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 14, 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 2.02. Results of Operations and Financial Condition.

On November 14, 2023, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 2023. 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 exhibit is furnished herewith:

Exhibit Number	Description
99.1	Press release issued by Mustang Bio, Inc., dated November 14, 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 14, 2023

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

Exhibit 99.1

Mustang Bio Reports Third Quarter 2023 Financial Results and Recent Corporate Highlights

Worcester, MA – November 14, 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 financial results and recent corporate highlights for the third quarter that ended September 30, 2023.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "In the third quarter of 2023, Mustang continued to make meaningful progress in the development of our lead clinical candidate MB-106, a CD20-targeted, autologous CAR-T cell therapy to treat relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHL") and chronic lymphocytic leukemia ("CLL"). We announced the first data from our ongoing multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating MB-106's safety and efficacy. The data were consistent with efficacy and safety results from the ongoing investigator-sponsored trial at Fred Hutchinson Cancer Center ("Fred Hutch") which have shown complete remission for as long as three years. In the multicenter trial, substantial clinical benefit was observed in all four indolent lymphoma patients treated at dose level 1 (3.3×10^6 cells/kg), including two complete responses in follicular lymphoma ("FL") patients, one of whom was previously treated with CD19 CAR-T cell therapy. A third patient, with a diagnosis of Waldenstrom macroglobulinemia ("WM"), who had nine prior treatments and high disease burden, achieved a very good partial response, which is generally the best response that can be achieved in this disease. No cytokine release syndrome greater than Grade 1 was observed in any of the four patients, and no occurrences of immune effector cell-associated neurotoxicity syndrome were reported. Additional safety and efficacy data from the multicenter trial will be reported at the 65th American Society of Hematology ("ASH") Annual Meeting in December, including follow-up for the four dose-level-1 patients and data from all patients treated at dose level 2 (1.0×10^7 cells/kg) who have had at least 28 days of follow-up. At the End-of-Phase 1 meeting with the FDA expected in the first quarter of 2024, Mustang anticipates recommending dose level 2 as the Phase 2 dose for indolent lymphoma. Mustang further anticipates that results from the Phase 1 indolent lymphoma arm of the multicenter trial will support an accelerated Phase 2 registration strategy for WM, with the first pivotal Phase 2 WM patient to be treated potentially in mid-2024. Additionally, we plan to initiate a pivotal Phase 2 clinical trial in at least one additional B-cell malignancy in 2025."

Dr. Litchman continued, "Mustang also announced that the U.S. Food and Drug Administration ("FDA") accepted the Company's Investigational New Drug ("IND") application to initiate a Phase 1 open label, multicenter clinical trial to assess the safety, tolerability and efficacy of 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 ("GBM") and high-grade astrocytoma. The FDA's safe-to-proceed within 30 days of IND filing is testimony to the talent and resourcefulness of our team, in light of the complexity of the clinical trial, which involves the interplay of 2 complex biologic agents, each with its own unique safety profile."

Financial Results:

- As of September 30, 2023, Mustang's cash and cash equivalents and restricted cash totaled $10.3 million, compared to $16.1 million at June 30, 2023, and $76.7 million as of December 31, 2022, a decrease of $5.8 million for the quarter and a decrease of $66.4 million year-to-date. Subsequent to the end of the third quarter, Mustang raised approximately $4.4 million of gross proceeds in a registered direct offering completed in October 2023.

- Research and development expenses were $9.5 million for the third quarter of 2023, compared to $15.5 million for the third quarter of 2022. Non-cash, stock-based expenses included in research and development were $(19) thousand for the third quarter of 2023, compared to $0.3 million for the third quarter of 2022.
- Gain on the sale of property and equipment was $1.4 million, in connection with the sale of assets to uBriGene.
- General and administrative expenses were $2.1 million for the third quarter of 2023, compared to $3.4 million for the third quarter of 2022. Non-cash, stock-based expenses included in general and administrative expenses were $0.1 million for the third quarter of 2023, compared to $0.2 million for the third quarter of 2022.
- Net loss attributable to common stockholders was $10.1 million, or $1.23 per share, for the third quarter of 2023, compared to a net loss attributable to common stockholders of $19.0 million, or $2.42 per share, for the third quarter of 2022.

