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 7, 2024

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 7, 2024, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended March 31, 2024. 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 of 1933, as amended, 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 7, 2024.
104	Interactive Data File (embedded within the Inline XBRL document).

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: May 7, 2024

By: /s/ Michael Rossi
Michael Rossi
President and Chief Executive Officer

Y-mAbs Reports First Quarter 2024 Financial Results and Recent Corporate Developments

- **Reported U.S. DANYELZA® net product revenues of $18.6 million for the first quarter of 2024, representing a YoY increase of 11%**
- **Reported Worldwide DANYELZA net product revenues of $19.4 million for the first quarter of 2024, representing a 4% YoY decrease due to international volumes**
- **Cash and cash equivalents of $75.7 million as of March 31, 2024, and cash burn of only $2.9 million for the quarter ended March 31, 2024**
- **Management reiterates full year 2024 financial guidance and anticipated cash runway into 2027**
- **The Company will host a conference call on Wednesday, May 8, 2024, at 8:00 a.m. ET**

New York, NY, May 7, 2024 (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 radioimmunotherapy and, antibody-based therapeutic products for the treatment of cancer, today reported financial results for the first quarter ended March 31, 2024.

"We continued to make meaningful progress across our commercial and clinical development initiatives during the first quarter of this year," said Mike Rossi, President and Chief Executive Officer. "On the commercial front, the first quarter of 2024 marked the highest quarter of U.S. demand for DANYELZA® (naxitamab-gqgk) since its initial launch. Our recorded net product revenues in the first quarter were primarily driven by heightened demand across both new and existing U.S. accounts. DANYELZA remains a leading anti-GD2 therapy, and we continue to believe in its potential to serve patients beyond the high-risk relapse/refractory neuroblastoma market. In addition, we are highly encouraged by the clinical advancement of our Self-Assembly DisAssembly ("SADA") Pretargeted Radioimmunotherapy ("PRIT") Technology platform. With the potential to deliver optimal therapy with minimal toxicity, increase physician participation in the patient treatment journey, and leverage existing infrastructure as a potentially isotope-agnostic platform, we believe SADA PRIT has the potential to make a positive and lasting impact on patient care."

First Quarter 2024 and Recent Corporate Developments

- In April 2024, Y-mAbs' distribution partner in Latin America, Adium, initiated the commercial launch of DANYELZA in Brazil and Mexico.
- On April 25, 2024, Y-mAbs announced several abstracts to be presented at the 2024 American Society of Clinical Oncology ("ASCO") Annual Meeting taking place May 31 through June 4, 2024, in Chicago, IL. The Company will be available to comment at booth #35151 on the Exhibition Floor of McCormick Place.
- On March 8, 2024, Bo Kruse, Executive Vice President, Chief Financial Officer, Secretary and Treasurer of Y-mAbs informed the Company of his intention to resign from such offices effective as of the date the Company appoints his successor and such successor commences employment with the Company and to resign from employment with the Company effective July 31, 2024. A search firm has been retained to assist in the recruitment of a new Chief Financial Officer.
- On February 29, 2024, the Board of Directors of Y-mAbs increased the size of the Board from eight to nine directors and elected Mary A. Tagliaferri, M.D., to serve as a Class I director of the Company. Dr. Tagliaferri's term as a Class I director continues until the Company's 2025 annual meeting of stockholders.

Financial Results

Revenues

DANYELZA total net product revenues were $19.4 million for the quarter ended March 31, 2024, which represented a decrease of 4% over $20.3 million in the comparable period of 2023. Y-mAbs' U.S. DANYELZA net product revenues were $18.6 million for the quarter ended March 31, 2024, an increase of 11% over $16.8 million in the comparable period of 2023. The Company had international DANYELZA net product revenues of $0.8 million and $3.4 million in the quarters ended March 31, 2024 and 2023, respectively. The decrease in the quarter ended March 31, 2024, compared to the quarter ended March 31, 2023, was a result of a 2023 initial product stocking shipment of $2.5 million to Y-mAbs' distribution partner, WEP, in connection with an early access program for DANYELZA in Europe. The Company did not have a shipment to WEP in the quarter ended March 31, 2024. Volumes for international shipments can vary from quarter to quarter, and the Company expects a higher volume to resume in future quarters in 2024.

U.S. DANYELZA net product revenues increased 3% compared to the quarter ended December 31, 2023, when excluding the $0.3 million and $1.3 million impact of a Medicaid accrual change in estimate recognized as increases in net product revenues in the quarters ended March 31, 2024 and December 31, 2023, respectively. DANYELZA total net product revenues of $19.4 million in the first quarter of 2024, represented a 17% decrease compared to the fourth quarter of 2023, primarily driven by decreased international revenues.

