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): May 26, 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 7.01 Regulation FD Disclosure.

On May 26, 2023, Y-mAbs Therapeutics, Inc. (the "Company") issued two press releases. The first press release announced that the Company plans to present a poster presentation featuring interim clinical data on naxitamab, a recombinant, humanized anti-GD2 monoclonal antibody, in combination with granulocyte-macrophage colony-stimulating factor, at the American Society of Clinical Oncology's annual meeting to be held June 2, 2023 through June 6, 2023, in Chicago, Illinois (the "ASCO Meeting"). The second press release announced that the Company plans to present a poster featuring the design of its Phase 1 clinical trial evaluating the Company's Self-Assembly DisAssembly Pre-targeted Radioimmunotherapy at the ASCO Meeting.

Copies of the above-referenced press releases are attached hereto as Exhibits 99.1 and 99.2, respectively, and are hereby incorporated by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 and Exhibit 99.2 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release, Announcing Presentation of Naxitamab Data at the American Society of Clinical Oncology, dated May 26, 2023, issued by Y-mAbs Therapeutics, Inc.
99.2	Press Release, Announcing Presentation of GD2-SADA Study at the American Society of Clinical Oncology, dated May 26, 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: May 26, 2023

By:/s/ Thomas Gad

Thomas Gad

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

Exhibit 99.1

Y-mAbs Announces Presentation of Naxitamab Data at ASCO

New York, NY, May 26, 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 interim clinical data on naxitamab, a recombinant, humanized anti-GD2 monoclonal antibody, in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF") will be presented at the American Society of Clinical Oncology ("ASCO") Annual Meeting to be held June 2-6, 2023, in Chicago, Illinois.

Patients with high-risk neuroblastoma ("HR-NB") commonly develop metastases in the bone and/or bone marrow. Approximately 15% of HR-NB patients are refractory to induction therapy and approximately 50% will relapse. The ongoing Phase 2 Trial 201 (NCT03363373) evaluates naxitamab in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF") in patients with relapsed or refractory HR-NB with residual disease limited to bone and/or bone marrow. Patients with disease in soft tissues or actively progressing disease were excluded from the trial.

Curie Score ("CS") is a semi-quantitative scoring system used to assess the extent of bone metastases and treatment response. Higher CS indicates more extensive bone involvement and may suggest a poorer prognosis.

An interim analysis of Trial 201 (data cutoff December 31, 2021) included 52 patients in the efficacy group and 74 patients in the safety group. The efficacy analyses included the overall response rate (ORR; complete response or partial response) and the reduction in CS by baseline disease status, i.e., refractory or relapsed disease. Clinically meaningful ORRs and reductions in CS were seen in patients regardless of baseline disease status. The ORR was 58% in patients with refractory disease and 42% in patients with relapsed disease. Furthermore, from a mean baseline CS of 5.5 and 5.7 in the refractory and relapsed subgroups (range 1-20 across the two subgroups), the mean change to end of naxitamab treatment was -4.2 and -1.2, respectively. Maximum reductions in CS for relapsed and refractory subgroups were -17 and -18, respectively. Overall, the most common naxitamab related serious adverse events were hypotension, pain, urticaria, and bronchospasm. Baseline CS did not affect the safety profile of naxitamab. Patients with refractory disease had a lower frequency of serious naxitamab related adverse events compared to patients with relapsed disease.

Naxitamab was licensed by the Company from Memorial Sloan Kettering ("MSK"). MSK has institutional financial interests in the compound.

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, 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 treat high-risk neuroblastoma, the safety profile of naxitamab, expectations with respect to Trial 201, including with respect to results and timing, the Company’s product candidates and pipeline, including with respect to the development of naxitamab, the Company’s presentation at ASCO, 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, our Quarterly Report on Form 10-Q for the quarter ending March 31, 2023 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.

Contact:

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Exhibit 99.2

Y-mAbs Announces Presentation of GD2-SADA Study at ASCO

New York, NY, May 26, 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 the design of its Phase 1 clinical trial, evaluating the Company's Self-Assembly DisAssembly Pre-targeted Radioimmunotherapy ("SADA Y-PRIT") Theranostic Platform for the treatment of certain GD2-positive solid tumors, including small cell lung cancer, sarcoma and malignant melanoma will be presented at the American Society of Clinical Oncology ("ASCO") Annual Meeting to be held June 2-6, 2023 in Chicago, Illinois.

The Phase 1 dose-escalation, single-arm, open-label, non-randomized, multicenter trial (NCT05130255) has three parts: Part A will explore dose-finding for the GD2-SADA molecule and testing of dosing intervals between the protein and the 177Lu-DOTA payload; Part B will determine the optimal dose of 177Lu-DOTA; and Part C will evaluate safety and initial signals of efficacy using repeated dosing. Dose escalation is based two patients in cohort 1 and 2, followed by a classical 3+3 design. The study is actively enrolling, and the Company expects Parts A, B, and C will include 18, 12, and 32 patients, respectively, across 6-10 U.S. sites.

The GD2-SADA construct was created using the Company's SADA Y-PRIT Theranostic Platform, which was licensed by the Company from Memorial Sloan Kettering Cancer Center ("MSK") and Massachusetts Institute of Technology ("MIT"). In research, it was shown that SADA Y-PRIT utilizes a pre-targeted payload delivery method where antibody constructs assemble into tetramers and bind to the tumor target. In prior nonclinical studies, unbound constructs predictably disassembled into smaller antibody fragments and were taken up by the liver or excreted through the kidneys within a few days after administration. In a second infusion, a radioactive payload designed specifically to target the SADA molecules attached to the tumor target. Y-mAbs believes this approach provides the possibility of targeting tumors with precision while minimizing radiation of normal tissues, and that the SADA Y-PRIT Theranostic Platform may have the potential to deliver a variety of payloads and be developed against multiple tumor targets, as well as for theranostic purposes.

Researchers at MSK developed the SADA technology for radioimmunotherapy, which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests related to the technology and Y-mAbs.

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, 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 SADA technology platform and expectations with respect to SADA, the potential of SADA to provide the possibility of targeting tumors with precision while minimizing radiation of normal tissues, the potential of SADA to deliver a variety of payloads and be developed against multiple tumor targets as well as for theragnostic purposes, and the design of the Phase 1 trial in SADA, including with respect to enrollment and timing; the Company’s presentation at ASCO; expectations with respect to our products and product candidates including the potential of the SADA technology and the potential benefits 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’’ 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, our Quarterly Reports on Form 10-Q for the quarter ending March 31, 2023, 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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