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 26, 2022

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 26, 2022, Y-mAbs Therapeutics, Inc., (the "Company") issued a press release announcing data from the naxitamab-based chemoimmunotherapy trial in patients with chemoresistant high-risk neuroblastoma ("HR-NB"), that Dr. Shakeel Modak, MD from Memorial Sloan Kettering ("MSK") will present at the American Society of Clinical Oncology ("ASCO") Annual Meeting to be held June 3-7, 2022. 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 26, 2022, 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 26, 2022

By: /s/ Thomas Gad
Thomas Gad
Founder, President, Interim Chief Executive Officer, and Head of Business Development & Strategy

Exhibit 99.1

Y-mAbs Announces Naxitamab Chemoimmunotherapy Investigational Trial for High-Risk Neuroblastoma Meets Primary Endpoint

New York, NY, May 26, 2022 (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 Dr. Shakeel Modak, MD from Memorial Sloan Kettering ("MSK") will present results from the naxitamab-based chemoimmunotherapy trial in patients with chemoresistant high-risk neuroblastoma ("HR-NB"), at the American Society of Clinical Oncology ("ASCO") Annual Meeting to be held June 3-7, 2022.

This clinical trial studied the combination of Humanized anti-GD2 antibody naxitamab, Irinotecan, Temozolomide and Sargramostim (GM-CSF), ("HITS") protocol, and included cohort of patients that were treated at MSK in a phase 2 protocol, and at Hospital Sant Joan de Déu ("HJSD") per protocol on compassionate use basis. Health authorities have not established the safety and efficacy of the HITS protocol, as it is investigational and has not been approved by health authorities.

Eligibility criteria included evaluable or measurable chemoresistant disease. Prior anti-GD2 or irinotecan/temozolomide therapy was permitted. Each cycle, administered 3-5 weeks apart, comprised irinotecan, temozolomide, naxitamab and GM-CSF. The primary endpoint of the phase 2 trial at MSK was complete response ("CR") and partial response ("PR") after 4 cycles.

Of 90 previously heavily treated patients, (38 at MSK in the phase 2 trial, and 52 at HJSD), eight had HR-NB refractory to induction chemotherapy and 82 had up to six prior relapses.

The primary endpoint was reached in the MSK phase 2 trial: Objective Response Rate ("ORR") according to the International Neuroblastoma Response Criteria ("INRC") of 30.6 %, with a lower boundary of 20.4%. In the entire cohort, responses were 26% for CR, 11% for PR, 9% for mixed response, 27% for stable disease and 27% for progressing disease ("PD"). In the MSK phase 2 trial, the ORR was 64% for all patients, with soft tissue (48%) and skeletal MIBG uptake (66%). CR in bone marrow was seen in 57% of the patients. The ORR in patients with MYCN-amplification was 25%, in patients with refractory disease 100%, and in patients with relapsed disease 61%. Moreover, in patients who had previously received irinotecan/temozolomide or naxitamab, the ORR was 64% and 68%, respectively. In patients who had previously received dinutuximab/irinotecan/temozolomide, the ORR was 42% (five out of 12 patients).

Toxicities included myelosuppression and diarrhea as expected with irinotecan/temozolomide, pain and hypertension as expected with naxitamab, plus febrile neutropenia. No other >grade 2 unexpected toxicities occurred, and the treatment was outpatient. In this trial, human anti-human antibody did not develop in any of the 50 patients providing samples for testing.

"We are very pleased to present data for the HITS protocol," stated Thomas Gad, Founder, President and Interim CEO. "Responses in patients with relapsed or progressive high-risk neuroblastoma are challenging, as chemo-resistant disease is considered an obstacle, so we are excited to see this study met its primary endpoint. This further demonstrates the potential role for DANYELZA in HR-NB. No other GD2 antibody has been studied in such a heavily pre-treated patient population."

Researchers at Memorial Sloan Kettering Cancer Center MSK developed naxitamab, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests in the compound.

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 at the registration-stage, 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 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 its variants such as Delta and Omicron, risks associated with Russia’s recent invasion of Ukraine 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, 2021 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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