As of March 31, 2024, Y-mAbs has delivered DANYELZA to 63 centers across the U.S. since initial launch, with five new accounts added in the first quarter of 2024. During the quarter ended March 31, 2024, approximately 60% of the vials sold in the U.S. were sold outside of Memorial Sloan Kettering Cancer Center ("MSK"), compared to 55% in the fourth quarter ended December 31, 2023.

The Company had license revenues of $0.5 million for the quarter ended March 31, 2024. License revenue for the quarter ended March 31, 2024 arose from the January 2024 acceptance of the Brazilian Medicines Market Regulation Chamber ("CMED") price for DANYELZA. The Company did not have license revenue for the quarter ended March 31, 2023.

Operating Costs and Expenses

Cost of Goods Sold

Cost of goods sold was $2.1 million for the quarters ended March 31, 2024 and 2023, respectively.

The Company's gross margin in the quarters ended March 31, 2024 and 2023 remained approximately constant at 89% and 90%, respectively. The Company defines gross margin as net product revenues less cost of goods sold divided by net product revenues.

Research and Development

Research and development expenses were $13.3 million for the quarter ended March 31, 2024, a decrease of 1% compared to $13.4 million for the quarter ended March 31, 2023. The $0.1 million decrease was mainly due to decreased personnel related costs of $2.6 million, inclusive of the impact of the Company's restructuring charge recorded in the quarter ended March 31, 2023, partially offset by a $2.5 million increase in clinical trial expenses related to the Company's investments in SADA PRIT Technology in 2024.

Selling, General, and Administration

Selling, general, and administrative expenses were $11.4 million for the quarter ended March 31, 2024, which was a $0.8 million decrease compared to $12.2 million for the quarter ended March 31, 2023. The $0.8 million decrease in selling, general, and administrative expenses was primarily attributable to a decrease in personnel related costs related to the Company's $1.1 million restructuring charge recorded in the quarter ended March 31, 2023.

Interest and Other Income

Interest and other income was $0.4 million for the quarter ended March 31, 2024, as compared to $1.1 million for the quarter ended March 31, 2023. The decrease of $0.7 million was primarily due to a $0.6 million decrease in foreign currency transaction income.

Net Loss

Y-mAbs reported a net loss for the quarter ended March 31, 2024, of $(6.6) million, or $(0.15) per basic and diluted share, which was relatively flat compared to net loss of $(6.4) million, or $(0.15) per basic and diluted share, for the quarter ended March 31, 2023.

Cash and Cash Equivalents

As of March 31, 2024, Y-mAbs had approximately $75.7 million in cash and cash equivalents which, together with anticipated DANYELZA product revenues, is expected to support operations as currently planned into 2027. This estimate reflects the Company's current business plan that is supported by assumptions that may prove to be inaccurate, such that Y-mAbs could use its available capital resources sooner than it currently expects. The cash burn for the first quarter of 2024 was $2.9 million.

2024 Financial Guidance

Management reiterates its full year 2024 guidance:

- Anticipated total DANYELZA® net product revenues of between $95 million and $100 million;
- Anticipated operating expenses of between $115 million and $120 million;
- Anticipated total annual cash burn of between $15 million and $20 million; and
- Cash and cash equivalents anticipated to continue to support operations as currently planned into 2027.

Webcast and Conference Call

Y-mAbs will host a conference call on Wednesday, May 8, 2024, at 8:00 a.m. ET. To participate in the call, please use the following dial-in information:

Investors (domestic): (888) 999-5318
Investors (international): (848) 280-6460

To access the live webcast, please use this link. Prior to the call and webcast, a slide presentation pertaining to the Company's quarterly earnings will be made available on the Investor Relations section of the Y-mAbs website, www.ymabs.com, shortly before the call begins.

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, radioimmunotherapy and antibody-based therapeutic cancer products. The Company's technologies include its investigational Self-Assembly DisAssembly ("SADA") Pretargeted Radioimmunotherapy Platform ("PRIT") and bispecific antibodies generated using the Y-BiClone platform. The Company's broad and advanced product pipeline includes the anti-GD2 therapy DANYELZA® (naxitamab-gqgk), the first FDA-approved treatment for patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow after a partial response, minor response, or stable disease to prior therapy.

