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): May 9, 2022

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 May 9, 2022, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended March 31, 2022. 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 May 9, 2022.
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: May 9, 2022

By: /s/ Thomas Gad
Thomas Gad
Founder, President, Interim Chief Executive Officer and Head of Business Development & Strategy

Exhibit 99.1

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

- **Completed resubmission to the FDA of omburtamab BLA**
- **DANYELZA® adoption drove a 9% sequential revenue increase to $10.5 million**
- **Company issues 2022 full-year DANYELZA® revenue guidance of $45-$50 million**
- **Strong cash position with $156.7 million as of March 31, 2022, providing runway through mid-2024**
- **The Company will host a conference call on Tuesday, May 10, 2022, at 9 a.m. EST**

New York, NY, May 9, 2022 (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 first quarter 2022.

"Y-mAbs had a successful first quarter. We resubmitted the omburtamab BLA, bringing us one step closer to the potential approval and achieving our goal of delivering omburtamab to children suffering from high-risk neuroblastoma brain tumors,” said Thomas Gad, Interim Chief Executive Officer. “We are very encouraged by our first quarter financial results, driven by our continued execution of the DANYELZA launch which generated revenues of $10.5 million. Based on the steady progress and a strong first quarter we anticipate full-year 2022 DANYELZA revenues in the range of $45-50 million. Our strong balance sheet with $156.7 million in cash, and anticipated revenues from product sales, is expected to support us through multiple potentially value-creating catalysts and into mid-2024.”

First Quarter 2021 and Recent Corporate Developments

- On April 27, 2022, Y-mAbs announced a management change. Dr. Claus Moller has stepped down as Chief Executive Officer and Board Member, and Thomas Gad, the Company’s Founder, Chairman, and President has assumed the role of Interim CEO. The Board, under the newly appointed Chairman Dr. Jim Healy, has begun a search for Dr. Moller’s successor.
- On April 8, 2022, Y-mAbs presented pre-clinical data from the GD2-SADA construct at the American Association for Cancer Research (AACR) 2022 Annual Meeting. Pre-clinical models indicated that treatment with GD2-SADA increased tumor antigen binding, uptake, and persistence in tumor tissue in-vivo with activity lasting over 100 days after the treatment.
- On April 1, 2022, Y-mAbs announced that on March 31, 2022, the Company completed the resubmission of its Biologics License Application for omburtamab to the FDA. The FDA has a 60-day review period to determine whether the BLA is complete and acceptable for filing.

Financial Results

Revenues

Y-mAbs reported net revenues of $10.5 million for the quarter ended March 31, 2022, which was a 94% increase over $5.4 million in the comparable quarter of 2021. Additionally, net revenues were up 9% from the fourth quarter 2021. The Company has now delivered DANYELZA to 34 centers across the nation, corresponding to an increase of more than 20% since the end of the fourth quarter of 2021. Approximately 50% of the vials sold in the U.S. are now sold outside Memorial Sloan Kettering (“MSK”), a notable increase over the approximately 40% of the vials sold outside MSK in prior quarters.

Operating Expenses

Research and Development

Research and development expenses were $22.9 million for the three months ended March 31, 2022, compared to $21.6 million for the three months ended March 31, 2021. The $1.3 million increase reflects our increased clinical trial activity and employee-related costs, partially offset by decreased outsourced manufacturing expenses. Having completed the resubmission of the BLA for omburtamab on March 31, 2022, Y-mAbs is focusing pipeline development on DANYELZA label expansion, omburtamab, and advancing the SADA constructs into the clinic.

Selling, General, and Administration

Selling, general, and administrative expenses were $13.4 million for the three months ended March 31, 2022, which was a $1.4 million increase compared to $12.0 million for the three months ended March 31, 2021. The increase in selling, general, and administrative expenses was primarily due to costs related to the launch and commercialization of DANYELZA; which includes a $0.7 million increase in personnel costs due to the expansion of our commercial team that is poised to drive further adoption of DANYELZA in 2022 and beyond.

