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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **March 11, 2024**

**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-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
<b>Common Stock, par value \$0.0001 per share</b>	<b>MBIO</b>	<b>NASDAQ Capital Market</b>

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. "

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**Item 2.02. Results of Operations and Financial Condition.**

On March 11, 2024, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the fiscal year ended December 31, 2023. A copy of such press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information, including Exhibit 99.1, in this Current Report on 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 Current Report on 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:

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press release issued by Mustang Bio, Inc., dated March 11, 2024.</a>
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.

Date: March 11, 2024

**Mustang Bio, Inc.**  
(Registrant)

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

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### Mustang Bio Reports Full-Year 2023 Financial Results and Recent Corporate Highlights

**Worcester, MA – March 11, 2024** – 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 financial results and recent corporate highlights for the full-year ended December 31, 2023.

"2023 was an exciting year for Mustang filled with many highlights, including compelling interim data from Mustang’s multicenter Phase 1/2 clinical trial of MB-106 presented at the 2023 American Society of Hematology Annual Meeting, which builds upon the stellar data presented earlier in the year from the MB-106 Phase 1/2 single institution clinical trial conducted at Fred Hutch. In both the multicenter Phase 1/2 trial and the single institution Phase 1/2 trial, the observed deepening and durability of responses are very gratifying. We believe the CAR T-cell persistence of up to 3 years in the original single institution trial at Fred Hutch and up to 1 year in the current Mustang-sponsored multicenter trial are important potential contributors to the deepening and durability of responses," said Manuel Litchman, M.D., President and Chief Executive Officer of Mustang. "We plan to move ahead with the first ever registrational CAR-T trial focused on relapsed or refractory Waldenstrom macroglobulinemia (“WM”), a subtype of indolent lymphoma with no FDA-approved therapy or standard of care in the third-line setting and no FDA-approved CAR-T for any line of therapy. We expect to treat the first patient in the second half of 2024, which could enable topline results in the second half of 2026. In order to facilitate interactions with the FDA throughout this process, we anticipate requesting Regenerative Medicine Advanced Therapy (“RMAT”) designation for indolent lymphoma – which includes WM – from the FDA in the first half of 2024. Advantages of the RMAT designation include all the benefits of the Fast Track and Breakthrough Therapy Designation programs, including early interactions with FDA."

Dr. Litchman continued, "Additionally, we are evaluating the potential to initiate a first-ever 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 (IL13R $\alpha$ 2-targeted CAR T-cell therapy) and MB-108 (HSV-1 oncolytic virus) in adult patients with recurrent GBM and high-grade astrocytomas that express IL13R $\alpha$ 2 on the surface of the tumor cells. The combination leverages MB-108 to reshape the tumor microenvironment (“TME”) and make cold tumors “hot,” which could potentially enhance the clinical effect of MB-101 CAR T-cell therapy. As per a recent publication in *Nature Medicine*, 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 66+ months, respectively. Also noteworthy is our continued work with the Mayo Clinic to progress our exclusively licensed novel *in vivo* CAR-T technology platform, for which we anticipate an upcoming publication of proof-of-concept research in a murine tumor model in 2024."

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### **Financial Results:**

- As of December 31, 2023, Mustang's cash and cash equivalents and restricted cash totaled \$7.0 million, compared to \$76.7 million as of December 31, 2022, a decrease of \$69.7 million year-over-year. In 2023 Mustang made a \$30.4 million payment to terminate existing debt. Mustang continues to evaluate opportunities to reduce its cash utilization while focusing on its top priority development programs.
- Research and development expenses were \$40.5 million for the year ended December 31, 2023, compared to \$62.5 million for 2022. Non-cash, stock-based compensation expenses included in research and development were \$0.1 million for the year ended December 31, 2023, compared to \$1.6 million for 2022.
- Mustang recorded a gain on the sale of property and equipment of \$1.5 million, in connection with the sale of assets to uBriGene.
- General and administrative expenses were \$9.7 million for the year ended December 31, 2023, compared to \$12.2 million for 2022. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$0.4 million for the year ended December 31, 2023, compared to \$0.7 million for 2022.
- Net loss attributable to common stockholders was \$51.6 million, or \$6.00 per share, for the year ended December 31, 2023, compared to a net loss attributable to common stockholders of \$77.5 million, or \$10.09 per share, for 2022.

