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): **March 22, 2019**

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 2.02 Results of Operations and Financial Condition.

On March 22, 2019, Y-mAbs Therapeutics, Inc., announced its financial results for the fiscal year ended December 31, 2018. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and 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 in any filing under the Securities Act of 1933, as amended or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Y-mAbs Therapeutics, Inc., on March 22, 2019 furnished herewith.

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: March 22, 2019

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

Exhibit 99.1

Y-mAbs Announces 2018 Financial Results and Corporate Development Highlights

New York, NY, March 22, 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, today reported financial results for 2018.

"We are very pleased to report our first full year financials after Y-mAbs' successful IPO in September, which we believe has put us in a strong financial position to continue the important work on our two lead pediatric compounds, naxitamab and omburtamab. We plan to file BLAs for both of these compounds by the end of 2019." stated Thomas Gad, Founder, President and Head of Business Development and Strategy.

Dr. Moller, Chief Executive Officer continued, "We believe we have made solid clinical progress with naxitamab and omburtamab during 2018. In 2019, we have much to do and also many catalysts that have the potential to solidify us as a leader in pediatric oncology and as a company focused on rapidly developing therapies to extend and enhance the lives of those living with rare pediatrics cancers."

Financial Year 2018 and Corporate Development Highlights

- On December 13, 2018, Y-mAbs announced the appointment of Dr. Gérard Ber, PhD to its board of directors, and the planned departure of Dr. Michael Buschle, PhD. Dr. Ber most recently served as Chief Operating Officer of Advanced Accelerator Applications SA, which he co-founded in 2002. Dr. Ber brings over 30 years of experience in molecular nuclear medicines, including development, production and commercialization of diagnostics and therapeutic products for several indications in oncology, cardiology, neurology and infectious/inflammatory diseases.

- On December 10, 2018, Y-mAbs announced FDA clearance of the IND for the Company's humanized bispecific GD2 antibody. The IND was submitted by Memorial Sloan Kettering Cancer Center, who has licensed the antibody to Y-mAbs. A Phase 1/2 clinical trial has been initiated for 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. 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.

- On November 1, 2018, Y-mAbs announced that that Dr. Jeong A Park from the Department of Pediatrics of Memorial Sloan-Kettering Cancer Center would present preclinical data from the Company's bispecific GD2 antibody at the American Society of Hematology (ASH) Annual Meeting. Bispecific GD2 antibodies were tested in solid tumors in preclinical models with T-cells and were shown to exert anti-tumor effect against GD2(+) tumor xenografts or PDX tumors. Further, the bispecific GD2 antibodies induced rapid and quantitative T-cell homing to tumors, mediating antibody dependent T-cell mediated cytotoxicity (ADTC) against GD2, and were shown to infiltrate tumors with little to no immune response, also known as cold tumors.

- On October 23, 2018, Y-mAbs announced that the Committee for Orphan Medicinal Products of the European Medicines Agency recommended the granting of orphan medicinal product designation in the European Union for naxitamab for the treatment of relapsed or refractory high-risk neuroblastoma. Further, the positive opinion for orphan medicinal product designation had been sent to the European Commission, which subsequently granted the orphan drug designation.

- On September 25, 2018, Y-mAbs announced the closing of its initial public offering of 6,900,000 shares of its common stock, including the exercise in full of the underwriters' option to purchase 900,000 additional shares of common stock, at a public offering price of $16.00 per share. The gross proceeds to Y-mAbs, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, were approximately $110.4 million. All of the shares of common stock were offered by the Company, and Y-mAbs' common stock is listed on The Nasdaq Global Select Market.

- On August 21, 2018, Y-mAbs announced that it had received Breakthrough Therapy designation for naxitamab, in combination with GM-CSF, for the treatment of high risk neuroblastoma refractory to initial therapy or with incomplete response to salvage therapy in patients older than 12 months of age with persistent, refractory disease limited to bone marrow with or without evidence of concurrent bone involvement.

- On July 10, 2018, Y-mAbs announced that it had entered into an exclusive sublicense with MabVax Therapeutics for its patented neuroblastoma vaccine, which is a bi-valent ganglioside based vaccine intended to treat neuroblastoma. The neuroblastoma vaccine was originally developed by Memorial Sloan Kettering Cancer Center and licensed to MabVax as part of a portfolio of anti-cancer vaccines. MabVax was granted Orphan Drug Designation for the vaccine. Under the terms of the sublicense, the Company has agreed to pay MabVax up to $1.3 million, consisting of an upfront payment of $700,000, and an additional payment of $600,000 on the first anniversary of the sublicense.

