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): **May 12, 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)

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 May 12, 2022, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the first quarter ended March 31, 2022. A copy of such press release is being furnished as Exhibit 99.1 to this report.

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 May 12, 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: May 12, 2022

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

Exhibit 99.1

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

Data from two programs selected for oral presentations at the upcoming American Society of Gene & Cell Therapy 25th Annual Meeting and the European Hematology Association 2022 Hybrid Congress this quarter

Worcester, MA– May 12, 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 first quarter ended March 31, 2022.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "Mustang started strong in 2022, with multiple data announcements and key clinical milestones achieved across our robust pipeline of CAR T cell and gene therapies. In the first quarter, data were presented on three of our CAR T cell therapies and our oncolytic virus clinical candidate at prestigious medical conferences by our academic collaborators at City of Hope and Fred Hutchinson Cancer Center ("Fred Hutch"). City of Hope's Dr. Tanya Dorff presented Phase 1 clinical trial data on MB-105, our prostate stem cell antigen ("PSCA") chimeric antigen receptor ("CAR") T-cell therapy for treatment of PSCA-positive metastatic castration-resistant prostate cancer ("mCRPC") at the 2022 American Society of Clinical Oncology ("ASCO") Genitourinary ("GU") Cancers Symposium that demonstrated its potential as a PSCA-targeted CAR T-cell therapy for prostate cancer and other solid tumors that express PSCA. Fred Hutch's Dr. Mazyar Shadman presented updated interim Phase 1/2 clinical trial data on MB-106, our CD20-targeted, autologous CAR T cell therapy for treatment of relapsed or refractory B-cell non-Hodgkin lymphomas ("NHL") and chronic lymphocytic leukemia ("CLL"), at the 2022 Tandem Meetings I Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy and Center for International Blood & Marrow Transplant Research ("2022 Tandem Meetings") and at the 4th International Workshop on CAR-T and Immunotherapies ("*iw*CAR-T"). The data demonstrated high efficacy and a favorable safety profile, with an overall response rate ("ORR") of 96% and complete response ("CR") rate of 72% observed in all patients across all dose levels. The data included two patients previously treated with CD19-directed CAR T therapy who relapsed and responded to MB-106, demonstrating its potential as an immunotherapy option for these patients. Additionally, City of Hope's Dr. Christine Brown presented Phase 1 clinical trial data from a late-breaking poster regarding MB-108 (C134 oncolytic virus licensed from Nationwide Children's Hospital) and MB-101 (IL13Rα2-targeted CAR T cell therapy licensed from City of Hope) for the treatment of recurrent glioblastoma ("rGBM"), at the American Association for Cancer Research ("AACR") Annual Meeting 2022 that support the safety of administering these two therapies sequentially to optimize treatment in a regimen designated as MB-109."

"Looking ahead, we have additional upcoming data presentations for MB-106 at the European Hematology Association 2022 ("EHA2022") Hybrid Congress and for our MB-107 gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID") in newly diagnosed infants under the age of two at the American Society of Gene & Cell Therapy ("ASGCT") 25th Annual Meeting. We plan to dose the first patient under Mustang's IND in a multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL at the end of this quarter. In the second half of 2022, we plan to file an IND to initiate a Phase 1 clinical trial for MB-109 for the treatment of rGBM and enroll the first patient in a pivotal multicenter Phase 2 clinical trial under Mustang's IND to evaluate MB-107. It's an incredibly exciting time for our team and we look forward to continuing to advance our cell and gene therapies to help meet the needs of patients with hard-to-treat diseases."

Financial Results:

- As of March 31, 2022, Mustang's cash and cash equivalents and restricted cash totaled $123.2 million, compared to $110.6 million as of December 31, 2021, an increase of $12.6 million year-to-date.

- Research and development expenses were $16.3 million for the first quarter of 2022, compared to $11.6 million for the first quarter of 2021. Non-cash, stock-based expenses included in research and development were $0.5 million for the first quarter of 2022, compared to $0.7 million for the first quarter of 2021.

- General and administrative expenses were $3.3 million for the first quarter of 2022, compared to $3.5 million for the first quarter of 2021. Non-cash, stock-based expenses included in general and administrative expenses were $1.0 million for the first quarter of 2022, compared to $1.5 million for the first quarter of 2021.

- Net loss attributable to common stockholders was $19.8 million, or $0.20 per share, for the first quarter of 2022, compared to a net loss attributable to common stockholders of $15.0 million, or $0.19 per share, for the first quarter of 2021.

Recent Corporate Highlights:

- In February 2022, Mustang was selected as the Bronze winner for the Central region in the Eighteenth Annual Team Massachusetts Economic Impact Awards presented by MassEcon. The award winners were honored at Gillette Stadium on April 7, 2022.
- Also in February 2022, Phase 1 data on MB-105, a PSCA-targeted CAR T cell therapy administered systemically to patients with PSCA-positive mCRPC, were presented by City of Hope at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium. The data indicated that PSCA-targeted CAR T-cell therapy is feasible in patients with mCRPC with dose-limiting toxicity ("DLT") of cystitis and is associated with preliminary anti-tumor effect at a dose of 100 million cells plus lymphodepletion. It was concluded that escalation up to the next dose level of 300 million cells plus modified lymphodepletion can proceed in the trial.
- In March 2022, Mustang completed a $75 million long-term debt facility with Runway Growth Capital LLC (with $30.0 million funded on the closing date and the remaining $45.0 million becoming available if Mustang achieves certain predetermined milestones).
- In April 2022, Mustang announced that interim Phase 1/2 data on MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell NHL and CLL, were presented at the 2022 Tandem Meetings. Data demonstrated high efficacy and a favorable safety profile in all patients (n=25). Five dose levels were used during the study, and complete responses were observed at all dose levels. Durable responses were observed in a wide range of hematologic malignancies including follicular lymphoma ("FL"), CLL, diffuse large B-cell lymphoma ("DLBCL"), and Waldenstrom macroglobulinemia. An ORR of 96% and CR rate of 72% was observed in all patients across all dose levels. Additionally, two patients had been previously treated with CD19-directed CAR T therapy and subsequently relapsed, and both responded to treatment, one patient with FL with a CR and the other with DLBCL with a partial response. A copy of the abstract can be viewed on the meeting website here. Mustang expects to dose the first patient in a multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL later this quarter.
- Also in April 2022, MB-106 data focused on CLL were presented at the 4th*iw*CAR-T.
- Additionally, in April 2022, Mustang announced its plan to file an IND in the second half of 2022 to initiate a Phase 1 clinical trial combining CAR T cells and an oncolytic virus for the treatment of rGBM, supported by interim data from two ongoing investigator-sponsored Phase 1 clinical trials evaluating two clinical candidates, MB-101 (IL13Rα2-targeted CAR T cell therapy licensed from City of Hope) and MB-108 (C134 oncolytic virus licensed from Nationwide Children's Hospital). The data are from a late-breaking poster presented at the AACR Annual Meeting 2022. Preclinical data also presented support the safety of administering these two therapies sequentially to optimize treatment in a regimen designated as MB-109.
- In May 2022, Mustang announced that MB-106 CD20-targeted CAR T therapy data were selected for an oral presentation at EHA2022 taking place June 9 – 12 in Vienna. Dr. Mazyar Shadman of Fred Hutch will present updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL. A copy of the abstract can be viewed online through the EHA2022 website here.

- In May 2022, Mustang announced that interim Phase 1/2 data on MB-107, Mustang's lentiviral gene therapy for the treatment of XSCID, also known as bubble boy disease, in newly diagnosed infants under the age of two, were selected for an oral presentation during the Clinical Trials Spotlight Symposium at the ASGCT 25th Annual Meeting taking place May 16-19, 2022, both virtually and in Washington, D.C. The presentation will include updated data from a multicenter Phase 1/2 clinical trial for XSCID in newly diagnosed infants under the age of two at St. Jude Children's Research Hospital, UCSF Benioff Children's Hospital in San Francisco and Seattle Children's Hospital. The abstract can be viewed on the meeting websitehere.
- In the second half of 2022, Mustang expects to enroll the first patient in a pivotal multicenter Phase 2 clinical trial under Mustang's IND to evaluate MB-107, a lentiviral gene therapy for the treatment of infants under the age of two with XSCID.
- Mustang filed an IND application in December 2021 for its pivotal multicenter Phase 2 clinical trial of MB-207, a lentiviral gene therapy for the treatment of patients with XSCID who have been previously treated with hematopoietic stem cell transplantation ("HSCT") and for whom re-treatment is indicated. The trial is currently on hold pending CMC clearance from the FDA and, based on feedback from the Agency, Mustang Bio expects to enroll the first patient in a pivotal multicenter Phase 2 clinical trial in the first quarter of 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 is registered under the Securities Exchange Act of 1934, as amended, and 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.

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

	March 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 122,216	$ 109,618
Other receivables - related party	32	50
Prepaid expenses and other current assets	1,905	2,038
Total current assets	124,153	111,706
Property, plant and equipment, net	8,468	9,025
Fixed assets - construction in process	2,043	2,027
Restricted cash	1,000	1,000
Other assets	286	362
Operating lease right-of-use asset, net	1,011	1,050
Total Assets	**$ 136,961**	**$ 125,170**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 9,615	$ 9,744
Payables and accrued expenses - related party	811	723
Operating lease liabilities - short-term	358	348
Total current liabilities	**10,784**	**10,815**
Deferred income	270	270
Note payable, long-term (net of discount of $4,064 and nil as of March 31, 2022 and December 31, respectively)	26,986	—
Operating lease liabilities - long-term	1,590	1,685
Total Liabilities	**39,630**	**12,770**
Commitments and Contingencies		
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 March 31, 2022 and December 31, 2021, respectively	—	—
Common Stock ($0.0001 par value), 150,000,000 and 125,000,000 shares authorized as of March 31, 2022 and December 31, 2021, respectively		
Class A common shares, 845,385 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	—	—
Common shares, 100,287,838 and 93,582,991 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	10	9
Common stock issuable, 27,393 and 2,536,607 shares as of March 31, 2022 and December 31, 2021, respectively	27	4,329
Additional paid-in capital	368,933	359,906
Accumulated deficit	(271,639)	(251,844)
Total Stockholders' Equity	**97,331**	**112,400**
Total Liabilities and Stockholders' Equity	**$ 136,961**	**$ 125,170**

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

	For the three months ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 16,289	$ 11,618
General and administrative	3,349	3,469
Total operating expenses	19,638	15,087
Loss from operations	(19,638)	(15,087)
Other income (expense)		
Interest income	73	134
Interest expense	(230)	(4)
Total other income (expense)	(157)	130
Net Loss	**$ (19,795)**	**$ (14,957)**
Net loss per common share outstanding, basic and diluted	$ (0.20)	$ (0.19)
Weighted average number of common shares outstanding, basic and diluted	97,914,916	80,466,049