

**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 1, 2019 (October 31, 2019)**

Y-MABS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38650
(Commission
File Number)

47-4619612
(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))

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 x

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. x

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

Item 8.01. Other Events.

In the afternoon on October 31, 2019, we received an e-mail notification from the U.S. Food and Drug Administration, or FDA, that, upon their review of our omburtamab pre-Biologics License Application, or pre-BLA, meeting submission, our pre-BLA meeting with the FDA, which was originally scheduled for November 2019, has now been converted to a general guidance meeting. The FDA did not indicate a reason for this change or provide any additional information, although we are currently seeking additional information. As a result, we now expect that our rolling BLA submission for omburtamab, which we intended to commence in December 2019, will not begin until after a new pre-BLA meeting has been scheduled. Our pre-BLA meeting could still take place in 2019, or may be rescheduled for the first quarter of 2020.

We remain confident in the contents of our pre-BLA meeting submission and do not believe that this change in the timing of the pre-BLA meeting with the FDA will impact our previously disclosed and anticipated timing for our complete omburtamab BLA submission, which we still expect to complete by the end of the first quarter of 2020. As previously disclosed, we expect to have completed all required components of our anticipated BLA filing by the end of the first quarter of 2020, and expect to have the flexibility to file our BLA either via a rolling submission or via a single submission ahead of our expected completion date at the end of the first quarter of 2020. In addition, we believe that the overall commercialization timeline will not be affected.

As previously announced, in a pre-BLA meeting for naxitamab we reached alignment with the FDA on an accelerated approval pathway for naxitamab and intend to begin submission of a rolling BLA for naxitamab in November 2019. We still expect to begin submission of the rolling BLA for naxitamab in November 2019 and complete it in the first quarter of 2020.

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.

Y-MABS THERAPEUTICS, INC.

Date: November 1, 2019

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