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 Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, statements about our business model, including financial outlook for 2024 and beyond, including estimated operating expenses, cash burn and DANYELZA product revenue and sufficiency of cash resources and related assumptions; implied and express statements regarding the future of the Company's business, including with respect to

expansion and its goals; the Company's plans and strategies, development, commercialization and product distribution plans; expectations with respect to the Company's products and product candidates, including potential territory and label expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the potential of the SADA PRIT Technology and potential benefits and applications thereof; statements with respect to the potential of SADA PRIT to deliver optimal therapy with reduced toxicity, increase physician participation in the patient treatment journey, leverage existing infrastructure as a potentially isotope-agnostic platform and make a meaningful and lasting impact to patient care; expectations relating to key anticipated development milestones, including potential expansion of international commercialization efforts with respect to DANYELZA development efforts and the SADA PRIT Technology, including potential indications and applications, and the timing thereof; expectations with respect to current and future clinical and pre-clinical studies and the Company's research and development programs, including with respect to timing and results; expectations related to the timing of the initiation and completion of regulatory submissions; additional product candidates and technologies; expectations regarding collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of cash and cash equivalents, and the need for, timing and amount of any future financing transaction; expectations with respect to the Company's future financial performance; 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’’, ‘‘guidance,’’ 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 financial condition and need for additional capital; the risks that actual results of the Company's restructuring plan and revised business plan will not be as expected; risks associated with the Company's development work; cost and success of the Company's product development activities and clinical trials; the risks of delay in the timing of the Company's regulatory submissions or failure to receive approval of its drug candidates; the risks related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of product candidates; development of sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for products; the risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture; the Company's inability to enter into partnerships; the risks related to government regulation; risks related to market approval, risks associated with protection of the Company's intellectual property rights; risks related to employee matters and managing growth; risks related to the Company's common stock, risks associated with macroeconomic conditions, including the conflict between Russia and Ukraine and sanctions related thereto, the state of war between Israel and Hamas and the related risk of a larger regional conflict, inflation, increased interest rates, uncertain global credit and capital markets and disruptions in banking systems; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 and future filings and reports by the Company. 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.

Investor Contact:

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

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 75,749	$ 78,637
Accounts receivable, net	20,588	22,454
Inventories	8,448	5,065
Other current assets	3,482	4,955
Total current assets	108,267	111,111
Property and equipment, net	153	224
Operating lease right-of-use assets	1,179	1,412
Intangible assets, net	2,543	2,631
Other assets	11,173	12,491
TOTAL ASSETS	$ 123,315	$ 127,869
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 6,728	$ 6,060
Accrued liabilities	9,989	13,166
Operating lease liabilities, current portion	888	902
Total current liabilities	17,605	20,128
Accrued milestone and royalty payments	5,375	5,375
Operating lease liabilities, long-term portion	293	517
Other liabilities	853	864
TOTAL LIABILITIES	24,126	26,884
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at March 31, 2024 and December 31, 2023; 43,852,638 and 43,672,112 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	562,436	558,002
Accumulated other comprehensive income	848	449
Accumulated deficit	(464,099)	(457,470)
TOTAL STOCKHOLDERS' EQUITY	99,189	100,985
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 123,315	$ 127,869

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

	Three months ended March 31,	
	2024	2023
REVENUES		
Product revenue, net	$ 19,431	$ 20,251
License revenue	500	—
Total revenues	19,931	20,251
OPERATING COSTS AND EXPENSES		
Cost of goods sold	2,097	2,083
License royalties	50	—
Research and development	13,267	13,418
Selling, general, and administrative	11,425	12,251
Total operating costs and expenses	26,839	27,752
Loss from operations	(6,908)	(7,501)
OTHER INCOME, NET		
Interest and other income	439	1,111
LOSS BEFORE INCOME TAXES	(6,469)	(6,390)
Provision for income taxes	160	—
NET LOSS	$ (6,629)	$ (6,390)
Other comprehensive income/(loss)		
Foreign currency translation	399	(306)
COMPREHENSIVE LOSS	$ (6,230)	$ (6,696)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.15)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	43,779,456	43,671,589

Y-MABS THERAPEUTICS, INC.
Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Three months ended March 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (6,629)	$ (6,390)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	159	182
Stock-based compensation	3,846	5,304
Foreign currency and other transactions	492	(456)
Changes in assets and liabilities:		
Accounts receivable, net	1,866	(6,171)
Inventories	(3,383)	(2,243)
Other current assets	1,473	1,722
Other assets	1,318	(2,983)
Accounts payable	176	(4,771)
Accrued liabilities and other	(2,795)	2,682
NET CASH USED IN OPERATING ACTIVITIES	(3,477)	(13,124)
CASH FLOWS FROM INVESTING ACTIVITIES	—	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercised stock options	588	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	588	—
Effect of exchange rates on cash and cash equivalents	1	(9)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,888)	(13,133)
Cash and cash equivalents at the beginning of period	78,637	105,762
Cash and cash equivalents at the end of period	$ 75,749	$ 92,629