### **2023 and Recent Corporate Highlights:**

#### **General Corporate:**

- In July 2023, Mustang announced that it amended its previously announced asset purchase agreement with uBriGene (Boston) Biosciences Inc. ("uBriGene") 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 manufacturing facility in Worcester, Massachusetts, for upfront consideration of \$6 million in cash. An additional \$5 million contingent payment will be payable to Mustang upon (i) Mustang 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. Unless and 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 there its lead product candidate, MB-106. Clearance for assignment of Mustang's lease to uBriGene remains under review by the U.S. Committee on Foreign Investment in the United States ("CFIUS"), and Mustang and uBriGene are continuing discussions with CFIUS regarding the nature and extent of national security risk posed by the assignment.
- In October 2023, Mustang completed a registered direct offering priced at-the-market for approximately \$4.4 million in gross proceeds.

#### **MB-106 (CD20-targeted CAR T-cell therapy):**

- 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 follicular lymphoma ("FL"). MB-106 continues to demonstrate a favorable safety and efficacy profile in both the Fred Hutch single institution and Mustang multicenter Phase 1/2 clinical trials.
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- In December 2023, Mustang announced initial 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 at the 2023 American Society of Hematology (ASH) Annual Meeting. Initial data show that all patients responded clinically to treatment with MB-106 (n=9), with a 100% overall response rate for patients with FL and WM. 100% of patients with FL (n=5) had a complete response; 1 very good partial response and 2 partial responses were observed in WM patients (n=3); and the hairy cell leukemia variant (“HCL-v”) patient experienced stable disease, with prolonged, ongoing independence from blood transfusions. Complete responses were observed in patients previously treated with CD19-targeted CAR T-cell therapy. MB-106 demonstrated a tolerable safety profile in patients with indolent NHL, with no occurrence of cytokine release syndrome (“CRS”) above grade 1, and no immune effector cell-associated neurotoxicity syndrome (“ICANS”) of any grade, despite not using prophylactic tocilizumab or dexamethasone. Outpatient administration was allowed and found to be feasible. MB-106 CAR T-cell expansion and persistence in patients was demonstrated.
- 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 2024.
- 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; 1 patient experienced a very good partial response; and 1 patient experienced a partial response. No patients experienced CRS or ICANS greater than Grade 2. None of the six patients with WM has needed to start new therapy for their disease.

**MB-109 (IL13R $\alpha$ 2-targeted CAR T-cells + HSV-1 oncolytic virus for recurrent glioblastoma):**

- In October 2023, Mustang 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 (IL13R $\alpha$ 2-targeted CAR T-cell therapy) and MB-108 (HSV-1 oncolytic virus), for the treatment of recurrent GBM and high-grade astrocytoma. Mustang is evaluating plans to initiate the clinical trial and request orphan drug designation for GBM, subject to resource allocation, in 2024.
  - 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.
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- In March 2024, data from the Phase 1 trial evaluating MB-101 IL13R $\alpha$ 2-targeted CAR T-cells in high-grade glioma were 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 in high grade glioma patients. The two patients who achieved complete response both had high levels of intratumoral CD3+ T-cells pre-therapy (i.e., “hot” tumors), and their responses lasted 7.5 and 66+ months, respectively. In the cohort with dual intratumoral (ICT)/ intraventricular (ICV) delivery and an optimized manufacturing process there was a ~70% improvement in median overall survival (10.2 months) compared to the expected survival rate of six months in this patient population.

