
**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 23, 2022**

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 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 March 23, 2022, 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, 2021. 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
<u>99.1</u> 104	<u>Press release issued by Mustang Bio, Inc., dated March 23, 2022.</u> 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 23, 2022

Mustang Bio, Inc.
(Registrant)

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



Mustang Bio Reports Full-Year 2021 Financial Results and Recent Corporate Highlights

Worcester, MA – March 23, 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 full year ended December 31, 2021.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “In 2021, we continued to make great strides in advancing our cell and gene therapy programs. Notably, the U.S. Food and Drug Administration (“FDA”) approved two Mustang Investigational New Drug (“IND”) applications, the first to initiate a pivotal multicenter Phase 2 clinical trial to evaluate MB-107, a lentiviral gene therapy for the treatment of infants under the age of two with X-linked severe combined immunodeficiency (“XSCID”), and the second to initiate a multicenter Phase 1/2 clinical trial investigating the safety and efficacy of MB-106, a CD20-targeted autologous CAR T cell therapy for relapsed or refractory B-cell non-Hodgkin lymphomas (“B-NHL”) and chronic lymphocytic leukemia (“CLL”). Additionally, we received a \$2 million grant from the National Cancer Institute to partially fund our MB-106 Phase 2 clinical trial. Interim data from the ongoing Phase 1/2 clinical trial of MB-106 presented at the 63rd American Society of Hematology Annual Meeting (“ASH2021”) by our collaborators at Fred Hutchinson Cancer Research Center (“Fred Hutch”) showed a 95% overall response rate, 65% complete response rate and favorable safety profile. We also expanded our product portfolio by executing an exclusive license agreement with Leiden University Medical Centre for a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID and enhanced our CAR T program with an exclusive license agreement with Mayo Clinic for a novel technology to create *in vivo* CAR T cells that has the potential to transform the administration of CAR T therapies and be used as an off-the-shelf therapy.”

Dr. Litchman continued, “We anticipate another productive year in 2022, with several Mustang IND clinical trial initiations and data updates from our ongoing clinical programs at prominent medical conferences. In February, City of Hope presented Phase 1 data on MB-105, our prostate stem cell antigen (“PSCA”) CAR T-cell therapy for the 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 to treat patients with mCRPC. In April, our collaborators at Fred Hutch will present interim Phase 1/2 clinical trial data on MB-106 at the 2022 Tandem Meetings I Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy (“ASTCT”) and Center for International Blood & Marrow Transplant Research (“CIBMTR”) which show its compelling clinical activity and favorable safety profile. In the first half of 2022 we anticipate enrolling the first patient in Mustang’s multicenter Phase 1/2 clinical trial to evaluate MB-106, and in the second half of 2022 we expect to enroll the first patient in Mustang’s multicenter pivotal Phase 2 clinical trial to evaluate MB-107. We also plan to advance additional Mustang clinical candidates, including filing an IND for MB-109 (MB-101 autologous IL13Rα2-directed CAR T cells + MB-108 oncolytic virus) for the treatment of glioblastoma. With this steady progress across our clinical programs, and with our robust pipeline and strong cash position following completion of the debt facility with Runway Growth Capital, Mustang is poised to continue its success building an integrated cell and gene therapy company.”

Financial Results:

- As of December 31, 2021, Mustang’s cash and cash equivalents and restricted cash totaled \$110.6 million, compared to \$98.8 million as of December 31, 2020, an increase of \$11.8 million year-to-date.
- Research and development expenses were \$49.9 million for the year ended December 31, 2021. This compares to \$37.2 million for 2020. Non-cash, stock-based compensation expenses included in research and development were \$2.3 million for the year ended December 31, 2021, compared to \$1.4 million for 2020.
- Research and development expenses from license acquisitions totaled \$5.8 million for the year ended December 31, 2021, compared to \$10.1 million for 2020. Non-cash, stock-based compensation expenses included in research and development – licenses acquired were \$4.2 million for the year ended December 31, 2021, compared to \$7.6 million for 2020.
- General and administrative expenses were \$11.0 million for the year ended December 31, 2021. This compares to \$9.5 million for 2020. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$2.9 million for the year ended December 31, 2021, compared to \$4.0 million for 2020.
- Net loss attributable to common stockholders was \$66.4 million, or \$0.76 per share, for the year ended December 31, 2021, compared to a net loss attributable to common stockholders of \$60.0 million, or \$1.14 per share, for 2020.

