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 5, 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 5, 2023, Y-mAbs Therapeutics, Inc., (the "Company") issued a press release announcing that the first patient has been dosed with both the protein dose and the 177Lu-DOTA imaging dose in its Phase 1 clinical trial, evaluating the Company's pre-targeted radioimmunotherapy Self-Assembly and Disassembly-Bispecific ("SADA") technology platform for the treatment of certain GD2-positive solid tumors, including small cell lung cancer, sarcoma and malignant melanoma. 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 April 5, 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 5, 2023

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

Exhibit 99.1

Y-mAbs Announces First Patient Dosed in Phase 1 Clinical Trial of GD2-SADA

New York, NY, April 5, 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 the first patient has been dosed with both the protein dose and the 177Lu-DOTA imaging dose in its Phase 1 clinical trial, evaluating the Company's pre-targeted radioimmunotherapy Self-Assembly and Disassembly-Bispecific ("SADA") technology platform for the treatment of certain GD2-positive solid tumors, including small cell lung cancer, sarcoma and malignant melanoma. The two-step approach separating the administration of SADA protein ("pre-targeting") from the administration of radioactive ligand is believed to differentiate SADA constructs from most other radioimmunotherapy approaches.

"We are excited to advance our SADA platform into the clinic for the first time with the initiation of patient dosing in this trial. This is a significant milestone for Y-mAbs in our efforts to potentially build a global franchise of radiotherapeutic assets" said Thomas Gad, Founder, President, and Interim CEO. "SADA can potentially generate the clinical data to further unlock the potential of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses. Further, during the first part of the study, Part A, we plan to collect imaging data to assess tumor targeting and assess the PK profile of GD2-SADA, as this could potentially allow for early evaluation of the program and more informed development decisions."

The Phase 1 dose-escalation, single-arm, open-label, non-randomized, multicenter trial (NCT05130255) targets malignant melanoma, sarcoma and small cell lung cancer. The trial will have three parts: Part A will explore dose-finding for the 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 be evaluating safety and initial signals of efficacy using repeated dosing. The Company expects a total of approximately 60 patients to be enrolled in the trial across 6-10 U.S. sites.

The GD2-SADA construct was created using the Company's SADA platform, which was licensed by the Company from Memorial Sloan Kettering Cancer Center ("MSK") and Massachusetts Institute of Technology ("MIT"). SADA utilizes a pre-targeted payload delivery method where antibody constructs assemble in 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. We believe this approach provides the possibility of targeting tumors with precision while minimizing radiation of normal tissues. We believe the SADA platform has the potential to deliver a variety of payloads and be developed against multiple tumor targets, as well as for theragnostic purposes.

Researchers at MSK, including Dr. Nai-Kong Cheung, developed the SADA technology for radioimmunotherapy, which is exclusively licensed by MSK to Y-mAbs. Dr. Cheung has intellectual property rights and interests in the technology, and as a result of this licensing arrangement, and MSK has institutional financial interests in the technology.

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 SADA technology platform and expectations with respect to SADA, including its potential to be differentiated from most other radioimmunotherapy approaches and to generate clinical data to unlock the potential of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses, 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; our business model, including the Company's plans and strategies, development, commercialization and product distribution plans, as well as our efforts to potentially build a global franchise of radiotherapeutic assets; 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, 2021, our Quarterly Reports on Firm 10-Q for the quarters ending 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.

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