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 5, 2021

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))

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

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 5, 2021, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended June 30, 2021. 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 5, 2021.
104	Interactive Data File (embedded within the Inline XBRL document).

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 5, 2021

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

Exhibit99.1

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

New York, NY, August 5, 2021 (GLOBE NEWSWIRE) – Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB) a commercial-stage 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 of 2021.

"We are very pleased with our second quarter 2021 results. The commercialization of DANYELZA® (naxitamab-gqgk) is progressing throughout the U.S. as we continue to see new sites gaining experience with DANYELZA. In addition, the DANYELZA BLA submission has recently been accepted by the National Medical Products Administration of China ("NMPA"), and we continue to advance our deep pipeline. We ended the quarter with a cash balance of $233.6 million, so we believe we are well positioned to elevate our business to new levels," stated Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, continued, "We submitted the European Marketing Authorization Application to the European Medicines Agency (the "EMA") for omburtamab in April. In parallel, after our Type B meeting with the FDA in June, we believe we now have a clearer path towards the resubmission of the omburtamab BLA to the FDA. Pending a positive Type B meeting with the FDA in the third quarter, we hope to initiate rolling resubmission of the omburtamab BLA by the end of the year."

Recent Corporate Developments

- After the close of the first quarter, on July 6, 2021, Y-mAbs announced that SciClone Pharmaceuticals had submitted the Biologics License Application to the National Medical Products Administration ("NMPA") of China for DANYELZA for the treatment of patients with relapsed/refractory high-risk neuroblastoma.

- On June 25, 2021, Y-mAbs announced that 177Lu-omburtamab-DTPA for the treatment of medulloblastoma had received a positive opinion on Orphan Medicinal Product Designation by EMA.

- On June 23, 2021, Y-mAbs announced updated timelines for resubmission of the BLA for omburtamab for neuroblastoma, with an anticipated initiation of a rolling BLA submission by the end of 2021.

- On May 19, 2021, Y-mAbs announced an exclusive distribution agreement with Adium Pharma S.A. for DANYELZA and omburtamab in Latin America.

- On April 27, 2021, Y-mAbs announced the submission to the EMA of a European Marketing Authorization Application for omburtamab for the treatment of pediatric patients with central nervous system/leptomeningeal metastasis from neuroblastoma.

- On April 12, 2021, Y-mAbs announced data from GPA33-SADA, which in a xenograft model of colorectal cancer showed radioactivity uptake with a tumor to blood ratio of 122 measured 24 hours after injection. We expect to file an IND for GPA33-SADA next year.

Financial Results

Y-mAbs reported net loss of $22.9 million, or ($0.53) per basic and diluted share, for the quarter ended June 30, 2021, compared to a net loss of $40.4 million, or ($1.01) per basic and diluted share, reported for the quarter ended June 30, 2020. The decreased net loss was caused by the DANYELZA revenues in 2021 and the reduced R&D expenses for the quarter ended June 30, 2021 compared to June 30, 2020.

For the six months ended June 30, 2021, Y-mAbs reported a net income of $10.5 million, or $0.25 per basic share and $0.23 per diluted share, compared to the net loss of $66.6 million, or ($1.67) per basic and diluted share, reported for the six months ended June 30, 2020. The net income was primarily caused by the sale of a priority review voucher and the DANYELZA revenues in the first six months of 2021.

Revenues

Y-mAbs reported net revenues of $11.0 million for the quarter ended June 30, 2021, consisting of $9.0 million of DANYELZA revenues and $2.0 million of licensing revenue.

Revenues were $16.3 million for the six months ended June 30, 2021 and consisted of $14.3 million from the sales of DANYELZA and $2.0 million of licensing revenue.

No revenues were reported for the quarter ended and six months ended June 30, 2020.

Operating Expenses

Research and Development

Research and development expenses were $19.8 million for the three months ended June 30, 2021, compared to $30.1 million for the three months ended June 30, 2020, a decrease of $10.3 million. The decrease in research and development expenses was primarily due to the following:

- $13.3 million decrease in milestone payments and license acquisition costs driven by the $13.3 million SADA agreement entered into in 2020 which included an upfront payment of $2.0 million, $3.3 million in equity issuances to Memorial Sloan Kettering (“MSK”) and Massachusetts Institute of Technology (“MIT”), $7.4 million for the issuance of shares to two non-employees, and $0.6 million for milestone payments which were deemed probable for the period ending June 30, 2020.This decrease was partially offset by a $3.0 million increase in personnel costs.

Research and development expenses were $41.4 million for the six months ended June 30, 2021, compared to $48.7 million for the six months ended June 30, 2020, a decrease of $7.3 million. The decrease in research and development expenses was primarily due to:

- $13.3 million decrease in milestone payments and license acquisition costs driven by the $13.3 million SADA agreement which included an upfront payment of $2.0 million, $3.3 million in equity issuances to MSK and MIT, $7.4 million for the issuance of shares to two non-employees, and $0.6 million for milestone payments which were probable for the period ending June 30, 2020; and
- $3.5 million decrease in outsourced manufacturing expenses.

