
**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 9, 2020

Y-MABS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38650
(Commission
File Number)

47-4619612
(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 9, 2020, Y-mAbs Therapeutics, Inc., (the “Company”) issued a press release announcing a clinical update on DANYELZA® (naxitamab-ggqk) for the treatment of Refractory/Relapsed High-Risk Neuroblastoma given at the ESMO Immuno-Oncology Virtual Congress 2020, which is being held December 9 through December 12, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1 104	Press Release, dated December 9, 2020 issued by Y-mAbs Therapeutics, Inc. 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 9, 2020

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



Y-mAbs Announces Update on DANYELZA® (naxitamab-gqgk) at ESMO

New York, NY, December 9, 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 a clinical update on DANYELZA® (naxitamab-gqgk) for the treatment of Refractory/Relapsed High-Risk Neuroblastoma was given at the ESMO Immuno-Oncology Virtual Congress 2020, which is being held December 9 through December 12, 2020. The DANYELZA data was presented by Dr. Jaume Mora from SJD Barcelona Children's Hospital, Spain and Dr. Daniel A. Morgenstern from The Hospital for Sick Children, Toronto, Canada.

In the Company's Study 201, a total of 95% of the infusions were administered in an outpatient setting. The median infusion time was 37 minutes, and all infusions were completed in less than 2 hours. The adherence rate was deemed very satisfactory, as 98% of the infusions were completed as planned, and the treatments appeared to be generally well tolerated. By independent review, the overall response rate (“ORR”) in Study 201 was 68% with 59% complete responses (“CR”). In refractory patients, the ORR was 71% with 64% CR, and in relapsed patients the ORR was 63% with 50% CR.

DANYELZA 40mg/10ml was recently approved by the U.S. FDA. 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. DANYELZA is a humanized, monoclonal antibody that targets the ganglioside GD2, which is highly expressed in various neuroectoderm-derived tumors and sarcomas. During the Company's Study 201, DANYELZA was primarily administered to patients in an outpatient setting three times in a week and the treatment was repeated every four weeks.

“I am very pleased to see that 98% of the infusions were completed as planned and 95% of the infusions were outpatient. Furthermore, the response rates achieved in these patients, who were either refractory to frontline treatment or had relapsed are notable, as this is a difficult to treat patient population, and the responses are based on antibody treatment alone, and not combination treatment with chemotherapy,” said Thomas Gad, founder, Chairman and President.

“We are pleased that Study 201 showed that when DANYELZA is given in an outpatient setting with a high degree of treatment adherence, it addressed a significant unmet medical need in an efficient way. In addition, in Study 201 we saw that the median infusion time was just over half an hour, and when compared to the duration of the first infusion, the subsequent infusion times were generally lower, which we believe is great news for children living with refractory/relapsed high-risk neuroblastoma,” said Dr. Claus Moller, Chief Executive Officer.

Researchers at Memorial Sloan Kettering Cancer Center (“MSK”) developed DANYELZA, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests related to the compound and Y-mAbs.

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 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 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.

“DANYELZA” and “Y-mAbs” are registered trademarks of Y-mAbs Therapeutics, Inc.

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