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): May 19, 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 May 19, 2021, Y-mAbs Therapeutics, Inc., (the "Company") issued a press release announcing that the Company had entered into an exclusive distribution agreement with Adium Pharma S.A. to be the exclusive distributor in Latin America of the Company's antibodies, DANYELZA® (naxitamab-gqgk) for the treatment of patients with relapsed/refractory high-risk neuroblastoma and omburtamab, if approved, for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. 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 May 19, 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: May 19, 2021

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

Exhibit 99.1

Y-mAbs Enters into Exclusive Distribution Agreement with Adium Pharma S.A. for DANYELZA® (naxitamab-gqgk) and Omburtamab in Latin America

New York, NY, May 19, 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 announced today that it has entered into an exclusive distribution agreement with Adium Pharma S.A. ("Adium") to be the exclusive distributor in Latin America of the Company's antibodies, DANYELZA® (naxitamab-gqgk) for the treatment of patients with relapsed/refractory high-risk neuroblastoma and omburtamab, if approved, for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma.

DANYELZA (naxitamab-gqgk) 40mg/10mL was approved by the U.S. Food and Drug Administration ("FDA") on November 25, 2020 and 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.

Omburtamab is an investigational, monoclonal antibody that targets B7-H3 and is radiolabeled before intraventricular administration. B7-H3 is an immune checkpoint molecule that is widely expressed in tumor cells of several cancer types. In April 2021, the Company submitted a Marketing Authorization Application ("MAA") to the European Medicines Agency for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. The Company aims to resubmit its Biologics License Application ("BLA") to the FDA for omburtamab by the end of the second quarter or in the third quarter 2021.

The distribution agreement includes the territories of Argentina, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay, and certain Caribbean islands. Under the terms of the agreement, Adium will employ its sales and marketing expertise to distribute DANYELZA and omburtamab, if approved, in the territory. In addition, Adium will submit registration files on behalf of the Company in certain parts of the territory. All other unpartnered geographies worldwide remain with the Company. Financial details were not disclosed.

"We are very pleased to enter this distribution agreement with Adium, a company with a commercial presence in 18 countries and a sustained oncology and rare disease business. We hope to leverage Adium's footprint in Latin America to make DANYELZA and omburtamab, if approved, available to children with unmet medical needs," said Thomas Gad, founder, Chairman and President at Y-mAbs.

Researchers at Memorial Sloan Kettering Cancer Center ("MSK") developed DANYELZA and omburtamab, which are exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests in the compounds and in 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 and anaphylaxis, and neurotoxicity, such as severe neuropathic pain and transverse myelitis. 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.

About Adium

Adium is a private pharmaceutical company based in Montevideo, Uruguay. Adium distributes its products in 18 Latin American & Caribbean countries including Brazil, Mexico and Colombia. Adium has been distributing products from leading international companies in the field of Oncology, Urology, Hematology and Rare Diseases, for more than 20 years. Adium provides its partners a full set of local capabilities including commercial, market access, regulatory and pharmacovigilance.

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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