Net Result

Y-mAbs reported a net loss for the quarter ended March 31, 2022, of $28.1 million, or $0.64 per basic and diluted share, compared to net income of $33.4 million, or $0.80 per basic share and $0.75 per diluted share, for the quarter ended March 31, 2021. The decrease in earnings was primarily driven by a one-time $62.0 million net gain from the sale of our DANYELZA Priority Review Voucher in the quarter ended March 31, 2021, partially offset by the favorable impact of increasing DANYELZA revenues.

Cash and Cash Equivalents

The Company had approximately $156.7 million in cash and cash equivalents as of March 31, 2022, which, when combined with anticipated revenues from product sales, is expected to be sufficient to fund the current operations to mid-2024.

Webcast and Conference Call

Y-mAbs will host a conference call on Tuesday, May 10, 2022, at 9 a.m. Eastern Time. To participate in the call, please dial 877-407-0792 (domestic) or 201-689-8263 (international) and reference the conference ID 13729248.

A webcast will be available at: https://services.choruscall.com/mediaframe/webcast.html?webcastid=yCAEVjRU

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic cancer products. In addition to conventional antibodies, the Company’s technologies include bispecific antibodies generated using the Y-BiClone platform and the SADA platform. The Company’s broad and advanced product pipeline includes one FDA-approved product, DANYELZA (naxitamab-gqgk), which targets tumors that express GD2, and one product candidate at the registration-stage, 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 its variants such as Delta and Omicron, risks associated with Russia’s recent invasion of Ukraine 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 for the year ended December 31, 2021 filed with the SEC 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.

“DANYELZA” and “Y-mAbs” are registered trademarks of Y-mAbs Therapeutics, Inc.

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)

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 156,724	$ 181,564
Accounts receivable, net	9,324	7,712
Inventories	5,588	5,512
Other current assets	6,103	7,473
Total current assets	177,739	202,261
Property and equipment, net	1,697	1,847
Operating lease right-of-use assets	3,155	3,842
Intangible assets, net	1,618	1,663
Other assets	6,838	3,170
TOTAL ASSETS	$ 191,047	$ 212,783
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 14,661	$ 13,552
Accrued liabilities	12,930	12,540
Operating lease liabilities, current portion	1,451	1,783
Total current liabilities	29,042	27,875
Accrued milestone and royalty payments	2,100	2,100
Operating lease liabilities, long-term portion	1,598	1,851
Other liabilities	835	851
TOTAL LIABILITIES	33,575	32,677
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at March 31, 2022 and December 31, 2021; 43,718,165 and 43,694,716 shares issued at March 31, 2022 and December 31, 2021, respectively	4	4
Additional paid in capital	524,329	519,206
Accumulated other comprehensive income	1,682	1,371
Accumulated deficit	(368,543)	(340,475)
TOTAL STOCKHOLDERS' EQUITY	157,472	180,106
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 191,047	$ 212,783

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 March 31,	
	2022	2021
REVENUES		
Product revenue, net	$ 10,486	$ 5,383
Total revenues	10,486	5,383
OPERATING COSTS AND EXPENSES		
Cost of goods sold	1,831	93
Research and development	22,912	21,579
Selling, general, and administrative	13,438	11,970
Total operating costs and expenses	38,181	33,642
Loss from operations	(27,695)	(28,259)
OTHER INCOME / (LOSS), NET		
Gain from sale of priority review voucher, net	—	62,010
Interest and other loss	(373)	(338)
NET INCOME / (LOSS)	$ (28,068)	$ 33,413
Other comprehensive income / (loss)		
Foreign currency translation	311	435
COMPREHENSIVE INCOME / (LOSS)	$ (27,757)	$ 33,848
Net income / (loss) per share attributable to common stockholders, basic	$ (0.64)	$ 0.80
Weighted average common shares outstanding, basic	43,709,238	$ 41,870,759
Net income / (loss) per share attributable to common stockholders, diluted	$ (0.64)	$ 0.75
Weighted average common shares outstanding, diluted	43,709,238	44,383,791