
**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): August 6, 2020

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))

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 |

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 August 6, 2020, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended June 30, 2020. 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, dated August 6, 2020 issued by Y-mAbs Therapeutics, Inc. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Y-MABS THERAPEUTICS, INC.

Date: August 6, 2020

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



Y-mAbs Announces Second Quarter 2020 Financial Results and Recent Corporate Developments

New York, NY, August 6, 2020 (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 second quarter 2020.

“We are very pleased with our second quarter 2020 financial results, especially seen in conjunction with the recent completion of our omburtamab BLA submission to the FDA. We are also very excited about the FDA’s acceptance of our naxitamab BLA for priority review, and the continued commercial ramp-up for our potential launch of both compounds in the U.S.,” stated Thomas Gad, Founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, continued, “We also entered into an exclusive licensing agreement with MSK and MIT for the SADA technology, which we believe may be a potential game changer in therapeutic and diagnostic use of Liquid Radiation™. We were very pleased to designate the first four SADA constructs for preclinical development and hope to file the first IND next year.”

Second Quarter 2020 and Recent Corporate Developments

- Subsequent to the end of the second quarter, on August 6, 2020, Y-mAbs announced the completion of the submission of its omburtamab Biologics License Application to FDA for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma
- Also, subsequent to the end of the second quarter, on July 14, 2020, Y-mAbs announced an update on the SADA technology and presented B7-H3 as a new preclinical SADA construct
- On June 2, 2020, Y-mAbs announced that the FDA had accepted the Biologics License Application for Danyelza™ (naxitamab) for the treatment of neuroblastoma for priority review
- On April 24, 2020, Y-mAbs announced the appointment of Laura J. Hamill to its Board of Directors
- On April 15, 2020, Y-mAbs announced that it had entered into an agreement with Memorial Sloan Kettering Cancer Center and the Massachusetts Institute of Technology for a worldwide exclusive license and research collaboration for the SADA technology, a concept we refer to as Liquid Radiation™
- On April 1, 2020, Y-mAbs announced that the Company completed the submission of its rolling BLA submission to the FDA for naxitamab on March 31, 2020

Financial Results

Y-mAbs reported a net loss of \$40.4 million, or \$1.01 per basic and diluted share, for the three months ended June 30, 2020, compared to a net loss of \$18.0 million, or \$0.53 per basic and diluted share, reported for the three months ended June 30, 2019.

For the six months ended June 30, 2020, Y-mAbs reported a net loss of \$66.6 million, or \$1.67 per basic and diluted share, compared to the net loss of \$34.0 million, or \$0.99 per basic and diluted share, reported for the six months ended June 30, 2019.

Operating Expenses

Research and Development

Research and development expenses were \$30.1 million for the three months ended June 30, 2020, compared to \$14.5 million for the three months ended June 30, 2019, an increase of \$15.6 million. The increase in research and development expenses primarily reflects the following:

- \$13.3 million increase in milestones and license fees due to the \$2.0 million SADA upfront payment, \$10.7 million SADA stock grants accruals, and \$0.6 million for SADA milestone accrual; and
- \$1.8 million increase in personnel costs.



Research and development expenses were \$48.7 million for the six months ended June 30, 2020, compared to \$27.0 million for the six months ended June 30, 2019, an increase of \$21.7 million. The increase in research and development expenses primarily reflects the following:

- \$13.3 million increase in milestones and license fees due to the \$2.0 million SADA upfront payment, \$10.7 million SADA stock grants accruals, and \$0.6 million for SADA milestone accrual;
- \$3.9 million increase in personnel costs;
- \$2.3 million increase in outsourced research and supplies to support the expansion of our product development activities; and
- \$1.6 million increase in outsourced manufacturing for our two lead product candidates, naxitamab and omburtamab.

General and Administration

General and administrative expenses were \$10.4 million for the three months ended June 30, 2020, compared to \$4.1 million for the three months ended June 30, 2019, an increase of \$6.3 million. Such increase in general and administrative expenses primarily reflects the following:

- \$3.5 million increase in commercial infrastructure costs;
- \$1.9 million increase in personnel costs; and
- \$0.9 million increase in business insurance and professional fees.

