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): February 26, 2020

Y-MABS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38650**	**47-4619612**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

230 Park Avenue
Suite 3350
New York, New York 10169
(Address of principal executive offices) (Zip Code)

(646) 885-8505
(Registrant's telephone number, include area code)

N/A
(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**	**Name of each exchange on which registered:**
Common Stock, $0.0001 par value	YMAB	NASDAQ Global Select 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 8.01 Other Events

On February 26, 2020, Y-mAbs Therapeutics, Inc., (the "Company") issued a press release announcing that it has completed a positive Type B Pre-Biologics License Application meeting with the U.S. Food and Drug Administration ("FDA") regarding a potential pathway for FDA approval of omburtamab for the treatment of patients with CNS/leptomeningeal metastases from neuroblastoma. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished pursuant to Item 8.01 on this Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated February 26, 2020 issued by Y-mAbs Therapeutics, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Y-MABS THERAPEUTICS, INC.

Date: February 26, 2020

By: /s/ Thomas Gad
Thomas Gad
Founder, Chairman, President and Head of Business Development

Exhibit 99.1

Y-mAbs Announces Positive Pre-BLA Meeting with FDA for Omburtamab

New York, NY, February 26, 2020 (GLOBE NEWSWIRE) – Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB) a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer announced today that it has completed a positive Type B Pre-Biologics License Application ("Pre-BLA") meeting with the U.S. Food and Drug Administration ("FDA") regarding a potential pathway for FDA approval of omburtamab for the treatment of patients with CNS/leptomeningeal metastases from neuroblastoma.

At the pre-BLA meeting, the Company reached alignment with the FDA on an Accelerated Approval Pathway for omburtamab along with a rolling BLA submission. The Company expects to complete the rolling BLA within approximately 10 weeks.

Under omburtamab's breakthrough therapy designation ("BTD"), omburtamab qualifies for a rolling BLA submission, which allows for individual modules of the application to be submitted by the Company and reviewed by the FDA on a rolling basis, rather than waiting for all sections of the BLA application to be completed before submission. We believe the rolling application process will provide the Company with the opportunity for ongoing communications with the FDA, and, during this rolling process, the Company anticipates that it will be able to address any substantial matters raised by the FDA.

A previously announced data readout from a single-center study (Study 03-133), at Memorial Sloan Kettering Cancer Center ("MSK") where the 107 evaluable patients with CNS/leptomeningeal metastases from neuroblastoma received up to two doses of radiolabeled omburtamab, showed that patients had a median survival of 50.8 months, with the final median survival not yet being reached. The Company intends to announce the complete clinical data package later this year. In addition, the Company is planning for submission of a Marketing Authorization Application in Europe in the fourth quarter this year.

"We are very pleased with the positive outcome of the Pre-BLA meeting for omburtamab providing a clear regulatory path forward for a rolling BLA submission. We believe omburtamab to be essential in addressing substantial unmet medical needs for children suffering from high-risk neuroblastoma brain tumors," said Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer further notes, "We are pleased to firm up the timelines for the omburtamab BLA. We expect to complete submission of the BLA for naxitamab in late March and omburtamab shortly thereafter, and this execution reflects an outstanding performance of our team. We hope to see both compounds approved by the FDA later this year."

Researchers at MSK developed the omburtamab antibody, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests in the product and in Y-mAbs.

About Y-mAbs:

Y-mAbs is a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. The Company has a broad and advanced product pipeline, including two pivotal-stage product candidates—naxitamab and omburtamab—which target tumors that express GD2 and B7-H3, respectively.

Forward-Looking Statements:

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements” within the meaning of The Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about orphan drug and other regulatory approvals, clinical trial timing and plans, the achievement of clinical and commercial milestones, future financial and operating results, business strategies, market opportunities, financing, and other statements that are not historical facts. Words such as ‘‘anticipate,’’ ‘‘believe,’’ ‘‘continue,’’ ‘‘could,’’ ‘‘estimate,’’ ‘‘expect,’’ ‘‘intend,’’ ‘‘may,’’ ‘‘might,’’ ‘‘plan,’’ ‘‘potential,’’ ‘‘predict,’’ ‘‘project,’’ ‘‘should,’’ ‘‘target,’’ ‘‘would’’ and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including but not limited to: risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials including if we encounter difficulties enrolling patients in our clinical trials; the risks of delays in FDA and/or EU approval of our drug candidates or failure to receive approval; the risks related to commercializing any approved new pharmaceutical product including the rate and degree of market acceptance of our product candidates; development of our sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for our products; our inability to enter into collaboration or alliances with partners; risks associated with protection of our intellectual property rights; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 13, 2019, and in our other SEC filings. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Contact:

Y-mAbs Therapeutics, Inc.
230 Park Avenue, suite 3350
New York, NY 10169
USA

+1 646 885 8505

E-mail: info@ymabs.com