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 16, 2020

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 16, 2020, 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 16, 2020. 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 16, 2020 issued by Y-mAbs Therapeutics, Inc.
104	Cover Page lnteractive 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 16, 2020

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

Exhibit 99.1

Y-mAbs Announces Pipeline Update

New York, NY, December 16, 2020 (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 data for DANYELZA® (naxitamab-gqgk), omburtamab and nivatrotamab will be presented at the Company's R&D event, which takes place virtually today at 12 p.m. Eastern Time. Key opinion leaders, including Shakeel Modak, M.D., MRCP, Memorial Sloan Kettering ("MSK"), Jaume Mora, M.D., Ph.D., SJD Barcelona Children's Hospital, and Brian H. Santich, Ph.D., MSK, will discuss the current treatment landscape and unmet medical needs for high-risk neuroblastoma, osteosarcoma and other solid tumors. Investors, analysts, members of the media and public may access the event via a live webcast.

DANYELZA

Dr. Mora, who has experience treating frontline neuroblastoma patients with both DANYELZA and a competing anti-GD2 antibody, will present clinical data from both antibodies. Data from an investigator sponsored frontline study of DANYELZA comprised 73 patients with high-risk stage 4 neuroblastoma of which 55 patients were in their first complete remission ("CR") and 18 patients were in their second CR. Patients in first CR showed an overall 74.3% event free survival ("EFS") at 24 months and an overall survival ("OS") of 91.6% at 24 months. Patients in second CR showed an overall 38.5% EFS at 24 months and an OS of 88.1% at 24 months.

In osteosarcoma, the Company will present an update on its ongoing Phase 2 study, which started more than 4 years ago at MSK and has now been approved for recruitment at two other U.S. sites. A total of 33 patients have received DANYELZA. At 30 months of follow-up the EFS was in excess of 50%.

Omburtamab

The company will also reconfirm its plan to resubmit its omburtamab BLA for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma to the FDA in the beginning of 2021. Preliminary Overall Survival ("OS") data for the Company's multicenter Study 101 for the first 18 months appears supportive of the conclusion from an earlier Study 03-133 at MSK on survival improvement for these patients, with 75% of patients surviving after 18 months. Additionally, the preliminary propensity score analysis of Study 03-133 compared to external control subjects, shows a significant difference in three years overall survival ($p<0.001$). Finally, an independent radiographic evaluation of the tumor responses in Study 101, shows that for ten evaluable patients with measureable disease, a total of 40% of the patients responded to omburtamab, 20% with complete response ("CR") and 20% with partial response ("PR"), and another five patients had stable disease ("SD"). All nine patients with response or SD maintained these at six months follow up.

Nivatrotamab

The Company will also present a status on Study 18-034, covering the first six cohorts of the study, where patients have received up to 8 µg/kg per dose. A total of ten patients were enrolled in the study. In this initial part of the study, no CRs or PRs were achieved, but the Company is preparing for the Phase 2 studies, including a separate multicenter study in small cell lung cancer. Future protocols will be amended to subcutaneous administration, more frequent dose exposure and, in addition, the premedication regime will be altered with the objective of being able to further increase doses of nivatrotamab.

"I am delighted and excited to welcome this excellent group of key opinion leaders to our R&D event. It will be a great opportunity to learn more about the clinical experience of DANYELZA, omburtamab and nivatrotamab, also noting that SJD Barcelona Children's Hospital, a major pediatric center located in Barcelona, Spain, has produced promising frontline DANYELZA data," said Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer further notes, "We are excited to share this broad update on our pipeline and believe this to be class leading clinical results. The tumor response data for omburtamab paves the way for the resubmission of the BLA in early 2021."

Researchers at MSK developed DANYELZA, omburtamab and nivatrotamab, which are exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests related to the compounds 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, 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 and commercialization plans; the benefits, safety and efficacy of DANYELZA, 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,’’ ‘‘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 novel 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 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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