2021 and Recent Corporate Highlights:

- In February 2021, Mustang announced encouraging MB-107 and MB-207 clinical updates from its X-linked severe combined immunodeficiency (“XSCID”) investigator IND trials, as well as additional consistent safety and efficacy data. In the second half of 2022, Mustang expects to enroll the first patient in a pivotal multicenter Phase 2 clinical trial under Mustang Bio’s IND to evaluate MB-107, a lentiviral gene therapy for the treatment of infants under the age of two with XSCID, also known as bubble boy disease. 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 a hematopoietic stem cell transplantation (“HSCT”) and for whom re-treatment is indicated. The trial is currently on hold pending CMC clearance from FDA and, based on feedback from the Agency, Mustang expects to enroll the first patient in a pivotal multicenter Phase 2 clinical trial in the first quarter of 2023.
- In May 2021, Mustang announced that the FDA approved its IND application to initiate a multicenter Phase 1/2 clinical trial investigating the safety and efficacy of MB-106, a CD20-targeted autologous CAR T cell therapy for relapsed or refractory B-NHL and CLL. Mustang intends to dose the first patient in that trial in the first half of 2022.
- Also in May 2021, Mustang announced that the first patient was dosed at City of Hope in a clinical trial to establish the safety and feasibility of administering MB-101 (autologous IL13Rα2-directed CAR T cells) to patients with leptomeningeal brain tumors (e.g., glioblastoma, ependymoma or medulloblastoma).
- In June 2021, Mustang announced that MB-106 CD20-targeted CAR T cell therapy data were presented at the European Hematology Association 2021 Virtual Congress. Dr. Mazyar Shadman of Fred Hutch presented updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL, which showed a favorable safety profile and compelling clinical activity, with a 93% overall response rate and 67% complete response rate in patients treated with a modified cell manufacturing process.
- Also in June 2021, Mustang hosted a key opinion leader webinar featuring a presentation from Dr. Shadman, who discussed interim results from the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 CD20-targeted CAR T for B-NHL and CLL.
- Additionally in June 2021, Mustang announced that it was one of 28 recipients awarded tax incentives from the Massachusetts Life Sciences Center. The \$300,000 tax incentive amount that Mustang was awarded was based on a hiring commitment of 20 net new full-time equivalent employees for calendar year 2021 and retaining that headcount level through 2025.

