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): February 29, 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 February 29, 2024, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter and full year ended December 31, 2023. 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 February 29, 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: February 29, 2024

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

Exhibit 99.1

Y-mAbs Reports Fourth Quarter and Full Year 2023 Financial Results and Recent Corporate Developments

- **Record DANYELZA® net product revenues of $23.4 million and $84.3 million for Q4 and FY 2023 represents YoY growth of 42% and 71%, respectively**
- **Cash and cash equivalents of $78.6 million as of December 31, 2023; Reiterate anticipated cash runway into 2027**
- **Management announces full year 2024 financial guidance**
- **The Company will host a conference call on Friday, March 1, 2024, at 8:00 a.m. ET**

New York, NY, February 29, 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 quarter and full year ended December 31, 2023.

"Y-mAbs has made significant progress across both the development and commercial fronts of our business resulting in a momentous 2023," said Mike Rossi, President and Chief Executive Officer. "From a development standpoint, we demonstrated proof-of-concept of our Self-Assembly DisAssembly ("SADA") Pretargeted Radioimmunotherapy ("PRIT") platform, showing that GD2-SADA targets and binds to tumors in humans in a Phase 1 trial. We continue to expect to present mature data from Part A of our Phase 1 GD2-SADA clinical trial at a medical meeting in the second half of this year. In addition, we look forward to initiating our CD38-SADA Phase 1 trial this year. While we continue to advance our SADA PRIT platform and programs through clinical development, we are supported by the solid commercial performance of DANYELZA® (naxitamab-gqgk). We achieved record quarterly and annual net product revenues, and sales continue trending upward as more high-volume centers deploy DANYELZA for their patients. Our strong financial foundation and operational performance continue to fuel our mission of providing better and safe therapies for a variety of cancers and improve the lives of patients and their families."

Fourth Quarter 2023 and Recent Corporate Developments

- In December 2023, Y-mAbs announced that it was added to the NASDAQ Biotechnology Index (NASDAQ: NBI), effective December 18, 2023.
- On October 18, 2023, Y-mAbs announced that its Board of Directors appointed radiopharmaceutical industry veteran Mr. Rossi as President and Chief Executive Officer, effective November 6, 2023. Thomas Gad, who founded Y-mAbs in 2015 and has served as Interim Chief Executive Officer since 2022, transitioned to the role of Vice Chairman of the Board of Directors and Chief Business Officer.
- On October 17, 2023, the U.S. FDA cleared Y-mAbs' IND for CD38-SADA, marking the second clinical development program utilizing the Company's novel SADA PRIT technology platform.
- On October 16, 2023, Y-mAbs announced the publication of a study of naxitamab-based chemoimmunotherapy ("HITS") study in patients with refractory high-risk neuroblastoma ("HR-NB") in the journal *Cancers*. The study investigated the HITS combination in patients with HR-NB who did not respond well to induction or refractory therapy. Patients who received HITS immediately after induction had higher response rates (47% vs. 18%) and superior estimated three-year overall survival (85% vs. 29%), compared with those who received the same combination regimen later in the course of treatment. The publication is entitled, "Early Salvage Chemo-Immunotherapy with Irinotecan, Temozolomide and Naxitamab Plus GM-CSF (HITS) for Patients with Primary Refractory High-Risk Neuroblastoma Provide the Best Chance for Long-Term Outcomes."

- On October 11, 2023, Y-mAbs showcased three poster presentations, in addition to an online publication, of DANYELZA at the 55th Congress of the International Society of Pediatric Oncology in Ottawa, Canada.

Financial Results

Revenues

DANYELZA net product revenues were $23.4 million and $84.3 million for the quarter and year ended December 31, 2023, which represented increases of 42% and 71%, respectively, over $16.4 million and $49.3 million in the comparable periods of 2022. The DANYELZA net product revenues of $23.4 million in the fourth quarter of 2023, represented a favorable 17% increase compared to the third quarter of 2023, primarily driven by increased U.S. sales.

As of December 31, 2023, Y-mAbs has delivered DANYELZA to 58 centers across the U.S. since initial launch, with ten new accounts added in 2023.

The Company did not have license revenues in the quarter ended December 31, 2023 and had license revenues of $0.5 million for the year ended December 31, 2023. The Company reported license revenues of $15.0 million and $16.0 million for the quarter and year ended December 31, 2022. License revenues for the year ended December 31, 2023 arose from the September 2023 achievement of marketing authorization for DANYELZA in Mexico under the Company's sublicense agreement with Adium. During the quarter and year ended December 31, 2022, the Company recognized a regulatory-based milestone of $15.0 million from SciClone Pharmaceuticals International Ltd. for the conditional approval of DANYELZA in China.

