# 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): April 18, 2023**

# 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 April 18, 2023, Y-mAbs Therapeutics, Inc., (the "Company") issued a press release announcing that a poster presentation featuring preclinical data on naxitamab, a recombinant, humanized anti-GD2 monoclonal antibody will be presented at the AACR Annual Meeting 2023, which takes place in Orlando, Florida from April 14-19, 2023. The poster, "Investigational novel humanized anti-GD2 antibody inhibits GD2-mediated immunosuppression by targeting GD2+ breast cancer stem-like cells," will be presented on April 18, 2023, from 1:30 to 5:00 pm EST. The press release further summarizes the contents of the poster presentation. A copy of the press release is attached hereto as Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated April 18, 2023, 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: April 18, 2023

By: /s/ Bo Kruse
Bo Kruse
Executive Vice President and Chief Financial Officer

**Exhibit 99.1**

**Y-mAbs Announces Presentation of Naxitamab data at AACR**

New York, NY, April 18, 2023 (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 a poster presentation featuring preclinical data on naxitamab, a recombinant, humanized anti-GD2 monoclonal antibody will be presented at the AACR Annual Meeting 2023, which takes place in Orlando, Florida from April 14-19, 2023. The poster, "Investigational novel humanized anti-GD2 antibody inhibits GD2-mediated immunosuppression by targeting GD2+ breast cancer stem-like cells," will be presented on April 18, 2023, from 1:30 to 5:00 pm EST.

The disialoganglioside GD2 has been shown to be upregulated in triple-negative breast cancer ("TNBC") and its high expression is associated with a poor prognosis. Furthermore, breast cancer stem-like cells ("BCSCs") are reported to be a major contributing factor for metastatic spread of TNBC and contribute to chemotherapy resistance, making them an important target for therapeutic intervention. Currently, there are no available therapeutic tools for targeting BCSCs. New preclinical data from M.D. Anderson Cancer Center demonstrate that TNBC with high GD2 expression inhibits immune cell infiltration and that naxitamab targets GD2+ BCSCs and may be able to inhibit the growth of BCSCs by enhancing macrophage-mediated phagocytosis, NK cell-mediated ADCC, and T cell-mediated cytotoxicity.

Y-mAbs provided naxitamab (DANYELZA) to this pre-clinical investigator sponsored study ("ISS") at M.D. Anderson Cancer Center as part of its strategy to continue to support ISS studies.

Researchers at Memorial Sloan Kettering Cancer Center ("MSK") developed DANYELZA, which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests related to the compound and Y-mAbs.

**About DANYELZA® (naxitamab-gqgk)**

DANYELZA® (naxitamab-gqgk) is indicated, in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF"), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. This indication was approved in the United States by the FDA under accelerated approval based on overall response rate and duration of response. Continued approval for this indication is contingent upon verification and description of clinical benefits in a confirmatory trial. DANYELZA® includes a Boxed Warning for serious infusion-related reactions, such as cardiac arrest and anaphylaxis, and neurotoxicity, such as severe neuropathic pain and transverse myelitis. See full Prescribing Information (https://labeling.ymabs.com/danyelza) for complete Boxed Warning and other important safety information**.**

**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, 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, statements with respect the potential of naxitamab to target GD2 and BCSCs and inhibit the growth of BCSCs by enhancing macrophage-mediated phagocytosis, NK cell-mediated ADCC, and T cell-mediated cytotoxicity, the Company's product candidates and pipeline, including with respect to the development of naxitamab 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'' 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; the risks that actual results of our restructuring plan and revised business plan will not be as expected; 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; 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, 2022 filed with the SEC 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.



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