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 24, 2021**

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-2b 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).

Emerging growth company ☒

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 24, 2021, 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, 2020. 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 March 24, 2021.
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: March 24, 2021

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

Exhibit 99.1

Mustang Bio Reports Full-Year 2020 Financial Results and Recent Corporate Highlights

New York, NY – March 24, 2021 – 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, 2020.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We are excited by the progress across our cell and gene therapy programs in 2020.Notably, MB-106 (CD20-targeted, autologous CAR T cell therapy) data were presented at the 62nd American Society of Hematology ("ASH") Annual Meeting which showed a favorable safety profile and clinical activity, with an 89% overall response rate and 44% complete response rate in patients with relapsed or refractory B-cell non-Hodgkin lymphomas who were treated with the modified cell manufacturing process. In August, we initiated an open-label, multicenter Phase 1/2 clinical trial to evaluate the safety and efficacy of MB-102 (CD123-targeted CAR T cell therapy) in patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm ("BPDCN"). In October, initial Phase 1 data on MB-105, a PSCA-targeted CAR T cell therapy administered systemically to patients with PSCA-positive metastatic castration-resistant prostate cancer ("mCRPC"), demonstrated a 94% reduction in prostate-specific antigen, near complete reduction of measurable soft tissue metastasis by computerized tomography, and improvement in bone metastases by magnetic resonance imaging in a 73-year-old male patient with PSCA-positive mCRPC who failed eight prior therapies."

Dr. Litchman continued, "In 2021, we anticipate multiple potential data disclosures from our collaborators' clinical trials, and we plan to have four open Mustang Investigational New Drug ("IND") applications. We look forward to advancing our lentiviral gene therapy clinical program for the treatment of X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease. In the second quarter, we plan to begin enrollment on our pivotal multicenter Phase 2 trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two and submit an IND application for a pivotal multicenter Phase 2 trial of MB-207 for the treatment of patients with XSCID who were previously treated with hematopoietic stem cell transplant ("HSCT") and for whom re-treatment is indicated. With a robust pipeline of therapies addressing highly challenging diseases, world-class R&D collaborators, a state-of-the-art cell processing facility and an experienced team, I believe we are very well positioned to continue building a fully integrated cell and gene therapy company."

Financial Results:

- As of December 31, 2020, Mustang's cash and cash equivalents and restricted cash totaled $98.8 million, compared to $62.4 million as of December 31, 2019, an increase of $36.4 million year-to-date.
- Research and development expenses were $37.2 million for the year ended December 31, 2020. This compares to $30.0 million for 2019. Non-cash, stock-based compensation expenses included in research and development were $1.4 million for the year ended December 31, 2020, compared to $0.9 million for 2019.
- Research and development expenses from license acquisitions totaled $10.1 million for the year ended December 31, 2020, compared to $6.3 million for 2019. Non-cash, stock-based compensation expenses included in research and development – licenses acquired were $7.6 million for the year ended December 31, 2020, compared to $4.9 million for 2019.

- General and administrative expenses were $9.5 million for the year ended December 31, 2020. This compares to $9.6 million for 2019. Non-cash, stock-based compensation expenses included in general and administrative expenses were $4.0 million for the year ended December 31, 2020, compared to $3.4 million for 2019.
- Net loss attributable to common stockholders was $60.0 million, or $1.14 per share, for the year ended December 31, 2020, compared to a net loss attributable to common stockholders of $46.4 million, or $1.29 per share, for 2019.

2020 and Recent Corporate Highlights:

- In February 2020, Mustang announced that the first subject treated with the modified MB-106 (CD20-targeted, autologous CAR T cell therapy) manufacturing process, developed in collaboration between Mustang Bio and the Fred Hutchinson Cancer Research Center ("Fred Hutch"), achieved a complete response at the lowest starting dose in an ongoing Phase 1/2 clinical trial. The trial is evaluating the safety and efficacy of MB-106 in subjects with relapsed or refractory B-cell non-Hodgkin lymphomas and chronic lymphocytic leukemia.
- In April 2020, Mustang announced that the European Medicines Agency ("EMA") granted Advanced Therapy Medicinal Product ("ATMP") classification to MB-107, a lentiviral gene therapy for the treatment of newly diagnosed infants with XSCID.
- In May 2020, Mustang submitted an IND with the U.S. Food and Drug Administration ("FDA") to initiate a pivotal multicenter Phase 2 trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two. The trial is expected to enroll 10 patients who, together with 15 patients enrolled in the current multicenter trial led by St. Jude Children's Research Hospital, will be compared with 25 matched historical control patients who have undergone HSCT. The primary efficacy endpoint will be event-free survival.
- Also in May 2020, City of Hope presented two posters pertaining to MB-104, an innovative CS1 CAR T cell therapy, at the virtual 23rd Annual Meeting of the American Society of Gene & Cell Therapy.
- In June 2020, Mustang raised gross proceeds of approximately $37.2 million in an underwritten public offering of common stock, including the exercise of the underwriter's option.
- In August 2020, Mustang announced that the FDA granted Rare Pediatric Disease Designations to MB-107 for the treatment of XSCID in newly diagnosed infants and to MB-207 for the treatment of XSCID in patients who were previously treated with HSCT and for whom re-treatment is indicated.
- In September 2020, Mustang announced that the FDA granted Orphan Drug Designations to MB-107 for the treatment of XSCID in newly diagnosed infants and to MB-207 for the treatment of XSCID in patients who were previously treated with HSCT and for whom re-treatment is indicated.

