcomes for patients with recurrent GBM and high-grade astrocytomas. Recurrent GBM remains a major challenge to treat, with a median overall survival rate of 6 months. We are committed to finding better treatment options for patients living with difficult-to-treat cancers and look forward to initiating our MB-109 Phase 1 clinical trial in 2024. The fact that this will be the first ever industry-sponsored trial to combine a CAR-T cell therapy with an oncolytic virus underscores Mustang's commitment to innovation in the oncology and cell therapy space. Furthermore, FDA acceptance of our IND within 30 days of initial submission – despite the innovative aspect of the combination therapy and the complexity of the trial design – is testimony to the talent and resourcefulness of our team."

About MB-109 (MB-101 (IL-13Rα2 targeted CAR-T cells) + MB-108 oncolytic virus)
MB-109 is Mustang's designation for the treatment regimen combining MB-101 (COH-developed IL13Rα2-targeted CAR-T cell therapy) with MB-108 (Nationwide-developed HSV-1 oncolytic virus). The combination is designed to leverage MB-108 to make cold tumors "hot" and potentially improve the efficacy of MB-101 CAR-T cell therapy. MB-108 oncolytic virus is first injected to infect tumor cells which, in turn, leads to reshaping of the TME through recruitment of endogenous CD8- and CD3-positive effector T-cells. This inflamed TME potentially permits MB-101 CAR-T cells injected into and around the tumor to better infiltrate into and throughout the tumor mass, undergo activation and, ideally, effect tumor cell killing.

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 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 whether the Company's third-party manufacturer 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 of the consummation of the sale of the Company's manufacturing facility 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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