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): October 17, 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 October 17, 2023, Y-mAbs Therapeutics, Inc. (the "Company") issued a press release announcing that the Company received clearance from the U.S. Food and Drug Administration for its Investigational New Drug application for CD38-SADA, the Company's second program within its Self-Assembly DisAssembly Pre-targeted Radioimmunotherapy Theranostic Platform.

A copy of the above-referenced 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, Announcing U.S. FDA Clearance of Investigational New Drug Application for CD38-SADA, dated October 17, 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: October 18, 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 Therapeutics Announces U.S. FDA Clearance of Investigational New Drug Application for CD38-SADA

Clearance of CD38-SADA IND marks the second clinical development program utilizing the Company's novel SADA technology platform

New York, NY, October 17, 2023 – 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 cleared the Company's Investigational New Drug ("IND") application for CD38-SADA, the Company's second program within its Self-Assembly DisAssembly Pre-targeted Radioimmunotherapy ("SADA Y-PRIT") Theranostic Platform. The Phase 1 trial is a first-in-human, dose-escalation, open-label, single-arm, multi-center trial (Study 1201) investigating the safety and tolerability of the CD38-SADA: ^{177}Lu-DOTA Drug Complex in patients with Relapsed or Refractory non-Hodgkin Lymphoma.

This trial will have two parts: Part A, CD38-SADA dose escalation with fixed ^{177}Lu-DOTA payload doses to explore optimal CD38-SADA protein dose and interval between the SADA protein administration and the payload; and Part B, ^{177}Lu-DOTA therapeutic dose escalation with the CD38-SADA dose determined in Part A. Patients will receive up to three cycles of therapy. The primary study outcome will evaluate safety and initial signals of efficacy using repeated dosing. Y-mAbs expects a total of approximately 30 patients and up to 12 U.S. sites to be included in the trial.

The CD38-SADA construct was created using SADA technology, which was licensed by the Company from Memorial Sloan Kettering Cancer Center ("MSK") and Massachusetts Institute of Technology ("MIT") in April 2020. The SADA technology platform utilizes a pre-targeted payload delivery method where antibody constructs assemble in tetramers and bind to the tumor target. Unbound constructs predictably disassemble into smaller antibody fragments and are predominantly excreted through the kidneys within hours after administration. In a second infusion, a radioactive payload binds to the antibody constructs attached to the tumor target in order to radiate the tumor. This provides the possibility of targeting tumors with precision while minimizing radiation of normal tissues. We believe that the SADA technology platform can deliver a variety of payloads and could potentially be developed against multiple tumor targets, as well as for theragnostic purposes.

"We are pleased by the FDA clearance of our IND for CD38-SADA, marking the second program utilizing our novel SADA technology platform to enter clinic development within just 15 months," said Thomas Gad, Founder, President and Interim Chief Executive Officer. "With our team's proven CD38-targeted drug development track record and our unique two-step SADA mechanism, we believe our CD38-SADA program has the potential to address a clear unmet medical need. We are incredibly excited about the potential of SADA to transform the treatment paradigm across a variety of targets."

"The FDA clearance of our IND paves the way for a new way of addressing CD38-positive tumors, with the potential for CD38-SADA to be a key addition to the physician toolbox in treating Relapsed or Refractory non-Hodgkin Lymphoma patients of both of B-cell and T-cell origin," said Steen Lisby, M.D., DMSc, SVP and Chief Scientific Officer, Global Head of Translational Medicine. "Despite the growing range of available treatment options for patients with lymphoma, many patients will develop disease that no longer responds to treatment and risk succumbing to the disease. Hence, there is still significant unmet medical need in Relapsed or Refractory non-Hodgkin Lymphoma. CD38-SADA marks our first hematology radiotherapy program. We look forward to initiating this Phase 1 trial and expect to dose the first patient in 2024."

Researchers at MSK, including Dr. 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, MSK has institutional financial interests in the technology and in 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 Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, statements about our business model and development, commercialization and product distribution plans, including without limitation statements about expectations with respect to CD38-SADA and the SADA technology platform; statements about current and future clinical and pre-clinical studies and our research and development programs, including without limitation statements about expectations with respect to the anticipated Phase 1 trial investigating the safety and tolerability of CD38-SADA: ^{177}Lu-DOTA Drug Complex in patients with Relapsed or Refractory non-Hodgkin Lymphoma; statements about the expected benefits of CD38-SADA and the SADA technology platform; 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'', "guidance," 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 macroeconomic conditions, including the conflict between Russia and Ukraine and sanctions related thereto, inflation, increased interest rates, uncertain global credit and capital markets and disruptions in banking systems; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 and future filings and reports by the Company. 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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