Operating Costs and Expenses

Cost of Goods Sold

Cost of goods sold was $2.0 million for the quarters ended December 31, 2023 and 2022, respectively. The cost of goods sold was $11.4 million and $7.5 million for the years ended December 31, 2023, and 2022, respectively. The increase in cost of goods sold in both periods was primarily driven by increased product revenues. The Company experienced inventory write-downs of $0.8 million and $1.2 million in the years ended December 31, 2023, and December 31, 2022, respectively.

The Company's gross margin, excluding the 2023 and 2022 inventory write-downs, increased in the fourth quarter of 2023 to 91% due to the gross margin increase from higher U.S. revenues. The Company's gross margin, excluding the 2023 and 2022 inventory write-downs, remained constant at 87% for the year ended December 31, 2023, compared to the year ended December 31, 2022, which was the net impact of the gross margin increase from higher U.S. revenues, offset by increased revenues from geographic areas outside the U.S., which were at a lower gross margin. 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 $13.4 million for the quarter ended December 31, 2023, a reduction of 32% compared to $19.8 million for the quarter ended December 31, 2022. The $6.4 million decrease was primarily due to decreased spending on deprioritized programs, which resulted in a $3.1 million decrease in outsourced manufacturing, a $2.0 million decrease in personnel-related costs, inclusive of stock-based compensation, and a $2.2 million decrease in outsourced research and supplies, partially offset by a $1.2 million increase in clinical trials expenses.

For the year ended December 31, 2023, research and development expenses were $54.2 million, a reduction of 41% compared to $91.6 million for the year ended December 31, 2022. The $37.4 million decrease was primarily due to decreased spending on deprioritized programs, resulting in a $21.0 million decrease in outsourced manufacturing, a $9.0 million decrease in outsourced research and supplies, a $6.1 million decrease in personnel-related costs, inclusive of stock-based compensation, and a $2.0 million decrease in clinical trials, partially offset by a $3.8 million increase in milestones and license acquisition costs primarily related to a $4.1 million increase in milestones accrued under the Company's SADA License Agreement, as the Company determined that achievement of certain time-based clinical milestones within the agreement are probable based on the availability of data and the assessment of clinical progress in the year of 2023.

The $2.0 million and $6.1 million decreases in personnel-related costs during the quarter and year ended December 31, 2023, respectively, were driven by the headcount reduction as part of the Company's restructuring plan announced in January 2023. The expense reduction in the year ended December 31, 2023 was partially offset by severance charges recognized in conjunction with the restructuring plan.

Selling, General, and Administration

Selling, general, and administrative expenses were $11.1 million for the quarter ended December 31, 2023, which was a slight increase compared to $10.8 million for the quarter ended December 31, 2022.

For the year ended December 31, 2023, selling, general, and administrative expenses were $44.9 million, a reduction of 26% compared to $60.9 million for the year ended December 31, 2022. The $16.0 million decrease in selling, general and administrative expenses was primarily attributable to a $10.9 million charge in the year ended December 31, 2022 related to contractual severance-related benefits for the Company's former Chief Executive Officer, and, to a lesser extent, a $3.4 million decrease in commercialization expenses, inclusive of costs of incurred in 2022 in anticipation of a potential omburtamab launch.

Interest and Other Income/(Loss)

Interest and other income/(loss) was relatively unchanged at $2.4 million as compared to $2.3 million during the quarters ended December 31, 2023 and 2022, respectively. Interest and other income/(loss) was $4.8 million of income as compared to $0.8 million of loss for the years ended December 31, 2023 and 2022, respectively. The $5.6 million favorable change in interest and other income/(loss), reflects increased interest income for the year ended December 31, 2023, and was driven by increased money market fund investment income. The Company recorded impairment charges totaling $1.4 million related to the write down of two Secured Promissory Notes during the year ended December 31, 2022.

Net Loss

Y-mAbs reported a net loss for the quarter ended December 31, 2023, of $1.0 million, or ($0.02) per basic and diluted share, compared to net income of $1.2 million, or $0.03 per basic and diluted share, for the quarter ended December 31, 2022. The net income for the quarter ended December 31, 2022, was after $15.0 million of license revenue recognized in the fourth quarter of 2022. For the year ended December 31, 2023, the Company reported a net loss of $21.4 million, or ($0.49) per basic and diluted share, compared to a net loss of $95.6 million, or ($2.19) per basic and diluted share, for the year ended December 31, 2022. The favorable decrease in net loss for the year ended December 31, 2023, was primarily driven by an increase in U.S. and international DANYELZA product revenues for the year ended December 31, 2023, as well as decreased research and development cost, and decreased selling, general and administration cost.