These decreases were partially offset by increases of:

- $5.5 million in personnel costs;
- $1.3 million in outsourced manufacturing;
- $0.5 million in clinical trials; and
- $1.0 million in premises expenses.

Selling, General, and Administration

- Selling, general, and administrative expenses were $13.5 million for the three months ended June 30, 2021, compared to $10.4 million for the three months ended June 30, 2020, an increase of $3.1 million. The increase in selling general and administrative expenses primarily reflects a $3.1 million increase in personnel costs due to the continued hiring of our commercialization team.

- Selling, general, and administrative expenses were $25.4 million for the six months ended June 30, 2021, compared to $18.5 million for the six months ended June 30, 2020, an increase of $6.9 million. The increase in selling general and administrative expenses primarily reflects a$6.4 million increase in personnel costs due to the continued hiring of our commercialization team.

Cash and Cash Equivalents

The Company had $233.6 million in cash and cash equivalents as of June 30, 2021, compared to $114.6 million as of December 31, 2020. The increase of $119.0 million was primarily attributable to the following:

- The completion of the sale of our DANYELZA priority review voucher in January 2021. Y-mAbs netted $62.0 million after paying 40% of the net proceeds from the sale to MSK pursuant to the terms of the license agreement with MSK, and
- $107.7 million in net proceeds raised in our public offering in February 2021.

These increases were partially offset by the net cash used in operational activities of $50.6 million for the six months ended June 2021.

Webcast and Conference Call

The Company will host a conference call on Friday, August 6, 2021 at 9 a.m. Eastern Time. To participate in the call, please dial 855-327-6838 (domestic) or 604-235-2082 (international) and reference the conference ID 10015973. A webcast will be available at: http://public.viavid.com/index.php?id=146072

About Y-mAbs

Y-mAbs is a commercial-stage 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 one FDA approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one pivotal-stage product candidate, omburtamab, which targets tumors that express B7-H3.

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, commercialization and product distribution plans; current and future clinical and pre-clinical studies and our research and development programs; expectations related to the timing of the initiation and completion of regulatory submissions; 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,’’ “hope,” ‘‘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 in the timing of our regulatory submissions 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, risks associated with the pandemic caused by the coronavirus known as COVID-19 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.

Contact:

Y-mAbs Therapeutics, Inc.
230 Park Avenue, Suite 3350
New York, NY 10169
USA

+1 646 885 8505

E-mail: info@ymabs.com

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

	June 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 233,587	$ 114,634
Accounts receivable, net	8,517	—
Inventories	3,820	—
Other current assets	3,445	7,729
Total current assets	249,369	122,363
Property and equipment, net	1,919	1,825
Operating lease right-of-use assets	3,398	4,569
Other assets	4,793	3,290
TOTAL ASSETS	$ 259,479	$ 132,047
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 6,803	$ 9,372
Accrued liabilities	12,169	8,197
Operating lease liabilities, current portion	2,014	1,966
Total current liabilities	20,986	19,535
Accrued milestone and royalty payments	2,250	2,695
Operating lease liabilities, long-term portion	988	2,013
Other liabilities	939	1,968
TOTAL LIABILITIES	25,163	26,211
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized at June 30, 2021 and December 31, 2020; none issued at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at June 30, 2021 and December 31, 2020; 43,576,950 and 40,688,447 shares issued at June 30, 2021 and December 31, 2020, respectively	4	4
Additional paid in capital	509,049	391,558
Accumulated other comprehensive income / (loss)	(13)	(526)
Accumulated deficit	(274,724)	(285,200)
TOTAL STOCKHOLDERS' EQUITY	234,316	105,836
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 259,479	$ 132,047

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
REVENUE				
Product revenue, net	$ 8,951	$ —	$ 14,334	$ —
License revenue	2,000	—	2,000	—
Total revenue	10,951	—	16,334	—
OPERATING COSTS AND EXPENSES				
Cost of goods sold	200	—	293	—
Royalties	210	—	210	—
Research and development	19,778	30,059	41,357	48,681
Selling, general, and administrative	13,475	10,393	25,445	18,519
Total operating costs and expenses	33,663	40,452	67,305	67,200
Loss from operations	(22,712)	(40,452)	(50,971)	(67,200)
OTHER INCOME				
Gain from sale of priority review voucher	—	—	62,010	—
Interest and other income, net	(225)	59	(563)	628
NET INCOME / (LOSS)	$ (22,937)	$ (40,393)	$ 10,476	$ (66,572)
Other comprehensive income				
Foreign currency translation	78	(91)	513	(66)
COMPREHENSIVE INCOME / (LOSS)	$ (22,859)	$ (40,484)	$ 10,989	$ (66,638)
Net income/(loss) per share attributable to common stockholders, basic	$ (0.53)	$ (1.01)	$ 0.25	$ (1.67)
Weighted average common shares outstanding, basic	43,569,482	39,972,174	42,724,813	39,862,878
Net income/(loss) per share attributable to common stockholders, diluted	$ (0.53)	$ (1.01)	$ 0.23	$ (1.67)
Weighted average common shares outstanding, diluted	43,569,482	39,972,174	45,080,419	39,862,878

Contact:

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New York, NY 10169
USA

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