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 15, 2021

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 December 15, 2021, Y-mAbs Therapeutics, Inc., (the "Company") issued a press release announcing a pipeline update to be presented at the Company's R&D event, which takes place virtually at 12 p.m. Eastern Time on December 15, 2021. 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 December 15, 2021 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 15, 2021

By: /s/ Thomas Gad
Thomas Gad
Founder, Chairman, President and Head of Business Development & Strategy

Y-mAbs Announces Pipeline Update

New York, NY, December 15, 2021 (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 clinical experience for naxitamab and data from the Company's SADA technology programs will be presented at the Company's R&D event, which will take place virtually today at 12 p.m. Eastern Time.

Investors, analysts, members of the media and public may access the event via a live webcast.

The Y-mAbs research and development day will feature presentations from oncology key opinion leaders ("KOLs") Javier E. Oesterheld, M.D. (Atrium Health) and Jaume Mora, M.D., Ph.D. (SJD Barcelona Children's Hospital). An update on Y-mAbs' broad and advanced product pipeline, including the Company's SADA Technology, will follow from 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 present new details on the proposed mechanism of action for the SADA Technology. The Company plans to file an Investigational New Drug Application ("IND") with the US Food & Drug Administration ("FDA") for GD2-SADA by the end of this year.

Naxitamab

Dr. Mora, who has experience treating neuroblastoma patients with both naxitamab and a competing anti-GD2 antibody, will present compassionate use data regarding an investigational infusion protocol for naxitamab, systematically increasing the infusion rate during the treatment. Using the revised infusion rate, for which a provisional patent application has been filed by Y-mAbs and the co-inventors Jaume Mora from SJD Barcelona Children's Hospital and Dr. Nai-Kong Cheung, MD, PhD, and Shakeel Modak, MD, both from Memorial Sloan Kettering Cancer Center ("MSK") in New York, it was observed that the protocol may help with managing Grade 3 and Grade 4 adverse events.

DANYELZA® (naxitamab-gqgk)

Dr. Oesterheld will present his personal experience from Levine Children's Hospital after several patient treatment experiences with DANYELZA® (naxitamab-gqgk).

"I am delighted to see that the efforts led by Dr. Mora and supported by Y-mAbs as well as Dr. Cheung and Dr. Modak from MSK has led to what we believe may be a significant discovery. After years of experience in the clinic, we believe that Dr. Mora's method of managing the infusion rate of naxitamab now potentially may open up the use of naxitamab for a wide range of GD2 positive indications, such as breast cancer, melanoma, sarcomas, small-cell lung cancer and other cancers, for which we can now consider planning Phase 2 studies," said Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer further notes, "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 many cancer treatments known today."

Researchers at MSK developed naxitamab and the SADA Technology, which are exclusively licensed by MSK to Y-mAbs. As a result of these licensing arrangements, MSK has institutional financial interest related to the compound and technology and Y-mAbs.

About DANYELZA® (naxitamab-gqgk)

DANYELZA 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, anaphylaxis, hypotension, bronchospasm and stridor and neurotoxicity, such as severe neuropathic pain, transverse myelitis and reversible posterior leukoencephalopathy syndrome. 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 products for the treatment of cancer. The Company has a broad and advanced product pipeline, including one FDA approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one pivotal-stage 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 about our business model and development, commercialization and product distribution plans; current and future clinical and pre-clinical studies and our research and development programs; expectations related to the timing of the initiation and completion of regulatory submissions; regulatory, marketing and reimbursement approvals; rate and degree of market acceptance and clinical utility as well as pricing and reimbursement levels; retaining and hiring key employees; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position and strategy; additional product candidates and technologies; collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of our cash and cash equivalents, and the need for, timing and amount of any future financing transaction; our financial performance, including our estimates regarding revenues, expenses, capital expenditure requirements; developments relating to our competitors and our industry; 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; 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 pandemic caused by the coronavirus known as COVID-19 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, 2020 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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