# 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): November 13, 2018

# 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 33rd Floor 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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 x

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. x

# **Item 2.02 Results of Operations and Financial Condition**

On November 13, 2018, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended September 30, 2018. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished pursuant to Item 2.02 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.

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Exhibit No.	Description
99.1	Press Release, dated November 13, 2018 issued by Y-mAbs Therapeutics, Inc.
	2

# 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: November 13, 2018 By: /s/ Thomas Gad

Thomas Gad

Founder, Chairman, President and Head of Business Development



#### Y-mAbs Announces Third Quarter 2018 Financial Results and Recent Corporate Developments

New York, NY, November 13, 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, today reported financial results for the third quarter of 2018.

"We are very pleased to report our first quarterly financials after Y-mAbs' successful IPO in September, which have 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 next year." stated Thomas Gad, Founder, President and Head of Business Development and Strategy.

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

### Third Quarter 2018 and Recent Corporate Developments

- · After the close of the quarter, on November 1, 2018, Y-mAbs announced that that Dr. Jeong A Park from the Department of Pediatrics of Memorial Sloan-Kettering Cancer Center (MSK) will present preclinical data from the Company's bispecific GD2 antibody in a poster presentation at the American Society of Hematology (ASH) Annual Meeting on December 3, 2018, at 9:00 PM Eastern. 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.
- · After the close of the quarter, 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 may grant the orphan drug designation within 30 days thereof.
- · 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 under the ticker symbol "YMAB."
- · 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.

#### **Financial Results**

Y-mAbs reported a net loss of \$11.4 million or \$0.42 per basic and diluted share for the third quarter of 2018 compared to a net loss of \$3.8 million or \$0.21 per basic and diluted share for the third quarter of 2017.

For the nine months ended September 30, 2018, Y-mAbs reported a net loss of \$29.2 million, or \$1.08 per basic and diluted share, compared to a net loss of \$9.9 million reported for the same period of 2017, or \$0.56 per basic and diluted share.

#### **Cost and Operating Expenses**

#### Research and development

Research and development expenses were \$8.7 million for the third quarter of 2018, compared to \$3.1 million for the same period of 2017, an increase of \$5.6 million. The increase in research and development expenses primarily reflects the following:

- · \$3.4 million increase in outsourced manufacturing for our lead product candidates, naxitamab and omburtamab
- · \$1.3 million increase in outsourced research and supplies to support expanding development activities
- · \$0.7 million increase in personnel costs

Research and development expenses were \$23.2 million for the nine months ended September 30, 2018, compared to \$7.7 million for the same period of 2017, an increase of 15.5 million. The increase in research and development expenses primarily reflects the following:

- · \$6.4 million increase in outsourced manufacturing for our lead product candidates, naxitamab and omburtamab
- \$3.5 million increase in outsourced research and supplies to support expanding development activities
- · \$2.1 million increase in clinical trial costs due to an increasing number of ongoing clinical trials
- · \$2.4 million increase in personnel costs
- \$0.6 million increase in milestone payments

#### General and administration

General and administrative expenses were \$2.7 million for the third quarter of 2018, compared to \$0.8 million for the same period of 2017, an increase of \$1.9 million. The increase in general and administrative expenses primarily reflects the following:

- · \$1.1 million increase in personnel costs
- · \$0.5 million increase in fees for auditors, legal advice and other consultancy services

General and administrative expenses were \$5.9 million for the nine months ended September 30, 2018, compared to \$2.3 million for the same period of 2017, an increase of \$3.6 million. The increase in general and administrative expenses primarily reflects the following:

- · \$1.4 million increase in personnel costs
- \$1.3 million increase in fees for auditors, legal advice and other consultancy services

#### Cash, Cash Equivalents, Investments and Restricted Investments

The Company had approximately \$163.3 million in cash and cash equivalents as of September 30, 2018 compared to \$90.5 million as of December 31, 2017. The increase is primarily driven by the \$100.5 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 the first three quarters of 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 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.

# Y-MABS THERAPEUTICS, INC. Consolidated Balance Sheets (unaudited)

(in thousands, except share data)

	September 30, 2018		December 31, 2017	
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$	163,292	\$	90,483
Restricted cash		31		32
Other current assets		2,721		840
Total current assets		166,044		91,355
Property and equipment, net		162		_
Deferred offering costs		_		772
Other assets		188		<u> </u>
TOTAL ASSETS	\$	166,394	\$	92,127
LIABILITIES AND STOCKHOLDERS' EQUITY	_			
LIABILITIES				
Accounts payable	\$	6,827	\$	5,909
Accrued liabilities		2,489		2,016
Total current liabilities		9,316		7,925
Accrued milestone and royalty payments		2,050		2,050
TOTAL LIABILITIES		11,366		9,975
STOCKHOLDERS' EQUITY				
Preferred stock \$0.0001 par value, 5,500,000 shares authorized at December 31, 2017, and 5,500,000 shares				
authorized at September 30, 2018; None issued at December 31, 2017 and September 30, 2018		_		_
Common stock, \$0.0001 par value, 100,000,000 and 50,000,000 shares authorized at September 30, 2018 and				
December 31, 2017, respectively, 34,193,666 and 26,749,666 shares issued at September 30, 2018 and				
December 31, 2017, respectively		3		3
Additional paid in capital		225,848		123,879
Accumulated other comprehensive income		(48)		(169)
Accumulated deficit		(70,775)		(41,561)
TOTAL STOCKHOLDERS' EQUITY		155,028		82,152
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	166,394	\$	92,127

# Y-MABS THERAPEUTICS, INC.

# Consolidated Statements of Net Loss and Comprehensive Loss (unaudited)

(In thousands, except share and per share data)

	For The Three Months Ended September 30, 2018	For The Three Months Ended September 30, 2017	For The Nine Months Ended September 30, 2018	For The Nine Months Ended September 30, 2017
OPERATING EXPENSES				
Research and development	\$ 8,731 \$	3,076	\$ 23,228	\$ 7,682
General and administrative	2,684	766	5,924	2,287
Total operating expenses	11,415	3,842	29,152	9,969
Loss from operations	(11,415)	(3,842)	(29,152)	(9,969)
OTHER INCOME/(EXPENSES)				
Other income (expenses)	(11)	15	(62)	62
NET LOSS	\$ (11,426) \$	(3,827)	\$ (29,214)	\$ (9,907)
Other comprehensive income/(loss)				
Foreign currency translation	39	(53)	121	(124)
COMPREHENSIVE LOSS	\$ (11,387) \$	(3,880)	\$ (29,093)	\$ (10,031)
Net loss per share attributable to common stockholders, basic				
and diluted	\$ (0.42) \$	(0.21)	\$ (1.08)	\$ (0.56)
Weighted average common shares outstanding, basic and diluted	27,330,579	17,945,198	26,945,432	17,745,854

# **Contact:**

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