- In August 2021, Mustang announced that the European Medicines Agency granted Priority Medicines (“PRIME”) designation to MB-107, a lentiviral gene therapy for the treatment of XSCID in newly diagnosed infants.
 - Also in August 2021, Mustang announced an exclusive license agreement with Mayo Clinic for a novel technology to create *in vivo* CAR T cells 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.
 - In October 2021, Christine Brown, Ph.D., Deputy Director, T Cell Therapeutics Research Laboratory and The Heritage Provider Network Professor in Immunotherapy at City of Hope, presented updated Phase 1 clinical data regarding MB-101 (IL13Ra2-targeted CAR T cells) for the treatment of glioblastoma at two scientific conferences, the First Annual Conference on CNS Clinical Trials, co-sponsored by the Society for Neuro-Oncology and American Society of Clinical Oncology, and the American Association for Cancer Research Virtual Special Conference: Brain Cancer.
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- In November 2021, Mustang announced the execution of an exclusive license agreement with Leiden University Medical Centre for a first-in-class *in vivo* lentiviral gene therapy for the treatment of RAG1-SCID.
- Also in November 2021, Mustang announced that it was awarded a grant of approximately \$2 million from the National Cancer Institute of the National Institutes of Health. This two-year award will partially fund the Mustang-sponsored multicenter trial to assess the safety, tolerability and efficacy of MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell NHL or CLL.
- In December 2021, Mustang announced that MB-106 data were presented at ASH2021. Dr. Shadman of Fred Hutch presented updated interim data showing a 95% overall response rate, 65% complete response rate and favorable safety profile from the ongoing Phase 1/2 clinical trial for B-NHL and CLL. A copy of the poster can be viewed online [here](#).
- Also in December 2021, Mustang hosted a key opinion leader webinar featuring a presentation from Dr. Shadman, who discussed interim results from the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 CD20-targeted, autologous CAR T cell therapy to treat B-NHL and CLL. A replay of the webinar can be found [here](#).
- Additionally in December 2021, Mustang was added to the NASDAQ Biotechnology Index® (NASDAQ: NBI).
- In January 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 selected for a poster presentation at the 2022 Tandem Meetings I Transplantation & Cellular Therapy Meetings of the ASTCT and CIBMTR, rescheduled to take place April 23-26, 2022, in Salt Lake City, Utah. A copy of the abstract can be viewed on the meeting website [here](#).
- 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 will be 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 results indicated that PSCA-CAR T-cell therapy is feasible in patients with mCRPC with dose limiting toxicity (“DLT”) of cystitis and show 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 can proceed in the trial.
- In March 2022, Mustang completed a \$75 million long-term debt facility with Runway Growth Capital LLC (“Runway”).
- Also in March 2022, Mustang announced that an abstract reporting on Phase 1 trials being conducted at the University of Alabama at Birmingham (UAB) and City of Hope of Mustang Bio’s exclusively licensed oncolytic viral and CAR T-cell therapies for the treatment of patients with glioblastoma (GBM) was selected as a late-breaking poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2022, taking place April 8 – 13, 2022, in New Orleans, Louisiana. The abstract will also be published in the online *Proceedings of the AACR*.

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 may contain “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 include, but are not limited to, any statements relating to our growth strategy and product development programs 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 SEC filings. 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 Contacts:

Jaclyn Jaffe and William Begien
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

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

	December 31, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 109,618	\$ 97,804
Other receivables - related party	50	15
Prepaid expenses and other current assets	2,038	1,715
Total current assets	111,706	99,534
Property, plant and equipment, net	9,025	7,529
Fixed assets - construction in process	2,027	499
Restricted cash	1,000	1,000
Other assets	362	250
Operating lease right-of-use asset, net	1,050	1,088
Total Assets	\$ 125,170	\$ 109,900
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 9,744	\$ 8,747
Payables and accrued expenses - related party	723	490
Operating lease liabilities - short-term	348	278
Total current liabilities	10,815	9,515
Deferred income	270	—
Operating lease liabilities - long-term	1,685	1,950
Total Liabilities	12,770	11,465
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 December 31, 2021 and 2020, respectively	—	—
Common Stock (\$0.0001 par value), 150,000,000 and 125,000,000 shares authorized as of December 31, 2021 and 2020, respectively	—	—
Class A common shares, 845,385 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Common shares, 93,582,991 and 70,920,693 shares issued and outstanding as of December 31, 2021 and 2020, respectively	9	7
Common stock issuable, 2,536,607 and 2,103,122 shares as of December 31, 2021 and 2020, respectively	4,329	7,939
Additional paid-in capital	359,906	275,963
Accumulated deficit	(251,844)	(185,474)
Total Stockholders' Equity	112,400	98,435
Total Liabilities and Stockholders' Equity	\$ 125,170	\$ 109,900

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

	For the year ended December 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 49,864	\$ 37,237
Research and development – licenses acquired	5,842	10,064
General and administrative	11,017	9,505
Total operating expenses	66,723	56,806
Loss from operations	(66,723)	(56,806)
Other income (expense)		
Interest income	368	708
Interest expense	(15)	(3,917)
Total other income (expense)	353	(3,209)
Net Loss	\$ (66,370)	\$ (60,015)
Net loss per common share outstanding, basic and diluted	\$ (0.76)	\$ (1.14)
Weighted average number of common shares outstanding, basic and diluted	87,885,235	52,588,781