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 12, 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 August 12, 2024, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended June 30, 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 August 12, 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: August 12, 2024

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

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

- *Reported Total DANYELZA net product revenues of $22.8 million for the second quarter of 2024, representing a 10% YoY increase*
- *Continued geographic expansion of DANYELZA with new market revenues recorded in the second quarter from Brazil and Mexico; DANYELZA now approved in Hong Kong*
- *Part A of Phase 1 GD2-SADA Trial from novel SADA-PRIT radiotherapy platform expected to be completed in the fourth quarter of 2024*
- *Appointed Peter Pfreundschuh as the new Chief Financial Officer and radiopharma industry veteran Norman LaFrance, M.D. as Chief Development Officer*
- *Cash and cash equivalents of $77.8 million held as of June 30, 2024, reflects $0.8 million cash burn in the six months ended June 30, 2024; management reiterates anticipated cash runway into 2027*
- *Management updates Full Year 2024 Total Net Revenue guidance*
- *The Company will host a conference call on Monday, August 12, 2024, at 8:00 a.m. ET*

New York, NY, August 12, 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 second quarter ended June 30, 2024.

"We demonstrated commercial progress with DANYELZA in the second quarter of this year while continuing to advance our development pipeline," said Mike Rossi, President and Chief Executive Officer. "Our dedicated U.S. sales team with deep neuroblastoma expertise continues to penetrate new centers with DANYELZA, a leading anti-GD2 therapy, added to two more hospital formularies in the second quarter of 2024, while our ex-U.S. distribution partners have gained traction in our Eastern Asia and Latin America markets. Additionally, we remain focused on advancing our novel Self-Assembly DisAssembly ("SADA") Pretargeted Radioimmunotherapy ("PRIT) technology platform and continue to evaluate potential expansion of indications for naxitamab in our mission of delivering better and safer therapies to patients. Looking ahead, we are on track to complete Part A of our GD2-SADA Phase 1 clinical trial in the fourth quarter of this year with a data readout to follow and are on track to dose the first patient in our CD38-SADA Phase 1 in Non-Hodgkin's Lymphoma trial in the second half of this year."

Second Quarter 2024 and Recent Corporate Highlights

- Appointed Peter Pfreundschuh as Chief Financial Officer and deepened radiopharmaceutical expertise with the appointment of Norman LaFrance, M.D. as Chief Development Officer.
- Y-mAbs' distribution partner in Latin America, Adium, initiated the commercial launch of DANYELZA in Brazil and Mexico.
- Entered into a distribution agreement with TRPharm İlaç Sanayi Ticaret A.Ş. and TRPharm FZ-LLC for the named patient program distribution of DANYELZA in Turkey.
- Received marketing authorization approval for DANYELZA in Hong Kong. Y-mAbs' Asian distribution partner, SciClone Pharmaceuticals, is expected to initiate the commercial launch of DANYELZA in Hong Kong this year.
- Presented preclinical GD2-SADA data at the Society of Nuclear Medicine & Molecular Imaging 2024 annual Meeting on June 8-11, 2024, in Toronto, Canada.
- Highlighted new interim analysis of Phase 2 data for naxitamab in several poster presentations and preclinical GD2-SADA data at the 2024 American Society of Clinical Oncology ("ASCO") Annual Meeting on May 31-June 4, 2024, in Chicago, IL.

Financial Results

Revenues

Total net product revenues were $22.8 million and $42.2 million for the quarter and six months ended June 30, 2024, which represented an increase of 10% and 3%, respectively, over $20.8 million and $41.0 million in the comparable periods of 2023.

DANYELZA total net product revenues of $22.8 million in the second quarter of 2024, represented a 10% increase compared to the second quarter of 2023, primarily driven by increased international revenues. Y-mAbs' international DANYELZA net product revenues were $7.6 million for the three months ended June 30, 2024, an increase of 55% over $4.9 million in the comparable period in 2023. The increase of net product revenue in the quarter ended June 30, 2024, compared to the quarter ended June 30, 2023, was a result of increased volume from Western Europe, as well as the commercial launch for Brazil and Mexico in Latin America. U.S. DANYELZA net product revenues were $15.2 million and $15.9 million for the three months ended June 30, 2024 and 2023, respectively, representing a 4% decline driven by a volume decrease due to the launch of competing therapy in another class of agents and some ongoing clinical trial activities.

The Company's total net product revenue was $42.2 million for the six months ended June 30, 2024, as compared to $41.0 million in the comparable period in 2023. The 3% increase was primarily driven by a $1.2 million increase in the U.S. DANYELZA net product revenue in the six months ended June 30, 2024, while international net product revenue was relatively flat.