Recent Corporate Highlights:

General Corporate:

- In July 2023, Mustang announced that the Company amended its previously announced asset purchase agreement with uBriGene, the U.S. subsidiary of uBriGene Group, a leading cell and gene therapy contract development and manufacturing organization, and closed the transaction. Per the terms of the amended asset purchase agreement, at closing, uBriGene acquired all of Mustang's assets primarily relating to the manufacturing and production of cell and gene therapies at Mustang's state-of-the-art clinical- and commercial-scale cell and gene therapy manufacturing facility in Worcester, Massachusetts, for upfront consideration of $6 million in cash. Mustang's lease to the premises on which the facility is located (as well as related contracts and manufacturing personnel) did not transfer at closing because such transfer requires the consent of the landlord, which has requested an additional thirty business days to consider the proposed transfer following the landlord's receipt of the final determination letter of the U.S. Committee on Foreign Investment in the United States ("CFIUS") regarding the transaction (as discussed further below) and a summary of Mustang's and uBriGene's reaction to such final determination. An additional $5 million contingent payment will be payable to Mustang upon (i) Mustang's raising $10 million in gross proceeds from equity raises following the closing of the transaction and (ii) completion of the assignment of Mustang's lease to uBriGene, which remains subject to landlord's approval, within two years of the closing. Until the lease is transferred to uBriGene, Mustang will retain its facility lease and facility personnel, and will continue to occupy the leasehold premises and manufacture its lead product candidate, MB-106, at that site.

  As previously disclosed, in connection with the sale of its manufacturing facility to uBriGene, Mustang and uBriGene previously submitted a voluntary notice with CFIUS to obtain clearance for the transaction, although obtaining such clearance was not a condition to closing the transaction. On November 13, 2023, CFIUS requested Mustang and uBriGene withdraw and re-file their joint voluntary notice to allow more time for review and discussion regarding the nature and extent of national security risk posed by the Transaction, and whether and to what extent mitigation of risk would be feasible. Upon CFIUS's request, Mustang and uBriGene submitted a request to withdraw and re-file their joint voluntary notice. On November 13, 2023, CFIUS granted this request, accepted the joint voluntary notice and commenced a new 45-day review period commencing on November 14, 2023, which may be followed by a 45-day investigation period. Mustang and uBriGene have been and will continue to be actively engaged with CFIUS, and they remain fully committed to obtaining clearance from CFIUS and completing the full transfer of the manufacturing facility to uBriGene. There can be no assurance, however, that CFIUS will ultimately provide clearance with respect to the transaction, or what mitigating measures may be required in order to obtain such clearance.

- In October 2023, Mustang completed a registered direct offering priced at-the-market for approximately $4.4 million in gross proceeds.

MB-106:

- Mustang's lead clinical candidate is MB-106, a CD20-targeted, autologous CAR-T cell therapy to treat a wide range of hematologic malignancies, including WM and FL. MB-106 continues to demonstrate a favorable safety and efficacy profile in both the Fred Hutch single institution and Mustang Bio multicenter Phase 1/2 clinical trials.

- In August 2023, Mustang Bio announced the first data from its ongoing multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 CAR-T cell therapy. Initial data show substantial clinical benefit in four of four indolent lymphoma patients, including two complete responses in FL patients, one who was previously treated with CD19 CAR-T cell therapy. From a safety perspective, 3 patients experienced Grade 1 cytokine release syndrome and no occurrences of immune effector cell-associated neurotoxicity syndrome were reported. These data align with ongoing results from the investigator-sponsored trial at Fred Hutch that show ongoing complete remission for more than three years.

- The FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, and results from this arm of the multicenter trial are expected to support an accelerated Phase 2 registration strategy for WM, with the first pivotal Phase 2 patient with WM to be treated potentially in mid-2024. Mustang Bio will report additional safety and efficacy data from the multicenter trial at the 65th ASH Annual Meeting, taking place December 9-12, 2023, in San Diego. Finally, Mustang Bio expects to initiate a pivotal Phase 2 clinical trial in at least one additional B-cell malignancy in 2025.

