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): **July 7, 2025**

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.)

95 Sawyer Road, Suite 110
Waltham, Massachusetts 02453
(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).

Emerging growth company ☐

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 July 7, 2025, Mustang Bio, Inc. (the "Company" or "Mustang") issued a press release to announce that the U.S. Food and Drug Administration has granted Orphan Drug Designation to the Company for MB-101 (IL13Ra2-targeted CAR T-cells) for the treatment of recurrent diffuse and anaplastic astrocytoma (astrocytomas) and glioblastoma (GBM). 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.

Exhibit No.	Description
99.1	Press Release, dated July 7, 2025
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: July 8, 2025

By: /s/ Manuel Litchman, M.D.
Name: Manuel Litchman, M.D.
Title: President, Chief Executive Officer and Interim Chief Financial Officer

Exhibit 99.1

Mustang Bio Granted Orphan Drug Designation by U.S. FDA for MB-101 (IL13Ra2-targeted CAR T-cells) to Treat Astrocytomas and Glioblastoma

In an ongoing Phase 1 trial published in Nature Medicine, MB-101 was well-tolerated and 50% of patients achieved stable disease or better with two partial responses and two complete responses lasting 7.5 and 66+ months, respectively

Preclinical data support a novel combination of MB-101 (IL13Rα2-targeted CAR-T cell therapy) and MB-108 (HSV-1 oncolytic virus) to optimize clinical results

FDA previously granted Orphan Drug Designation to Mustang for MB-108 for the treatment of malignant glioma

Worcester, MA – July 7, 2025 – Mustang Bio, Inc. ("Mustang" or the "Company") (Nasdaq: MBIO), a clinical-stage biopharmaceutical company focused on translating today's medical breakthroughs in cell therapies into potential cures for difficult-to-treat cancers, today announced that the U.S. Food and Drug Administration ("FDA") has granted Orphan Drug Designation to Mustang for MB-101 (IL13Ra2-targeted CAR T-cells) for the treatment of recurrent diffuse and anaplastic astrocytoma (astrocytomas) and glioblastoma (GBM).

The FDA grants Orphan Drug Designation to drugs and biologics that are intended for safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials upon approval and prescription drug user fee waivers. If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in which it has Orphan Drug designation, which is independent from intellectual property protection.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We are thrilled that MB-101 received Orphan Drug Designation on time and with a designation that is broader than the indication proposed. The Orphan Drug Designation for MB-101, coupled with the Orphan Drug Designation granted previously for MB-108, is strong validation for our science, as we hope to advance MB-101, in combination with MB-108, as a potential treatment option for patients living with malignant glioma, including patients with recurrent glioblastoma ("GBM") and high-grade astrocytomas. Our novel therapeutic strategy, combining our MB-101 CAR-T cell therapy with our MB-108 oncolytic virus, leverages MB-108 to reshape the tumor microenvironment ("TME") to make cold tumors "hot," thereby potentially improving the efficacy of MB-101 CAR-T cell therapy. This progress demonstrates our dedication to exploring new possibilities for improving outcomes in patients with challenging-to-treat cancers."

As previously reported, preclinical data presented at the American Association for Cancer Research ("AACR") Annual Meeting in 2022 supported a combination therapy to potentially optimize results to treat recurrent GBM. The combination leverages MB-108 to reshape the 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. As reported in City of Hope's 2024 *Nature Medicine* paper, 2 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 66+ months, respectively. Importantly, of the 57 City of Hope Phase 1 patients evaluable for survival in that paper, these 2 complete responses were observed in the cohort of 3 patients with the "hottest" tumors prior to treatment with MB-101. Phase 1 clinical trials of MB-101 at City of Hope and of MB-108 at The University of Alabama at Birmingham continue to enroll patients.

The Company's ability to further develop the MB-109 program for recurrent GBM and high-grade astrocytomas is contingent upon raising additional funding and / or consummating a strategic partnership.

About MB-109 (MB-101 (IL13Rα2 targeted CAR-T cells) + MB-108 oncolytic virus)

MB-109 is Mustang's designation for the treatment regimen combining MB-101 (IL13Rα2-targeted CAR-T cell therapy licensed from City of Hope) with MB-108 (HSV-1 oncolytic virus licensed from Nationwide Children's Hospital). 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 therapies into potential cures for difficult-to-treat cancers. 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. 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, our need for substantial additional funds in the immediate future, risks that any actual or potential clinical trials described herein may not initiate or complete in sufficient timeframes to advance the Company's corporate objectives, or at all, or that promising early results obtained therefrom may not be replicable; whether the 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; 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 28, 2025, 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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