- On April 16, 2018, Y-mAbs announced positive Phase I data from treatment with omburtamab in Desmoplastic Small Round Cell Tumor (DSRCT), which is a rare sarcoma of adolescents and young adults. The phase I study of radioiodinated omburtamab was conducted at Memorial Sloan Kettering Cancer Center evaluate toxicity, pharmacokinetics, biodistribution and efficacy. A total of 41 DSRCT patients were treated with escalated doses of intraperitoneal omburtamab as radioimmunotherapy, and the compound had a satisfactory safety profile and appeared to have activity against micro-metastatic DSRCT.

Financial Results

Y-mAbs reported a net loss of $43.3 million, or $1.50 per basic and diluted share, for the financial year 2018 compared to a net loss of $19.2 million, or $0.99 per basic and diluted share for 2017.

Cost and Operating Expenses

Research and development

Research and development expenses were $34.3 million for the year ended December 31, 2018, compared to $14.3 million for 2017, an increase of $20.0 million. The increase in research and development expenses primarily reflects the following:

- $7.5 million increase in outsourced manufacturing for our lead product candidates, naxitamab and omburtamab
- $4.6 million increase in outsourced research and supplies to support expanding development activities
- $2.8 million increase in clinical trial costs due to an increasing number of ongoing clinical trials
- $3.2 million increase in personnel costs
- $0.6 million increase in milestone payments

General and administration

General and administrative expenses were $9.0 million for the year ended December 31, 2018, compared to $4.9 million for the same period of 2017, an increase of $4.1 million. The increase in general and administrative expenses primarily reflects the following:

- $1.8 million increase in personnel costs
- $0.7 million increase in fees for auditors, legal advice and other consultancy services
- $0.4 million increase in leasehold expenses

Cash and Cash Equivalents

The Company had approximately $147.8 million in cash and cash equivalents as of December 31, 2018 compared to $90.5 million as of December 31, 2017. The increase is primarily driven by the $99.8 million net proceeds from the Company's initial public offering, which is partly offset by the use of cash to fund the Company's ongoing operations during 2018.

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.

Y-MABS THERAPEUTICS, INC.
Consolidated Balance Sheets
(in thousands, except share data)

	December 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 147,840	$ 90,483
Restricted cash	31	32
Other current assets	3,661	840
Total current assets	151,532	91,355
Property and equipment, net	205	—
Deferred offering costs	—	772
Other assets	187	—
TOTAL ASSETS	$ 151,924	$ 92,127
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 5,872	$ 5,909
Accrued liabilities	3,251	2,016
Total current liabilities	9,123	7,925
Accrued milestone and royalty payments	2,050	2,050
Other liabilities	224	—
TOTAL LIABILITIES	11,397	9,975
STOCKHOLDERS' EQUITY		
Preferred stock $0.0001 par value, 5,500,000 shares authorized at December 31, 2018 and December 31, 2017; none issued at December 31, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value, 100,000,000 and 50,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 34,193,666 and 26,749,666 shares issued at December 31, 2018 and December 31, 2017, respectively	3	3
Additional paid in capital	225,352	123,879
Accumulated other comprehensive income	7	(169)
Accumulated deficit	(84,835)	(41,561)
TOTAL STOCKHOLDERS' EQUITY	140,527	82,152
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 151,924	$ 92,127

Y-MABS THERAPEUTICS, INC.
Consolidated Statements of Comprehensive Loss
(In thousands, except share and per share data)

	For The Year Ended December 31, 2018	For The Year Ended December 31, 2017
OPERATING EXPENSES		
Research and development	$ 34,269	$ 14,307
General and administrative	8,961	4,937
Total operating expenses	43,230	19,244
Loss from operations	(43,230)	(19,244)
OTHER INCOME/(EXPENSES)		
Other income (expenses)	(44)	83
NET LOSS	$ (43,274)	$ (19,161)
Other comprehensive income/(loss)		
Foreign currency translation	175	(199)
COMPREHENSIVE LOSS	$ (43,099)	$ (19,360)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.50)	$ (0.99)
Weighted average common shares outstanding, basic and diluted	28,772,384	19,397,506

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