# 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): December 1, 2022**

# 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 December 1, 2022, Y-mAbs Therapeutics, Inc., (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has issued a complete response letter for the Biologics License Application for the investigational medicine $^{131}$I-omburtamab for the treatment of CNS/leptomeningeal metastasis 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 December 1, 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: December 1, 2022

By: /s/ Thomas Gad

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

**Exhibit 99.1**


**Y-mAbs Announces Complete Response Letter for Omburtamab Biologics License Application**

New York, NY, December 1, 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 that the U.S. Food and Drug Administration ("FDA") has issued a complete response letter ("CRL") for the Biologics License Application ("BLA") for the investigational medicine $^{131}$I-omburtamab ("omburtamab") for the treatment of CNS/leptomeningeal metastasis from neuroblastoma.

The letter indicates that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. This is consistent with the outcome of the Oncologic Drugs Advisory Committee Meeting in October. The CRL includes a recommendation for meeting with the agency to discuss adequate and well-controlled trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile.

Y-mAbs is assessing the implications of the CRL and its plans for the omburtamab program.

"We are disappointed by the CRL but not surprised based on the outcome of the ODAC meeting on October 28. We want to express our gratitude to all the patients, their families, and investigators who have participated in our clinical trials and advocated for the advancement of omburtamab," said Thomas Gad, President, and Interim Chief Executive Officer. "While we evaluate the implications of the CRL for the future of omburtamab, we are excited about refining our focus primarily to drive growth from DANYELZA and validate our SADA platform in the clinic, with the goal of bringing innovative solutions to patients and value to our shareholders.

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® ($^{131}$I-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 our expectations with respect to the omburtamab program; our expectations with respect to increasing efforts and refining focus on DANYELZA®, our SADA platform, and the rest of our pipeline; our goal of bringing innovative solutions to patients and value to our shareholders; 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, June 30, 2022, and September 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.



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