

**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, 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:

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

Item 2.02. Results of Operations and Financial Condition.

On November 13, 2019, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended September 30, 2019. 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.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Y-mAbs Therapeutics, Inc., on November 13, 2019.

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, 2019

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



Y-mAbs Announces Third Quarter 2019 Financial Results and Recent Corporate Developments

New York, NY, November 13, 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 the third quarter of 2019.

“We are very pleased with our third quarter results, highlighted by prudent spending combined with notable progress in the preparation of our BLAs for naxitamab and omburtamab, as well commercial ramp-up for the potential launch of both compounds. In addition, we successfully completed a follow-on offering in November, securing gross proceeds of \$143.8 million, which we believe will - together with our existing cash - be sufficient to cover our operating costs through 2022,” stated Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer, continued, “Over the third quarter, we have continued to work hard to make sure that our lead product candidates, naxitamab and omburtamab, advance towards rolling BLA submissions. We still expect the first portion of the rolling BLA for naxitamab to be submitted within the next few weeks, and we expect to file our BLA submission for omburtamab either via a rolling submission to begin in 2019 or early 2020 or via a single submission ahead of our expected completion date at the end of the first quarter of 2020.

Third Quarter 2019 and Recent Corporate Developments

- Subsequent to the end of the third quarter, on November 1, 2019, Y-mAbs announced the pricing of a follow-on shelf public offering, resulting in gross proceeds to the Company of approximately \$143.8 million.
 - Also, subsequent to the end of the third quarter, on November 1, 2019, Y-mAbs announced that the requested omburtamab pre-BLA meeting with the FDA, had been converted to a general guidance meeting. Y-mAbs still expects to complete the omburtamab BLA submission by the end of the first quarter of 2020, and believes that the overall commercialization timeline will not be affected.
 - Also, subsequent to the end of the third quarter, on October 28, 2019, Y-mAbs announced an update on omburtamab data, which was presented at the International Society of Pediatric Oncology conference.
 - After the close of the third quarter, on October 25, 2019, Y-mAbs announced an update on naxitamab data, which was presented at the International Society of Pediatric Oncology conference.
 - On August 30, 2019, Y-mAbs announced the acceptance of abstracts concerning DSRCT for presentation at the Connective Tissue Oncology Society (CTOS) Annual Meeting for omburtamab.
 - On July 8, 2019, Y-mAbs announced that it had completed a successful pre-BLA meeting with the FDA regarding a potential pathway for FDA approval of naxitamab for the treatment of relapsed/refractory high-risk neuroblastoma. During the meeting, the Company reached alignment with the FDA on an Accelerated Approval Pathway for naxitamab along with a rolling BLA submission.
 - On July 1, 2019, Y-mAbs announced the status of patient recruitment for the Company’s two pivotal phase II trials, one for omburtamab for the treatment of central nervous system/leptomeningeal metastasis (CNS/LM) from neuroblastoma and the other for naxitamab for the treatment of relapsed/refractory high-risk neuroblastoma.
 - Also, on July 1, 2019, Y-mAbs announced that the Company has entered into a development, manufacturing and supply agreement with SpectronRx in South Bend, Indiana, to secure access to clinical and commercial scale radiolabeling capacity for omburtamab. Under the terms of the agreement, SpectronRx has agreed to establish a manufacturing unit designated for Y-mAbs within its existing
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facilities, at which Y-mAbs believes both clinical and commercial supply of radiolabeled omburtamab can be produced.

Third Quarter 2019 Financial Results

Y-mAbs reported a net loss of \$23.9 million, or \$0.70 per basic and diluted share, for the three months ended September 30, 2019, compared to a net loss of \$11.4 million, or \$0.42 per basic and diluted share, for the three months ended September 30, 2018.

For the nine months ended September 30, 2019, Y-mAbs reported a net loss of \$57.9 million, or \$1.69 per basic and diluted share, compared to a net loss of \$29.2 million, or \$1.08 per basic and diluted share, reported for the nine months ended September 30, 2018.

Operating Expenses

Research and Development

Research and development expenses were \$19.7 million for the three months ended September 30, 2019, compared to \$8.7 million for the three months ended September 30, 2018, an increase of \$11.0 million. The increase in research and development expenses primarily reflects the following:

- \$7.3 million increase in outsourced manufacturing for our two lead product candidates, naxitamab and omburtamab;
- \$1.5 million increase in outsourced research and supplies to support expanding development activities; and
- \$0.7 million increase in personnel costs.