***In Vivo* CAR-T Technology Platform:**

- Mustang continues to collaborate with the Mayo Clinic to progress our exclusively licensed novel *in vivo* CAR-T technology platform that may be able to transform the administration of CAR-T therapies and has the potential to be used as an off-the-shelf therapy. Mustang anticipates the publication of proof-of-concept research in a murine tumor model in 2024.

**MB-117 and MB-217 Lentiviral Gene Therapies for X-Linked Severe Combined Immunodeficiency (XSCID):**

- In 2024, the first patients are expected to be treated in both new investigator-sponsored trials for newborns diagnosed with XSCID and for previously transplanted patients with XSCID. These trials with MB-117 and MB-217, respectively, are planned by our partners and will test a modified version of the current lentiviral vector.

**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](http://www.mustangbio.com).

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**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. These 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 the satisfaction of the conditions necessary to transfer the lease of Mustang’s manufacturing facility and receive the contingent payment in connection with Mustang’s sale of its manufacturing facility in the anticipated timeframe or at all; whether the purchaser of Mustang’s manufacturing facility is able to successfully perform its obligation to produce Mustang’s products under the manufacturing services agreement on a timely basis and to acceptable standards; disruption from the sale of Mustang’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 Mustang’s common stock; significant transaction costs; the development stage of Mustang’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, subsequent Quarterly 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 applicable 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:**

Jaclyn Jaffe and Nicole McCloskey  
Mustang Bio, Inc.  
(781) 652-4500  
ir@mustangbio.com

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

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 6,234	\$ 75,656
Other receivables - related party	-	36
Other receivables	3,879	263
Prepaid expenses and other current assets	1,233	2,897
<b>Total current assets</b>	<u>11,346</u>	<u>78,852</u>
Property, plant and equipment, net	3,218	8,440
Fixed assets - construction in process	29	951
Restricted cash	750	1,000
Other assets	833	261
Operating lease right-of-use asset, net	1,566	2,918
<b>Total Assets</b>	<u>\$ 17,742</u>	<u>\$ 92,422</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 14,017	\$ 13,731
Payables and accrued expenses - related party	834	766
Operating lease liabilities - short-term	520	612
<b>Total current liabilities</b>	<u>15,371</u>	<u>15,109</u>
Deferred income	270	270
Note payable, long-term, net	-	27,436
Operating lease liabilities - long-term	1,978	3,334
<b>Total Liabilities</b>	<u>17,619</u>	<u>46,149</u>
<b>Stockholders' Equity</b>		
Preferred stock (\$0.0001 par value), 2,000,000 shares authorized, 250,000 shares of Class A preferred stock issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Common stock (\$0.0001 par value), 200,000,000 shares authorized as of December 31, 2023 and 2022, respectively		
Class A common shares, 845,385 shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Common shares, 8,374,869 and 7,100,111 shares issued and outstanding as of December 31, 2023 and 2022, respectively	1	11
Common stock issuable, 419,089 and 187,134 shares as of December 31, 2023 and 2022, respectively	591	1,109
Additional paid-in capital	380,502	374,522
Accumulated deficit	(380,971)	(329,369)
<b>Total Stockholders' Equity</b>	<u>123</u>	<u>46,273</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 17,742</u>	<u>\$ 92,422</u>

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

	<b>For the year ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development	\$ 40,513	\$ 62,475
Research and development – licenses acquired	527	1,474
Gain on the sale of property and equipment	(1,466)	—
General and administrative	9,686	12,210
Total operating expenses	49,260	76,159
Loss from operations	(49,260)	(76,159)
Other income (expense)		
Other income	917	1,304
Interest income	850	689
Interest expense	(4,109)	(3,359)
Total other income (expense)	(2,342)	(1,366)
<b>Net Loss</b>	<b>\$ (51,602)</b>	<b>\$ (77,525)</b>
Net loss per common share outstanding, basic and diluted	\$ (6.00)	\$ (10.09)
Weighted average number of common shares outstanding, basic and diluted	8,604,104	7,684,508