
**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 6, 2020**

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 November 6, 2020, Mustang Bio, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 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
<u>99.1</u>	<u>Press release issued by Mustang Bio, Inc., dated November 6, 2020.</u>
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 6, 2020

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



Mustang Bio Reports Third Quarter 2020 Financial Results and Recent Corporate Highlights

Worcester, MA – November 6, 2020 – 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, 2020.

“Mustang had an eventful third quarter on the regulatory front, as the U.S. Food and Drug Administration (“FDA”) granted Rare Pediatric and Orphan Drug Designations to both of our gene therapy product candidates for the treatment of X-linked severe combined immunodeficiency (“XSCID”), MB-107, for newly diagnosed infants, and MB-207, for patients previously treated with hematopoietic stem cell transplantation (“HSCT”) and for whom re-treatment is indicated,” said Manuel Litchman, M.D., President and Chief Executive Officer of Mustang.

Dr. Litchman continued, “We are also pleased to report progress across our CAR T cell therapy programs during the third quarter and subsequent period. Most importantly, as recently reported, we have observed compelling efficacy without CAR T related toxicity in the first 4 non-Hodgkin lymphoma patients treated with MB-106, a CD20-targeted CAR T cell therapy, following a major revision in the cell manufacturing process at the Fred Hutch Cancer Research Center (“Fred Hutch”). We also dosed the first patient in a Phase 1/2 clinical trial of MB-102, a CD123-targeted CAR T cell therapy, under our own Investigational New Drug (“IND”) application for relapsed or refractory blastic plasmacytoid dendritic cell neoplasm, acute myeloid leukemia and high-risk myelodysplastic syndrome. Finally, we are encouraged by the significant response to MB-105, a prostate stem cell antigen (“PSCA”)–targeted CAR T therapy, reported by City of Hope in a 73-year-old patient with PSCA-positive metastatic castrate-resistant prostate cancer. This patient, who had failed eight prior therapies, experienced a 94 percent reduction in prostate-specific antigen, with a near complete reduction of measurable soft tissue metastasis by computerized tomography and improvement in bone metastases by magnetic resonance imaging. We look forward to achieving additional milestones in the coming months, as we expect to disclose additional promising clinical data from our MB-106 program at the American Society of Hematology (“ASH”) Annual Meeting next month. In addition, next quarter we expect to enroll the first patient on our pivotal MB-107 lentiviral gene therapy trial for newly diagnosed infants with XSCID and to file an IND for our pivotal MB-207 lentiviral gene therapy trial for previously transplanted patients with XSCID.”

Recent Corporate Highlights:

- In August 2020, Mustang announced that the FDA granted Rare Pediatric Disease Designation to MB-107, a lentiviral gene therapy for the treatment of XSCID, also known as bubble boy disease, in newly diagnosed infants and to MB-207, a lentiviral gene therapy for the treatment of patients with XSCID who have been previously treated with HSCT and for whom re-treatment is indicated.
 - In September 2020, the FDA granted Orphan Drug Designation to MB-107 for the treatment of XSCID in newly diagnosed infants and to MB-207 for the treatment of patients with XSCID who have been previously treated with HSCT and for whom re-treatment is indicated.
 - In October 2020, Mustang announced that the first patient had been dosed in a company-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 blastic plasmacytoid dendritic cell neoplasm (BPDCN), acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (hrMDS).
 - In October 2020, Mustang licensed LentiBOOST™ technology from SIRION Biotech GmbH for the development of MB-207.
 - In October 2020, City of Hope presented initial Phase 1 data on MB-105, a PSCA-targeted CAR T administered systemically to patients with PSCA-positive mCRPC, at the virtual 27th Annual Prostate Cancer Foundation Scientific Retreat.
 - Earlier this month, 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 non-Hodgkin lymphomas, were selected for a poster presentation at the 62nd ASH Annual Meeting. A link to the abstract can be found [here](#).
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Financial Results:

- As of September 30, 2020, the company's cash, cash equivalents and restricted cash totaled \$76.3 million, compared to \$86.4 million as of June 30, 2020, and \$62.4 million as of December 31, 2019.
- Research and development expenses were \$8.0 million for the third quarter of 2020. This compares to \$7.3 million for the third quarter of 2019. Non-cash, stock-based compensation expenses included in research and development were \$0.3 million for the third quarter of 2020, compared to \$0.7 million for the third quarter of 2019.
- Research and development expenses from license acquisitions totaled \$0.3 million for the third quarter of 2020, compared to \$0.7 million for the third quarter of 2019.
- General and administrative expenses were \$2.2 million for the third quarter of 2020. This compares to \$2.0 million for the third quarter of 2019. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$0.3 million for the third quarter of 2020, compared to \$0.4 million for the third quarter of 2019.
- Net loss attributable to common stockholders was \$13.0 million, or \$0.23 per share, for the third quarter of 2020, compared to a net loss attributable to common stockholders of \$10.2 million, or \$0.25 per share, for the third quarter of 2019.

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.
Condensed Balance Sheets
(\$ in thousands, except for share and per share amounts)

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 75,251	\$ 61,413
Other receivables - related party	37	19
Prepaid expenses and other current assets	344	1,631
Total current assets	75,632	63,063
Property, plant and equipment, net	7,250	6,779
Fixed assets - construction in process	821	1,157
Restricted cash	1,000	1,000
Other assets	250	250
Operating lease right-of-use asset, net	1,115	1,196
Total Assets	\$ 86,068	\$ 73,445
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Short-term notes payable	\$ —	\$ 1,250
Accounts payable and accrued expenses	7,054	5,668
Payables and accrued expenses - related party	305	596
Operating lease liabilities - short-term	271	257
Total current liabilities	7,630	7,771
Notes payable	—	12,179
Operating lease liabilities - long-term	2,022	1,843
Total Liabilities	9,652	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 September 30, 2020 and December 31, 2019, respectively	—	—
Common Stock (\$0.0001 par value), 85,000,000 shares authorized		
Class A common shares, 845,385 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	—	—
Common shares, 60,164,539 and 39,403,519 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	5	4
Common stock issuable, 65,810 and 1,206,667 shares as of September 30, 2020 and December 31, 2019, respectively	235	4,923
Additional paid-in capital	241,042	172,184
Accumulated deficit	(164,866)	(125,459)
Total Stockholders' Equity	76,416	51,652
Total Liabilities and Stockholders' Equity	\$ 86,068	\$ 73,445

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

	<u>For the three months ended September 30,</u>		<u>For the nine months ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating expenses:				
Research and development	\$ 7,987	\$ 7,309	\$ 27,131	\$ 21,092
Research and development – licenses acquired	287	700	1,837	1,350
General and administrative	2,153	1,987	7,100	7,520
Total operating expenses	<u>10,427</u>	<u>9,996</u>	<u>36,068</u>	<u>29,962</u>
Loss from operations	<u>(10,427)</u>	<u>(9,996)</u>	<u>(36,068)</u>	<u>(29,962)</u>
Other income (expense)				
Interest income	162	406	567	945
Interest expense	(2,687)	(578)	(3,906)	(1,163)
Total other income (expense)	<u>(2,525)</u>	<u>(172)</u>	<u>(3,339)</u>	<u>(218)</u>
Net Loss	<u>\$ (12,952)</u>	<u>\$ (10,168)</u>	<u>\$ (39,407)</u>	<u>\$ (30,180)</u>
Net loss per common share outstanding, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.25)</u>	<u>\$ (0.82)</u>	<u>\$ (0.87)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>57,253,715</u>	<u>39,875,209</u>	<u>48,116,158</u>	<u>34,752,938</u>