General and administrative expenses were \$18.5 million for the six months ended June 30, 2020, compared to \$7.9 million for the six months ended June 30, 2019, an increase of \$10.6 million. Such increase in general and administrative expenses primarily reflects the following:

- \$5.5 million increase in commercial infrastructure costs;
- \$3.6 million increase in personnel costs; and
- \$1.5 million increase in business insurance and professional fees.

Cash and Cash Equivalents

The Company had approximately \$158.1 million in cash and cash equivalents as of June 30, 2020, compared to \$207.1 million as of December 31, 2019. The decrease of \$49.0 million was primarily attributable to the increased costs of operation as the Company completed its BLA submission for naxitamab and advanced the rolling BLA for omburtamab, as well as build-up of the Company's commercial infrastructure, and increased personnel costs related to these activities.

Webcast and Conference Call

The Company will host a conference call on Friday, August 7, 2020 at 9 am eastern time. To participate in the call, please dial 877-407-0792 (domestic) or 201-689-8263 (international) and reference the access code 13705298. A webcast will be available at: <http://public.viavid.com/index.php?id=140271>

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,” “appear,” “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.

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

| | June 30, 2020 | December 31, 2019 |
|--|-------------------|----------------------|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 158,059 | \$ 207,136 |
| Other current assets | 5,261 | 4,819 |
| Total current assets | 163,320 | 211,955 |
| Property and equipment, net | 1,894 | 2,052 |
| Operating lease right-of-use assets | 1,758 | 1,989 |
| Other assets | 357 | 370 |
| TOTAL ASSETS | \$ 167,329 | \$ 216,366 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| LIABILITIES | | |
| Accounts payable | \$ 9,825 | \$ 8,520 |
| Accrued liabilities | 5,313 | 4,550 |
| Operating lease liabilities, current portion | 569 | 516 |
| Total current liabilities | 15,707 | 13,586 |
| Accrued milestone and royalty payments | 2,486 | 1,921 |
| Operating lease liabilities, long-term portion | 1,399 | 1,714 |
| Other liabilities | 1,729 | 242 |
| TOTAL LIABILITIES | 21,321 | 17,463 |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock, \$0.0001 par value, 5,500,000 shares authorized at June 30, 2020 and December 31, 2019; none issued at June 30, 2020 and December 31, 2019 | — | — |
| Common stock, \$0.0001 par value, 100,000,000 shares authorized at June 30, 2020 and December 31, 2019; 40,014,519 and 39,728,416 shares issued at June 30, 2020 and December 31, 2019, respectively | 4 | 4 |
| Additional paid in capital | 378,455 | 364,712 |
| Accumulated other comprehensive income | (16) | 50 |
| Accumulated deficit | (232,435) | (165,863) |
| TOTAL STOCKHOLDERS' EQUITY | 146,008 | 198,903 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 167,329 | \$ 216,366 |



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

| | Three months ended June 30 | | Six months ended June 30 | |
|---|----------------------------|--------------------|--------------------------|--------------------|
| | 2020 | 2019 | 2020 | 2019 |
| OPERATING EXPENSES | | | | |
| Research and development | \$ 30,059 | \$ 14,494 | \$ 48,681 | \$ 27,005 |
| General and administrative | 10,393 | 4,140 | 18,519 | 7,882 |
| Total operating expenses | 40,452 | 18,634 | 67,200 | 34,887 |
| Loss from operations | (40,452) | (18,634) | (67,200) | (34,887) |
| OTHER INCOME | | | | |
| Interest and other income, net | 60 | 598 | 628 | 917 |
| NET LOSS | \$ (40,392) | \$ (18,036) | \$ (66,572) | \$ (33,970) |
| Other comprehensive income | | | | |
| Foreign currency translation | (91) | (66) | (66) | (10) |
| COMPREHENSIVE LOSS | \$ (40,483) | \$ (18,102) | \$ (66,638) | \$ (33,980) |
| Net loss per share attributable to common stockholders, basic and diluted | \$ (1.01) | \$ (0.53) | \$ (1.67) | \$ (0.99) |
| Weighted average common shares outstanding, basic and diluted | 39,972,174 | 34,193,666 | 39,862,878 | 34,193,666 |

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