
**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): **March 29, 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 March 29, 2023, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the fourth quarter and full year ended December 31, 2022. 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 March 29, 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: March 29, 2023

Mustang Bio, Inc.
(Registrant)

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



Mustang Bio Reports Full-Year 2022 Financial Results and Recent Corporate Highlights

Worcester, MA – March 29, 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 hematologic cancers, solid tumors and rare genetic diseases, today announced financial results and recent corporate highlights for the full year ended December 31, 2022.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “In 2022, we advanced our cell and gene therapy programs and presented promising research supporting the potential of our clinical portfolio at several prestigious medical meetings. Our lead clinical candidate is 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”). MB-106 continues to generate compelling safety and efficacy data and remains attractive when compared to approved autologous CAR Ts, which are generating an annualized run rate of \$3 billion in net sales, based on reported sales in the third quarter of 2022. MB-106 data to date include an overall response rate (“ORR”) of 96% and complete response (“CR”) rate of 75% in a wide range of hematologic malignancies, including Waldenstrom macroglobulinemia (“WM”), in a clinical trial conducted by our collaborators at Fred Hutchinson Cancer Center (“Fred Hutch”). We expect to disclose additional data from this trial at medical meetings in the second quarter. 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 we anticipate escalation to the final dose level in the Phase 1 indolent lymphoma arm in the second quarter. The FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, and we have already treated the first WM in the indolent lymphoma arm of the trial. We expect that results from this arm will support an accelerated Phase 2 registration strategy for WM, with the first pivotal Phase 2 WM patient potentially to be treated in the first quarter of 2024. In 2023, we plan to report safety and efficacy data from the indolent lymphoma arm at medical meetings in the second quarter, with disclosure of updated data expected in the fourth quarter.”

Financial Results:

- As of December 31, 2022, Mustang’s cash and cash equivalents and restricted cash totaled \$76.7 million, compared to \$110.6 million as of December 31, 2021, a decrease of \$33.9 million year-over-year.
 - Research and development expenses were \$62.5 million for the year ended December 31, 2022. This compares to \$49.9 million for 2021. Non-cash, stock-based compensation expenses included in research and development were \$1.6 million for the year ended December 31, 2022, compared to \$2.3 million for 2021.
 - Research and development expenses from license acquisitions totaled \$1.5 million for the year ended December 31, 2022, compared to \$5.8 million for 2021. Non-cash, stock-based compensation expenses included in research and development – licenses acquired were \$1.1 million for the year ended December 31, 2022, compared to \$4.2 million for 2021.
 - General and administrative expenses were \$12.2 million for the year ended December 31, 2022. This compares to \$11.0 million for 2021. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$0.9 million for the year ended December 31, 2022, compared to \$2.9 million for 2021.
-

- Net loss attributable to common stockholders was \$77.5 million, or \$0.75 per share, for the year ended December 31, 2022, compared to a net loss attributable to common stockholders of \$66.4 million, or \$0.76 per share, for 2021.

2022 and Recent Corporate Highlights:

- In March 2022, Mustang completed a \$75 million debt financing with Runway Growth Capital. Thirty million was funded upon closing, with the additional \$45 million available upon Mustang achieving certain milestones.
- In June 2022, Mustang announced that the FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, a rare type of B-NHL. Mustang plans to treat additional patients with WM in the Mustang Bio-sponsored Phase 1 portion of its multicenter trial in order to potentially support an accelerated Phase 2 strategy for this indication.
- In October 2022, Mustang announced that the first patient was treated in Mustang's multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106, for the treatment of relapsed or refractory B-NHL and CLL. In 2023, the Company anticipates dose escalation and reporting response data at major medical meetings.
- Additionally, in October 2022, Mustang shared interim data from 28 patients treated in the initial, ongoing Phase 1/2 investigator-sponsored clinical trial at Fred Hutch. These data continue to support MB-106 as a viable CAR T cell therapy for B-NHLs and CLL. An ORR of 96% and CR rate of 75% were observed in a wide range of hematologic malignancies including follicular lymphoma ("FL"), CLL, diffuse large B-cell lymphoma ("DLBCL") and WM. Twelve patients have experienced CR for more than 12 months (10 ongoing), including four patients with CR for more than two years and the longest patient with CR at 33 months. Six patients with initial partial response at 28 days post-treatment improved to CR, presumably due to the demonstrated persistence of CAR T cells in these patients, and all remain in ongoing CR. All three patients previously treated with CD19 CAR T cell therapy responded to treatment with MB-106. A favorable safety profile for MB-106 as an outpatient therapy remains, with no cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome \geq Grade 3 reported to date on this trial.
- 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 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 hematologic cancers, solid tumors 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, 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. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; 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 our Annual Report on Form 10-K, 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 Contact:

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

Investor Relations Contact:

Daniel Ferry
LifeSci Advisors, LLC
(617) 430-7576
daniel@lifesciadvisors.com

Media Relations Contact:

Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com

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

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 75,656	\$ 109,618
Other receivables - related party	36	50
Prepaid expenses and other current assets	3,160	2,038
Total current assets	78,852	111,706
Property, plant and equipment, net	8,440	9,025
Fixed assets - construction in process	951	2,027
Restricted cash	1,000	1,000
Other assets	261	362
Operating lease right-of-use asset, net	2,918	1,050
Total Assets	\$ 92,422	\$ 125,170
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 13,731	\$ 9,744
Payables and accrued expenses - related party	766	723
Operating lease liabilities - short-term	612	348
Total current liabilities	15,109	10,815
Deferred income	270	270
Note payable, long-term, net	27,436	—
Operating lease liabilities - long-term	3,334	1,685
Total Liabilities	46,149	12,770
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 December 31, 2022 and 2021, respectively	—	—
Common stock (\$0.0001 par value), 200,000,000 and 150,000,000 shares authorized as of December 31, 2022 and 2021, respectively		
Class A common shares, 845,385 shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Common shares, 106,501,663 and 93,582,991 shares issued and outstanding as of December 31, 2022 and 2021, respectively	11	9
Common stock issuable, 2,807,008 and 2,536,607 shares as of December 31, 2022 and 2021, respectively	1,109	4,329
Additional paid-in capital	374,522	359,906
Accumulated deficit	(329,369)	(251,844)
Total Stockholders' Equity	46,273	112,400
Total Liabilities and Stockholders' Equity	\$ 92,422	\$ 125,170

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

	For the year ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 62,475	\$ 49,864
Research and development – licenses acquired	1,474	5,842
General and administrative	12,210	11,017
Total operating expenses	76,159	66,723
Loss from operations	(76,159)	(66,723)
Other income (expense)		
Grant income	1,304	—
Interest income	689	368
Interest expense	(3,359)	(15)
Total other income (expense)	(1,366)	353
Net Loss	\$ (77,525)	\$ (66,370)
Net loss per common share outstanding, basic and diluted	\$ (0.75)	\$ (0.76)
Weighted average number of common shares outstanding, basic and diluted	103,432,603	87,885,235