
**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): **August 14, 2023**

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
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 August 14, 2023, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the second quarter ended June 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 August 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.

Date: August 14, 2023

Mustang Bio, Inc.
(Registrant)

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



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

Worcester, MA – August 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 second quarter ended June 30, 2023.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “In the second quarter of 2023, Mustang continued to advance 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”). Data from the ongoing Phase 1/2 single-institution clinical trial at Fred Hutchinson Cancer Center (“Fred Hutch”) presented at two prestigious medical meetings in June continue to demonstrate the promise of MB-106 as a viable outpatient treatment option with a favorable safety and efficacy profile. On a parallel track, our multicenter, open-label, non-randomized Phase 1/2 clinical trial continues to accrue patients and we expect to disclose initial data soon. In particular, MB-106 has the potential to fill a significant unmet need in many difficult-to-treat cancers including Waldenström macroglobulinemia (“WM”), as there are currently no CAR T treatments for WM approved by the U.S. Food and Drug Administration (“FDA”). We anticipate the results from our multicenter Phase 1 indolent lymphoma arm of the multicenter clinical trial to support an accelerated Phase 2 registration strategy for WM, with the first pivotal Phase 2 patient with WM to be treated potentially in the first quarter of 2024. We also plan to report more extensive safety and efficacy data from the multicenter trial later this year and to initiate a pivotal phase 2 trial in at least one additional B-cell malignancy later in 2024.”

Dr. Litchman continued, “Mustang also announced a strategic transaction and partnership with uBriGene (Boston) Biosciences Inc. (“uBriGene”). Manufacturing support from uBriGene and its acquisition of our state-of-the-art clinical- and commercial-scale cell and gene therapy manufacturing facility allows us to significantly reduce annualized operating and interest expense by at least \$28 million to ensure focus on data readouts for key programs and extend our cash runway.”

Financial Results:

- As of June 30, 2023, Mustang’s cash and cash equivalents and restricted cash totaled \$16.1 million, compared to \$58.8 million at March 31, 2023, and \$76.7 million as of December 31, 2022, a decrease of \$42.7 million for the quarter and a decrease of \$60.6 million year-to-date, which reflects the repayment of the Runway Term Loan in April 2023.
 - Research and development expenses were \$10.8 million for the second quarter of 2023, compared to \$15.2 million for the second quarter of 2022. Non-cash, stock-based expenses included in research and development were \$(0.1) million for the second quarter of 2023, compared to \$0.4 million for the second quarter of 2022.
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- General and administrative expenses were \$3.1 million for the second quarter of 2023, compared to \$3.1 million for the second quarter of 2022. Non-cash, stock-based expenses included in general and administrative expenses were \$0.2 million for the second quarter of 2023, compared to \$0.2 million for the second quarter of 2022.
- Net loss attributable to common stockholders was \$16.2 million, or \$2.00 per share, for the second quarter of 2023, compared to a net loss attributable to common stockholders of \$19.1 million, or \$2.50 per share, for the second quarter of 2022.

Recent Corporate Highlights:

- 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 additional time to consider the proposed transfer. 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.
 - 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 Phase 1/2 Fred Hutch single institution and Mustang multicenter Phase 1/2 clinical trials.
 - In June 2023, Phase 1/2 data from the WM cohort in the Fred Hutch clinical trial for MB-106 were presented in a poster session at the European Hematology Association 2023 Hybrid Congress. All six patients in the study were previously treated with Bruton's tyrosine kinase inhibitors ("BTKi"), and their disease continued to progress while on BTKis. Overall, 83% (5/6) of the patients treated with MB-106 responded to treatment, including 2 complete responses ("CR"), 1 very good partial response ("VGPR"), 1 partial response ("PR") and 1 minor response. In addition, 1 patient experienced stable disease. One of the patients who achieved a CR has remained in remission for 22 months, with an immunoglobulin M ("IgM") level that decreased rapidly to the normal range after treatment with MB-106 and has remained normal since. No patient has started additional anti-WM treatment after being treated with MB-106. From a safety perspective, cytokine release syndrome ("CRS") occurred in five patients: two patients with grade 1 and three patients with grade 2. One patient experienced grade 1 immune effector cell-associated neurotoxicity syndrome ("ICANS"). No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS has been observed.
 - Also in June 2023, Fred Hutch presented MB-106 data from the FL cohort of its clinical trial in an oral presentation at the 17th International Conference on Malignant Lymphoma. A total of 20 patients with relapsed FL with confirmed CD20 expression participated in the study and had day 28 assessment.
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Median age was 63 years (range: 44 – 81), and median prior lines of treatment was 4 (range: 1 – 12). High-risk features included patients with progression of disease within 24 months of first-line chemoimmunotherapy (POD24) (n=15, 75%), history of histologic transformation (n=4, 20%), and prior treatment with a CD19 target CAR T (n=1, 5%). Overall response rate (“ORR”) was 95% (19/20), and CR rate was 80% (16/20). Patients who received higher dose levels (3.3×10^6 and 1.0×10^7 cells/kg) had an ORR of 100% and a CR rate of 91%. Ten patients are in remission over one year, seven of whom are over two years. One patient, previously treated with a CD19-targeted CAR T-cell therapy, achieved a CR and remains in remission after 18 months. From a safety profile perspective, all CRS events were grade 1 (n=5, 25%) or grade 2 (n=1, 5%), with no grade ≥ 3 CRS events. There was no occurrence of ICANS of any grade.