Research and development expenses were \$46.7 million for the nine months ended September 30, 2019, compared to \$23.2 million for the nine months ended September 30, 2018, an increase of \$23.5 million. The increase in research and development expenses primarily reflects the following:

- \$14.5 million increase in outsourced manufacturing for our two lead product candidates, naxitamab and omburtamab;
- \$5.0 million increase in outsourced research and supplies to support expanding development activities; and
- \$1.9 million increase in personnel costs.

General and Administration

General and administrative expenses were \$4.7 million for the three months ended September 30, 2019, compared to \$2.7 million for the three months ended September 30, 2018, an increase of \$2.0 million. Such increase in general and administrative expenses primarily reflects the following:

- \$0.8 million increase in personnel costs; and
- \$0.6 million increase in commercial infrastructure.

General and administrative expenses were \$12.6 million for the nine months ended September 30, 2019, compared to \$5.9 million for the nine months ended September 30, 2018, an increase of \$6.7 million. Such increase in general and administrative expenses primarily reflects the following:

- \$3.6 million increase in personnel costs; and
- \$1.4 million increase in commercial infrastructure costs.

Cash and Cash Equivalents

The Company had approximately \$98.2 million in cash and cash equivalents as of September 30, 2019, compared to \$147.8 million as of December 31, 2018. The decrease of \$49.6 million was primarily attributable to the increased costs of operation as the Company prepares for its submission of rolling BLAs for naxitamab and omburtamab and the build-up of the Company's commercial infrastructure.

Webcast and Conference Call

The Company will host a conference call today at 4:30 pm eastern time. To participate in the call, please dial 877-407-0792 (domestic) or 201-689-8263 (international) and reference the access code 13696442. A webcast will be available at: <http://public.viavid.com/index.php?id=136966>

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 Annual Report on 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
(unaudited)
(in thousands, except share data)

	September 30, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 98,192	\$ 147,840
Restricted cash	—	31
Other current assets	1,399	3,661
Total current assets	99,591	151,532
Property and equipment, net	1,689	205
Operating lease right-of-use lease assets	2,086	—
Other assets	318	187
TOTAL ASSETS	\$ 103,684	\$ 151,924
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	7,628	\$ 5,872
Accrued liabilities	5,848	3,251
Operating lease liabilities, current portion	516	—
Total current liabilities	13,992	9,123
Accrued milestone and royalty payments	1,932	2,050
Operating lease liabilities, long-term portion	1,821	—
Other liabilities	—	224
TOTAL LIABILITIES	17,745	11,397
STOCKHOLDERS' EQUITY		
Preferred stock \$0.0001 par value, 5,500,000 shares authorized at September 30, 2019 and December 31, 2018; none issued at September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.0001 par value, 100,000,000 shares authorized at September 30, 2019 and December 31, 2018; 34,593,666 and 34,193,666 shares issued at September 30, 2019 and December 31, 2018, respectively	3	3
Additional paid in capital	228,532	225,352
Accumulated other comprehensive income	131	7
Accumulated deficit	(142,727)	(84,835)
TOTAL STOCKHOLDERS' EQUITY	85,939	140,527
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 103,684	\$ 151,924

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
OPERATING EXPENSES				
Research and development	\$ 19,660	\$ 8,731	\$ 46,665	\$ 23,228
General and administrative	4,699	2,684	12,581	5,924
Total operating expenses	<u>24,359</u>	<u>11,415</u>	<u>59,246</u>	<u>29,152</u>
Loss from operations	<u>(24,359)</u>	<u>(11,415)</u>	<u>(59,246)</u>	<u>(29,152)</u>
OTHER INCOME/(EXPENSES)				
Interest and other income/(expenses)	437	(11)	1,354	(62)
NET LOSS	<u>\$ (23,922)</u>	<u>\$ (11,426)</u>	<u>\$ (57,892)</u>	<u>\$ (29,214)</u>
Other comprehensive income				
Foreign currency translation	134	39	124	121
COMPREHENSIVE LOSS	<u>\$ (23,788)</u>	<u>\$ (11,387)</u>	<u>\$ (57,768)</u>	<u>\$ (29,093)</u>
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.70)	\$ (0.42)	\$ (1.69)	\$ (1.08)
Weighted average common shares outstanding, basic and diluted	<u>34,371,927</u>	<u>27,330,579</u>	<u>34,253,739</u>	<u>26,945,432</u>

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