- In October 2020, Mustang announced that the first patient was dosed in a Mustang-sponsored, open-label, multicenter Phase 1/2 clinical trial to evaluate the safety and efficacy of MB-102 (CD123-targeted CAR T cell therapy) in patients with relapsed or refractory BPDCN.

- Also in October 2020, Mustang announced that initial 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 virtual 27th Annual Prostate Cancer Foundation Scientific Retreat. A 73-year-old male patient with PSCA-positive mCRPC was treated with MB-105 and lymphodepletion (a standard CAR T pre-conditioning regimen) after failing eight prior therapies. On day 28 of the patient's treatment, MB-105 demonstrated a 94% reduction in prostate-specific antigen, near complete reduction of measurable soft tissue metastasis by computerized tomography, and improvement in bone metastases by magnetic resonance imaging.

- Additionally, in October 2020, Mustang in-licensed LentiBOOST™ technology from SIRION Biotech GmbH for the development of MB-207.

- In November 2020, Mustang signed an agreement with Minaris Regenerative Medicine GmbH to enable technology transfer and GMP clinical manufacturing of the MB-107 lentiviral gene therapy program for the treatment of XSCID in Europe.

- Also in November 2020, Mustang announced that the European Commission issued a positive opinion on its application for Orphan Drug Designation for MB-107.

- In December 2020, Mustang announced positive interim Phase 1/2 data on MB-106 for patients with relapsed or refractory B-cell non-Hodgkin lymphomas, which were presented at the 62nd ASH Annual Meeting. The data demonstrated an extremely favorable safety profile and clinical activity with an 89% overall response rate and 44% complete response rate over 4 dose levels in 9 patients treated with the modified cell manufacturing process.

- Also in December 2020, Mustang announced that a Phase 1 single-center, two-arm clinical trial was initiated to establish the safety and feasibility of administering MB-101 to patients with leptomeningeal brain tumors (e.g., glioblastoma, ependymoma or medulloblastoma).

- In February 2021, Mustang announced encouraging MB-107 and MB-207 clinical updates from its investigator-IND XSCID trials, as well as additional consistent safety and efficacy data. On January 28, 2021, the FDA removed a CMC hold on the MB-107 Phase 2 clinical trial IND application after reviewing a comprehensive CMC package that was submitted by Mustang in late December 2020. The company expects to enroll the first patient in this pivotal multicenter trial in the second quarter of 2021 and is targeting topline data from the trial in the second half of 2022. The company also expects to file an IND in the second quarter of 2021 for its pivotal multicenter Phase 2 clinical trial of MB-207.

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 a lentiviral gene therapy for XSCID. 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.

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

	December 31, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 97,804	$ 61,413
Other receivables - related party	15	19
Prepaid expenses and other current assets	1,715	1,631
Total current assets	99,534	63,063
Property, plant and equipment, net	7,529	6,779
Fixed assets - construction in process	499	1,157
Restricted cash	1,000	1,000
Other assets	250	250
Operating lease right-of-use asset, net	1,088	1,196
Total Assets	**$ 109,900**	**$ 73,445**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 8,747	$ 5,668
Payables and accrued expenses - related party	490	596
Short-term notes payable	—	1,250
Operating lease liabilities - short-term	278	257
Total current liabilities	**9,515**	**7,771**
Notes payable	—	12,179
Operating lease liabilities - long-term	1,950	1,843
Total Liabilities	**11,465**	**21,793**
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, 2020 and December 31, 2019, respectively	—	—
Common Stock ($0.0001 par value), 125,000,000 shares authorized		
Class A common shares, 845,385 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	—	—
Common shares, 70,920,693 and 39,403,519 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	7	4
Common stock issuable, 2,103,122 and 1,206,667 shares as of December 31, 2020 and December 31, 2019, respectively	7,939	4,923
Additional paid-in capital	275,963	172,184
Accumulated deficit	(185,474)	(125,459)
Total Stockholders' Equity	**98,435**	**51,652**
Total Liabilities and Stockholders' Equity	**$ 109,900**	**$ 73,445**

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

	For the year ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 37,237	$ 30,042
Research and development – licenses acquired	10,064	6,273
General and administrative	9,505	9,570
Total operating expenses	56,806	45,885
Loss from operations	(56,806)	(45,885)
Other income (expense)		
Interest income	708	1,263
Interest expense	(3,917)	(1,767)
Total other income (expense)	(3,209)	(504)
Net Loss	**$ (60,015)**	**$ (46,389)**
Net loss per common share outstanding, basic and diluted	$ (1.14)	$ (1.29)
Weighted average number of common shares outstanding, basic and diluted	52,588,781	36,061,811