

**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): October 28, 2022

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))

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 October 28, 2022, Y-mAbs Therapeutics, Inc., (the “Company”) issued a press release announcing the that the Oncologic Drugs Advisory Committee of the U.S. Food and Drug Administration met to review the Company’s Biological License Application for its product candidate, OMBLASTYS® (omburtamab). The committee voted 16 to 0 that the Company had not provided sufficient evidence to conclude that omburtamab improves overall survival. A copy of the press release announcing the results of the ODAC meeting is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 28, 2022, issued by Y-mAbs Therapeutics, Inc.
104	Interactive Data File (embedded within the Inline XBRL document).

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: October 28, 2022

By: /s/ Thomas Gad

Thomas Gad

Founder, Chairman, President, Interim Chief Executive Officer and Head
of Business Development & Strategy



Y-mAbs Announces Outcome of FDA Advisory Committee Meeting on Omburtamab

New York, NY, October 28, 2022 (GLOBE NEWSWIRE) – Y-mAbs Therapeutics, Inc. (the “Company” or “Y-mAbs”) (Nasdaq: YMAB) a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer, today announced the outcome of the meeting of the U.S. Food and Drug Administration (“FDA”) Oncologic Drugs Advisory Committee (“ODAC”), which reviewed investigational ¹³¹I-omburtamab (“omburtamab”) for the treatment of CNS/leptomeningeal metastasis from neuroblastoma. The committee voted 16 to 0 that the Company had not provided sufficient evidence to conclude that omburtamab improves overall survival.

“We are disappointed by the outcome of today’s meeting, as patients with CNS/leptomeningeal metastasis from neuroblastoma are in need of effective and safe treatment options,” said Thomas Gad, President, and Interim Chief Executive Officer. “Y-mAbs is committed to working closely with the FDA on their review of the Biologic License Application (“BLA”) for omburtamab ahead of their decision. We want to thank all of the patients, caregivers, and healthcare providers who participated in the studies of this life-threatening condition.”

ODAC reviewed data from omburtamab’s clinical development program with a focus on study 03-133 (a pivotal phase 1 study) and study 101 (a pivotal phase 2 study) as well as the historical control group.

Y-mAbs BLA submission for omburtamab was accepted for Priority Review by the FDA on May 31, 2022, with a Prescription Drug User Fee Act (“PDUFA”) target date of November 30, 2022. The FDA is not bound by the Advisory Committee’s recommendations but generally takes the recommendation into consideration when making its decision.

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

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic cancer products. In addition to conventional antibodies, the Company’s technologies include bispecific antibodies generated using the Y-BiClone platform and the SADA platform. The Company’s broad and advanced product pipeline includes one FDA-approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one product candidate at the registration-stage, OMBLASTYS® (¹³¹I-omburtamab), which targets tumors that express B7-H3.



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 potential approval of omburtamab in the United States and the timing thereof; and other statements that are not historical facts. Words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “hope,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would”, “goal,” “aim,” 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 our financial condition and need for additional capital; risks associated with our development work; cost and success of our product development activities and clinical trials; the risks of delay in the timing of our regulatory submissions or failure to receive approval of our drug candidates; the risks related to commercializing any approved 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; the risks related to our dependence on third parties including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; the risks related to government regulation; risks related to market approval, risks associated with protection of our intellectual property rights; risks related to employee matters and managing growth; risks related to our common stock, risks associated with the COVID-19 pandemic, risks associated with the conflict between Russia and Ukraine and sanctions related thereto, macroeconomic conditions, including inflation and uncertain global credit and capital markets; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Annual Report on Form 10-K for the year ended December 31, 2021, our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, 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 except as required by law.

DANYELZA®, OMBLASTYS® and Y-mAbs® are registered trademarks of Y-mAbs Therapeutics, Inc.

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