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 10, 2018**

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))

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

On December 10, 2018, Y-mAbs Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has cleared the Investigational New Drug ("IND") application for a humanized bispecific GD2 antibody. It is anticipated that a Phase 1/2 clinical trial will soon be initiated to begin screening patients with relapsed/refractory neuroblastoma, high grade osteosarcoma and other GD2(+) solid tumors, where patients have relapsed or refractory disease that is resistant to standard therapy. 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 10, 2018 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: December 10, 2018

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

Exhibit 99.1

Y-mAbs Therapeutics Announces FDA Clearance of IND for its Bispecific GD2 Antibody

New York, NY, December 10, 2018 (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 announced today that the U.S. Food and Drug Administration ("FDA") has cleared the Investigational New Drug ("IND") application for a humanized bispecific GD2 antibody. It is anticipated that a Phase 1/2 clinical trial will soon be initiated to begin screening patients with relapsed/refractory neuroblastoma, high grade osteosarcoma and other GD2(+) solid tumors, where patients have relapsed or refractory disease that is resistant to standard therapy.

This bispecific product candidate is a fully humanized IgG-scFv format antibody, licensed by Memorial Sloan Kettering to Y-mAbs, in which the anti-CD3 scFv is linked to naxitamab IgG1 and the Fc region is mutated to help prevent cytokine release as well as complement-mediated pain side effects. Y-mAbs expects that this bispecific GD2 antibody may have potential advantages over other bispecific antibodies, such as improved potency due to bivalency, binding to neonatal Fc receptor and longer serum half-life, which obviates continuous infusion and enables more convenient administration to the patient.

Y-mAbs Founder, President and Head of Business Development and Strategy, Thomas Gad said, "This is a novel bivalent tumor targeting bispecific antibody for the treatment of GD2 positive solid tumors in both pediatric and adult cancers. We believe that these bispecific antibodies have the potential to overcome many of the limitations associated with existing bispecific constructs."

Dr. Claus Møller, Chief Executive Officer further notes, "I am excited to see this bispecific antibody make its way towards the clinic, to establish the safety profile and to determine the maximum tolerated dose."

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 orphan drug and other regulatory approvals, clinical trial timing and plans, the achievement of clinical and commercial milestones, future financial and operating results, business strategies, market opportunities, financing, and other statements that are not historical facts. Words such as ''anticipate,'' ''believe,'' ''continue,'' ''could,'' ''estimate,'' ''expect,'' ''intend,'' ''may,'' ''might,'' ''plan,'' ''potential,'' ''predict,'' ''project,'' ''should,'' ''target,'' ''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 the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials including if we encounter difficulties enrolling patients in our clinical

trials; the risks of delays in FDA and/or EU approval of our drug candidates or failure to receive approval; the risks related to commercializing any approved new 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; our inability to enter into collaboration or alliances with partners; risks associated with protection of our intellectual property rights; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Registration Statement on Form S-1 declared effective by the SEC on September 20, 2018 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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