Cash and Cash Equivalents

As of December 31, 2023, Y-mAbs had approximately $78.6 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.

2024 Financial Guidance

- Anticipated 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 Friday, March 1, 2024, at 8:00 a.m. ET. To participate in the call, please use the following dial-in information.

Investors (domestic):	(877) 407-0792
Investors (international):	(201) 689-8263
Conference ID:	13744085

To access a live webcast of the update, please use this link. Prior to the call and webcast, a slide presentation pertaining to our quarterly earnings will be made available in the investor relations section of our 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, including potential partnerships; expectations with respect to the Company's products and product candidates, including otential territory and label expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the potential of the SADA Technology and potential benefits and applications thereof; statements with respect to DANYELZA as a growing commercial product and SADA as a differentiated radioimmunotherapy platform positioning the Company on a path to potentially transform the treatment paradigm for a variety of cancers and improve patients' lives; expectations relating to key anticipated development milestones, including potential expansion of international commercialization efforts with respect to DANYELZA development efforts and the SADA 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 September 30, 2023 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:

Courtney Dugan
VP, Head of Investor Relations
cdu@ymabs.com

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

	As of	
	December 31, 2023	**December 31, 2022**
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 78,637	$ 105,762
Accounts receivable, net	22,454	12,531
Inventories	5,065	6,702
Other current assets	4,955	5,452
Total current assets	111,111	130,447
Property and equipment, net	224	604
Operating lease right-of-use assets	1,412	1,739
Intangible assets, net	2,631	2,986
Other assets	12,491	5,680
TOTAL ASSETS	$ 127,869	$ 141,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 6,060	$ 14,175
Accrued liabilities	13,166	13,241
Operating lease liabilities, current portion	902	868
Total current liabilities	20,128	28,284
Accrued milestone payments	5,375	2,250
Operating lease liabilities, long-term portion	517	899
Other liabilities	864	802
TOTAL LIABILITIES	26,884	32,235
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at December 31, 2023 and December 31, 2022	-	-
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2023 and December 31, 2022; 43,672,112 and 43,670,109 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	558,002	543,929
Accumulated other comprehensive income	449	1,331
Accumulated deficit	(457,470)	(436,043)
TOTAL STOCKHOLDERS' EQUITY	100,985	109,221
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 127,869	$ 141,456

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

	Three months ended December 31,		Years ended December 31,	
	2023	2022	2023	2022
REVENUES				
Product revenue, net	$ 23,363	$ 16,447	$ 84,319	$ 49,267
License revenue	—	15,000	500	16,000
Total revenues	23,363	31,447	84,819	65,267
OPERATING COSTS AND EXPENSES				
Cost of goods sold	2,039	2,020	11,366	7,467
License royalties	—	—	50	100
Research and development	13,388	19,787	54,219	91,572
Selling, general, and administrative	11,135	10,793	44,856	60,939
Total operating costs and expenses	26,562	32,600	110,491	160,078
Loss from operations	(3,199)	(1,153)	(25,672)	(94,811)
OTHER INCOME/(LOSS), NET				
Interest and other income/(loss)	2,406	2,310	4,806	(757)
LOSS BEFORE INCOME TAXES	(793)	1,157	(20,866)	(95,568)
Provision for income taxes	195	—	561	—
NET INCOME/(LOSS)	$ (988)	$ 1,157	$ (21,427)	$ (95,568)
Other comprehensive loss				
Foreign currency translation	(1,400)	(3,371)	(882)	(40)
COMPREHENSIVE LOSS	$ (2,388)	$ (2,214)	$ (22,309)	$ (95,608)
Net income/(loss) per share attributable to common stockholders, basic	$ (0.02)	$ 0.03	$ (0.49)	$ (2.19)
Weighted average common shares outstanding, basic	43,627,270	43,668,690	43,645,388	43,703,663
Net income/(loss) per share attributable to common stockholders, diluted	$ (0.02)	$ 0.03	$ (0.49)	$ (2.19)
Weighted average common shares outstanding, diluted	43,627,270	44,692,485	43,645,388	43,703,663