- In parallel, Mustang’s multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106, continues to accrue, and Mustang anticipates escalation to the final dose level in the Phase 1 indolent lymphoma arm in the third quarter of this year. The FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, and results from this arm 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 the first quarter of 2024. Mustang plans to report initial safety and efficacy data from the multicenter trial soon, with additional safety and efficacy data from the trial expected in the fourth quarter. Finally, Mustang expects to initiate a pivotal phase 2 trial in at least one additional B-cell malignancy later in 2024.
- Mustang continues to collaborate with the Mayo Clinic to progress its 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 2023.
- In April 2023, Mustang effected a 15-for-1 reverse stock split of its issued and outstanding common stock. Mustang’s common stock began trading on a split-adjusted basis on the Nasdaq Capital Market as of the commencement of trading on April 4, 2023.

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

	June 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 15,385	\$ 75,656
Other receivables - related party	—	36
Prepaid expenses and other current assets	2,843	3,160
Property, plant and equipment, held for sale	4,348	—
Total current assets	<u>22,576</u>	<u>78,852</u>
Property, plant and equipment, net	3,786	8,440
Fixed assets - construction in process	—	951
Restricted cash	750	1,000
Other assets	253	261
Operating lease right-of-use asset, net	1,721	2,918
Total Assets	<u>\$ 29,086</u>	<u>\$ 92,422</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 11,684	\$ 13,731
Payables and accrued expenses - related party	771	766
Operating lease liabilities - short-term	409	612
Total current liabilities	<u>12,864</u>	<u>15,109</u>
Deferred income	270	270
Note payable, long-term, net	—	27,436
Operating lease liabilities - long-term	2,239	3,334
Total Liabilities	<u>15,373</u>	<u>46,149</u>
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 June 30, 2023 and December 31, 2022, respectively	—	—
Common stock (\$0.0001 par value), 200,000,000 shares authorized as of June 30, 2023 and December 31, 2022, respectively	—	—
Class A common shares, 845,385 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	—	—
Common shares, 7,320,444 and 7,100,111 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	1	11
Common stock issuable, zero and 187,134 shares as of June 30, 2023 and December 31, 2022, respectively	—	1,109
Additional paid-in capital	376,009	374,522
Accumulated deficit	(362,297)	(329,369)
Total Stockholders' Equity	<u>13,713</u>	<u>46,273</u>
Total Liabilities and Stockholders' Equity	<u>\$ 29,086</u>	<u>\$ 92,422</u>

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

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 10,836	\$ 15,164	\$ 24,836	\$ 31,453
General and administrative	3,055	3,077	5,376	6,426
Total operating expenses	<u>13,891</u>	<u>18,241</u>	<u>30,212</u>	<u>37,879</u>
Loss from operations	<u>(13,891)</u>	<u>(18,241)</u>	<u>(30,212)</u>	<u>(37,879)</u>
Other income (expense)				
Other income	429	—	780	—
Interest income	159	77	612	150
Interest expense	(2,932)	(935)	(4,108)	(1,165)
Total other expense	<u>(2,344)</u>	<u>(858)</u>	<u>(2,716)</u>	<u>(1,015)</u>
Net Loss	<u>\$ (16,235)</u>	<u>\$ (19,099)</u>	<u>\$ (32,928)</u>	<u>\$ (38,894)</u>
Net loss per common share outstanding, basic and diluted	<u>\$ (2.00)</u>	<u>\$ (2.50)</u>	<u>\$ (4.06)</u>	<u>\$ (5.20)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>8,127,473</u>	<u>7,652,170</u>	<u>8,110,661</u>	<u>7,485,355</u>