- Mazyar Shadman, M.D., M.P.H., Study Chair, Associate Professor and physician at Fred Hutch and University of Washington also presented data from the ongoing Fred Hutch Phase 1/2 clinical trial, specific to two B-cell non-Hodgkin lymphoma cohorts, FL and WM. In the FL data cohort (n=20), an overall response rate ("ORR") of 95% was seen, of which 80% of patients experienced a complete response and 15% had a partial response. The complete response patients include a patient who was previously treated with a CD19-directed CAR-T cell therapy. Of the six patients who experienced cytokine release syndrome ("CRS"), only one had Grade 2, while the remaining five had Grade 1. Ten patients continue to experience complete response for more than 10 months, four patients have experienced complete response for more than two years (all ongoing), and the first patient enrolled has sustained complete response for more than 3 years. In the WM cohort (n=6), all of whom had received prior Bruton tyrosine kinase inhibitor, two patients experienced complete response, one of whom continues to be in complete response at more than 22 months. No patients experienced CRS or immune effector cell-associated neurotoxicity syndrome over Grade 2. None of the six patients with WM have needed to start new therapy for their disease.

MB-109:

- In October 2023, Mustang Bio announced that the FDA accepted the Company's IND to initiate a Phase 1 open label, multicenter clinical trial to assess the safety, tolerability and efficacy of 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 GBM and high-grade astrocytoma.

- As previously reported, preclinical data presented at the American Association for Cancer Research ("AACR") Annual Meeting 2022 supported this combination therapy to optimize results to treat recurrent GBM. The combination leverages MB-108 to 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 infusions were 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 City of Hope ("COH") Phase 1 patients disclosed at AACR meeting in 2022, these two complete responses were observed in the two patients with the "hottest" tumors prior to treatment with MB-101.

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, including statements regarding future clinical trial activities, statements about the Company's expectations with respect to receipt of the contingent payment in connection with the sale of its manufacturing facility, 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 the Company's receipt of the contingent payment in connection with the Company's sale of the its manufacturing facility in the anticipated timeframe or at all; whether uBriGene 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; whether CFIUS determines to require mitigating actions in connection with the sale of the Company's manufacturing facility, which may include suspension or termination of the transaction or the imposition of operating mechanisms that could make it more difficult for uBriGene to operate the facility; whether CFIUS determines to require the sale of the facility by uBriGene, which may jeopardize the Company's access to products manufactured at the facility; whether, even if CFIUS ultimately permits the sale of the Company's manufacturing facility, requisite consent from the landlord is not obtained; 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 to raise 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.

Company Contacts:

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

	September 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,562	$ 75,656
Other receivables - related party	—	36
Prepaid expenses and other current assets	4,026	3,160
Total current assets	13,588	78,852
Property, plant and equipment, net	3,502	8,440
Fixed assets - construction in process	—	951
Restricted cash	750	1,000
Other assets	1,083	261
Operating lease right-of-use asset, net	1,644	2,918
Total Assets	**$ 20,567**	**$ 92,422**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 12,708	$ 13,731
Payables and accrued expenses - related party	1,005	766
Operating lease liabilities - short-term	453	612
Total current liabilities	**14,166**	**15,109**
Deferred income	270	270
Note payable, long-term, net	—	27,436
Operating lease liabilities - long-term	2,122	3,334
Total Liabilities	**16,558**	**46,149**
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 September 30, 2023 and December 31, 2022, respectively	—	—
Common stock ($0.0001 par value), 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively		
Class A common shares, 845,385 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Common shares, 7,451,015 and 7,100,111 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	1	11
Common stock issuable, 6,987 and 187,134 shares as of September 30, 2023 and December 31, 2022, respectively	4	1,109
Additional paid-in capital	376,359	374,522
Accumulated deficit	(372,355)	(329,369)
Total Stockholders' Equity	**4,009**	**46,273**
Total Liabilities and Stockholders' Equity	**$ 20,567**	**$ 92,422**

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 9,477	$ 15,419	$ 34,313	$ 46,872
Research and development – licenses acquired	50	40	50	40
Gain on the sale of property and equipment	(1,351)	—	(1,351)	—
General and administrative	2,131	3,389	7,507	9,815
Total operating expenses	10,307	18,848	40,519	56,727
Loss from operations	(10,307)	(18,848)	(40,519)	(56,727)
Other income (expense)				
Other income	138	669	918	669
Interest income	115	216	727	366
Interest expense	(4)	(1,034)	(4,112)	(2,199)
Total other income (expense)	249	(149)	(2,467)	(1,164)
Net Loss	**$ (10,058)**	**$ (18,997)**	**$ (42,986)**	**$ (57,891)**
Net loss per common share outstanding, basic and diluted	$ (1.23)	$ (2.42)	$ (5.29)	$ (7.61)
Weighted average number of common shares outstanding, basic and diluted	8,171,582	7,850,208	8,131,191	7,608,309