

**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 14, 2019**

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))

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.

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class:</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered:</u>
Common Stock, \$0.0001 par value	YMAB	NASDAQ Global Select Market

Item 8.01 Other Events

On May 14, 2019, Y-mAbs Therapeutics, Inc., (the “Company”) issued a press release announcing a development update on the Company’s cancer vaccine program. 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 14, 2019 issued by Y-mAbs Therapeutics, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, 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 14, 2019

By: /s/ Thomas Gad

Thomas Gad

Founder, Chairman, President and Head of Business Development



Y-mAbs Announces Development Update on Cancer Vaccine Program

New York, NY, May 14, 2019 (GLOBE NEWSWIRE) — Y-mAbs Therapeutics, Inc. (the “Company” or “Y-mAbs”) (Nasdaq: YMAB) a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer, is pleased to announce a development update on its cancer vaccine program, the GD2-GD3 Vaccine.

At the Advances in Neuroblastoma Research (ANR) conference in San Francisco in May 2018, Phase 2 data utilizing GD2-GD3 Vaccine for Stage 4 high-risk neuroblastoma was presented. A total of 84 pediatric patients received the GD2-GD3 Vaccine, all of whom had prior relapses and finally regained second or later remissions before vaccine treatment. An interim analysis shows a progression free survival (PFS) of 51% and overall survival (OS) of 90% at 2 years. The GD2-GD3 Vaccine appears to be well tolerated, with no reported grade 3 or grade 4 toxicities. To date, more than 230 patients have been treated with the GD2-GD3 Vaccine at Memorial Sloan Kettering Cancer Center (MSK) in New York under a MSK sponsored IND.

“Since Y-mAbs licensed the GD2-GD3 Vaccine in June 2018, we have explored our options to establish commercial scale cGMP production. We believe we now have a viable route forward for manufacturing, and plan to begin using the newly manufactured cGMP drug product in the fourth quarter of 2019. Establishment of a clear path towards approval has been a prerequisite for advancing the GD2-GD3 Vaccine program and we are very excited to move the program forward. We believe the GD2-GD3 Vaccine for relapsed high-risk neuroblastoma may offer meaningful improvement in the long-term treatment paradigm for pediatric patients, serving as a natural extension post immunotherapy treatment with our naxitamab antibody based product candidate,” stated Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Møller, Chief Executive Officer continued, “We believe that the more than 230 patients treated to date represents the largest population ever to receive a neuroblastoma vaccine. The 84 patients reported on at ANR received seven subcutaneous injections of the GD2-GD3 Vaccine in the outpatient clinic without any measurable pain or significant adverse side effects. We are very encouraged with the two year OS of approximately 90% in these 84 patients. We hope to replicate these data with the newly manufactured cGMP drug product in a multicenter trial.”

About Y-mAbs

Y-mAbs is a late-stage clinical 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 two pivotal-stage product candidates—naxitamab and omburtamab—which target tumors that express GD2 and B7-H3, respectively.

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; current and future clinical and pre-clinical studies and our research and development programs; 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 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 and other risks and uncertainties affecting the Company including those described in the “Risk Factors” section included in our 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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