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, 2022**

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)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Former name or former address, if changed since last report)

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 Global 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, 2022, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the quarter ended September 30, 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 November 14, 2022.
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, 2022

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

Mustang Bio Reports Third Quarter 2022 Financial Results and Recent Corporate Highlights

Worcester, MA– November 14, 2022– 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 third quarter ended September 30, 2022.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We continued to make progress advancing our portfolio of cell and gene therapies during the third quarter. Notably, we treated the first patient in our multicenter Phase 1/2 clinical trial to evaluate the safety and efficacy of MB-106, our first-in-class CD20-targeted, autologous CAR T cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHL") and chronic lymphocytic leukemia ("CLL"). This first clinical trial under Mustang's Investigational New Drug application ("IND") builds upon the initial, ongoing Phase 1/2 clinical trial taking place at Fred Hutchinson Cancer Center ("Fred Hutch"). In the Fred Hutch trial, MB-106 continues to demonstrate high efficacy and a favorable safety profile across patients with a wide range of hematologic malignancies. Results from the Waldenstrom macroglobulinemia ("WM") cohort of the Fred Hutch trial were recently presented at the 11th International Workshop for Waldenstrom's Macroglobulinemia ("IWWM-11"), showing a 100% complete response ("CR") rate in patients with WM. Our MB-106 program was granted Orphan Drug Designation ("ODD") by the U.S. Food and Drug Administration ("FDA") for WM, and we plan to treat additional patients with WM in the Mustang-sponsored Phase 1 portion of our multicenter trial in order to support a fast-to-market Phase 2 strategy for this indication. We anticipate announcing early results from the Mustang-sponsored Phase 1 trial in December 2022."

"In summary, our CD20 CAR T remains our lead program, and we believe the product profile is favorable compared to the 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," said Dr. Litchman.

Recent Corporate Highlights:

- In July 2022, Mustang announced that the first patient successfully received LV-RAG1 *ex vivo* lentiviral gene therapy to treat RAG1-SCID, in an ongoing Phase 1/2 multicenter clinical trial taking place in Europe. LV-RAG1 is exclusively licensed by Mustang for the development of MB-110, a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID.
- In October 2022, Mustang announced that the first patient was treated in its multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106, Mustang's first-in-class CD20-targeted, autologous CAR T cell therapy for the treatment of relapsed or refractory B-NHL and CLL. This is the first MB-106 clinical trial under Mustang's IND.
- Also 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, 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 ("PR") 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 have 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 ≥ Grade 3.

- Additionally in October 2022, Mustang announced that results from the WM cohort and other interim data from the ongoing Phase 1/2 clinical trial of MB-106 at Fred Hutch were presented at IWWM-11 that took place in Madrid, Spain. Mustang's MB-106 program was granted ODD by the FDA for WM, and Mustang plans to treat additional WM patients in the Mustang-sponsored Phase 1 portion of its multicenter trial in order to support a fast-to-market Phase 2 strategy for this indication.
- Mustang expects to announce early results from the Mustang-sponsored multicenter MB-106 trial later this quarter.

Financial Results:

- As of September 30, 2022, Mustang's cash and cash equivalents and restricted cash totaled $92.4 million, compared to $108.4 million at June 30, 2022 and $110.6 million as of December 31, 2021, a decrease of $16.0 million for the quarter and a decrease of $18.2 million year-to-date.
- Research and development expenses were $15.5 million for the third quarter of 2022, compared to $14.7 million for the third quarter of 2021. Non-cash, stock-based expenses included in research and development were $0.3 million for the third quarter of 2022, compared to $0.7 million for the third quarter of 2021.
- General and administrative expenses were $3.4 million for the third quarter of 2022, compared to $2.4 million for the third quarter of 2021. Non-cash, stock-based expenses included in general and administrative expenses were $0.2 million for the third quarter of 2022, compared to $0.3 million for the third quarter of 2021.
- Net loss attributable to common stockholders was $19.0 million, or $0.18 per share, for the third quarter of 2022, compared to a net loss attributable to common stockholders of $17.0 million, or $0.19 per share, for the third quarter of 2021.

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 Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K filed on March 23, 2022, 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 (Unaudited)
(in thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 91,364	$ 109,618
Other receivables - related party	33	50
Prepaid expenses and other current assets	3,050	2,038
Total current assets	94,447	111,706
Property, plant and equipment, net	8,950	9,025
Fixed assets - construction in process	1,095	2,027
Restricted cash	1,000	1,000
Other assets	320	362
Operating lease right-of-use asset, net	3,024	1,050
Total Assets	**$ 108,836**	**$ 125,170**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 12,810	$ 9,744
Payables and accrued expenses - related party	152	723
Operating lease liabilities - short-term	595	348
Total current liabilities	**13,557**	**10,815**
Deferred income	270	270
Note payable, long-term, net	27,293	—
Operating lease liabilities - long-term	3,391	1,685
Total Liabilities	**44,511**	**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 September 30, 2022 and December 31, 2021, respectively	—	—
Common stock ($0.0001 par value), 200,000,000 and 150,000,000 shares authorized as of September 30, 2022 and December 31, 2021, respectively		
Class A common shares, 845,385 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	—	—
Common shares, 106,427,767 and 93,582,991 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	11	9
Common stock issuable, 6,987 and 2,536,607 shares as of September 30, 2022 and December 31, 2021, respectively	4	4,329
Additional paid-in capital	374,045	359,906
Accumulated deficit	(309,735)	(251,844)
Total Stockholders' Equity	**64,325**	**112,400**
Total Liabilities and Stockholders' Equity	**$ 108,836**	**$ 125,170**

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 15,419	$ 14,083	$ 46,872	$ 36,603
Research and development – licenses acquired	40	630	40	1,630
General and administrative	3,389	2,364	9,815	8,371
Total operating expenses	18,848	17,077	56,727	46,604
Loss from operations	(18,848)	(17,077)	(56,727)	(46,604)
Other income (expense)				
Grant income	669	—	669	—
Interest income	216	75	366	294
Interest expense	(1,034)	(3)	(2,199)	(11)
Total other income (expense)	(149)	72	(1,164)	283
Net Loss	**$ (18,997)**	**$ (17,005)**	**$ (57,891)**	**$ (46,321)**
Net loss per common share outstanding, basic and diluted	$ (0.18)	$ (0.19)	$ (0.57)	$ (0.54)
Weighted average number of common shares outstanding, basic and diluted	105,917,723	91,136,969	102,289,247	86,487,092