

**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 14, 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 7.01 Regulation FD Disclosure.

On December 14, 2022, Y-mAbs Therapeutics, Inc. (the “Company”) issued a press release regarding clinical updates for the Company’s naxitamab and SADA technology programs, which will be discussed at its previously announced annual Research and Development Day. The Company will host its annual Research and Development Day in person and via conference call and live webcast at 9:00 a.m., Eastern Time, on December 14, 2022. A live audio webcast of the presentation will be available on LifeSci Events’ website at <https://lifescievents.com/event/y-mabs-therapeutics-in-person-research-development-day/>. The presentation used during the webcast will also be archived on the Company’s website under the Presentations tab under the heading “For Investors”, (<https://ir.ymabs.com/events-and-presentations/presentations>) for at least 30 days following the call.

A copy of the above-referenced press release is attached hereto as Exhibits 99.1, and are hereby incorporated by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and 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 in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing. The Company’s and LifeSci’s website and the information contained on, or that can be accessed through, such websites will not be deemed to be incorporated by reference in, and are not considered part of, this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated December 14, 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 14, 2022

By: /s/ Thomas Gad

Thomas Gad

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



Y-mAbs Announces Pipeline Update

New York, NY, December 14, 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 a clinical update for naxitamab and the Company’s SADA technology programs will be presented at the Company’s R&D event, which will take place today at 9 a.m. Eastern Time.

Investors, analysts, members of the media and the public may access the event via a live webcast. The presentation materials can be found on the Company’s website under the Presentations tab under the heading For Investors.

The Y-mAbs research and development day will feature presentations from Thomas Gad, founder, President and Interim-CEO, Vignesh Rajah, MBBS, DCH, MRCP(UK), MBA, (SVP, Chief Medical Officer at Y-mAbs), and Steen Lisby, M.D., DMSc, (SVP, Chief Scientific Officer at Y-mAbs).

SADA Technology

Dr. Lisby will discuss the Company’s SADA Technology, including announcement of the Company’s first proprietary hematological SADA construct, CD38-SADA against Non-Hodgkin’s Lymphoma (“NHL”), and an update on GD2-SADA, which is being studied in an ongoing Phase 1 clinical trial in adults with small-cell lung cancer, sarcoma, and malignant melanoma.

DANYELZA® (naxitamab-gqgk)

Dr. Rajah, will present an update on DANYELZA® (naxitamab-gqgk), including potential label expansion into osteosarcoma, and a planned multicenter Phase 2 trial in patients with newly diagnosed high-risk neuroblastoma.

“We are excited to share these new updates on both our naxitamab program and the SADA Technology. We believe that the prospects for the SADA Technology, which combines antibodies and radioactive payloads, are highly encouraging and could potentially revolutionize cancer treatments known today. We believe a CD38-SADA construct will have high potential,” said Thomas Gad, founder, President and Interim CEO. “We are redoubling our efforts and refining our focus on DANYELZA® and are pleased to be working towards advancing the program with a potential label expansion into osteosarcoma, and a planned multicenter Phase 2 trial in patients with newly diagnosed high-risk neuroblastoma.”

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 under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be 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 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, OMBLASTYS® (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 about the potential of the Company's products and product candidates, including DANYELZA® and the SADA Technology, including SADA constructs, and the potential benefits thereof; the Company's business plans and prospects; collaborations or strategic partnerships and the potential benefits thereof; the Company's business model and development, commercialization and product distribution plans; current and future clinical and pre-clinical studies and our research and development programs; potential for DANYELZA territory and label expansion, and advancement of SADA; 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 filed with the Securities and Exchange Commission (the "SEC") and in our other SEC filings, including our Quarterly Reports on Form 10-Q for the quarters ending March 31, 2022, June 30, 2022, and September 30, 2022 as well as 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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