As of June 30, 2024, Y-mAbs has delivered DANYELZA to 65 centers across the U.S. since initial launch, with two new accounts added in the U.S. in the second quarter of 2024. During the quarter ended June 30, 2024, approximately 67% of the vials sold in the U.S. were sold outside of Memorial Sloan Kettering Cancer Center ("MSK"), compared to 60% in the first quarter ended March 31, 2024.

The Company did not have license revenue for the quarters ended June 30, 2024 and 2023. The Company had license revenues of $0.5 million for the six months ended June 30, 2024, from our distribution partner, Adium, related to our acceptance of the price for DANYELZA in Brazil from the Brazilian Medicines Market Regulation Chamber. There was no license revenue recorded for the six months ended June 30, 2023.

Operating Costs and Expenses

Cost of Goods Sold

Cost of goods sold was $3.0 million and $4.6 million for the quarter ended June 30, 2024 and 2023, respectively. Cost of goods sold was $5.1 million and $6.7 million for the six months ended June 30, 2024 and 2023, respectively. The Company defines gross margin as net product revenues less cost of goods sold divided by net product revenues. Our gross margins increased in the three and six months ended June 30, 2024, compared to the comparable periods in 2023, due to a favorable gross profit mix from lower vial volumes from our international regions.

Research and Development

Research and development expenses were $12.3 million for the quarter ended June 30, 2024, and relatively flat compared to $12.1 million for the quarter ended June 30, 2023. For the six months ended June 30, 2024 and 2023, research and development expenses were relatively flat at $25.6 million and $25.5 million, respectively.

Selling, General, and Administration

Selling, general, and administrative expenses were $17.2 million for the three months ended June 30, 2024, which was a $5.9 million increase compared to $11.3 million for the three months ended June 30, 2023. The increase was primarily attributable to a net impact of $3.6 million related to the Company's settlement of a shareholder class-action lawsuit, which is the net impact of the Company's $19.7 million accrued legal settlement, less the corresponding insurance recovery of $16.1 million and an additional legal settlement of $0.2 million in the three months ended June 30, 2024.

For the six months ended June 30, 2024, selling, general, and administrative expenses were $28.7 million, an increase of $5.2 million for the six months ended June 30, 2023. The increase was primarily attributable to a net impact of $3.8 million related to the Company's two legal settlements, as noted above.

Interest and Other Income

Interest and other income were $0.6 million for the three months ended June 30, 2024, as compared to $1.1 million for the three months ended June 30, 2023. The decrease of $0.5 million was primarily due to a $0.2 million gain from repayment of a secured promissory note in the three months ended June 30, 2023, and a $0.2 million increase in foreign currency transaction losses. The Company did not have the repayment of a secured promissory note in the three months ended June 30, 2024.

For the six months ended June 30, 2024 and 2023, the interest and other income was $1.1 million and $2.2 million, respectively. The decrease of $1.1 million was primarily due to a $0.8 million increase in foreign currency transaction losses related to the remeasurement of foreign currency denominated assets and liabilities.

Net Loss

Y-mAbs reported a net loss for the three months ended June 30, 2024, of $9.2 million, or ($0.21) per basic and diluted share, compared to net loss of $6.3 million, or ($0.14) per basic and diluted share, for the three months ended June 30, 2023. For the six months ended June 30, 2024, the Company reported a net loss of $15.9 million, or ($0.36) per basic and diluted share, as compared to net loss of $12.7 million, or ($0.29) per basic and diluted share, for the six months ended June 30, 2023. The increase in net loss for the three and six months ended June 30, 2024 was primarily driven by the net $3.8 million in charges related to the Company's two legal settlements, as described above.

Cash and Cash Equivalents

As of June 30, 2024, Y-mAbs had approximately $77.8 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. Cash utilized in the first half year of 2024 was $0.8 million, which was favorable to internal company forecasts.

2024 Financial Guidance

Management updates its full year 2024 guidance:

- Anticipated Total Net Revenues now expected to be between $87 million and $95 million;
- Anticipated Operating Expenses expected to remain between $115 million and $120 million;
- Anticipated Total Annual Cash Burn expected to remain 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 Monday, August 12, 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

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; the Company’s mission of delivering better and safer therapies to patients; expectations relating to key anticipated development milestones, including potential expansion and advancement of commercialization and development efforts, including potential indications, applications and geographies, 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,” “goal,” “objective,” 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 ability 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 quarterly period ended March 31, 2024, the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 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:

Courtney Dugan
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Y-MABS THERAPEUTICS, INC.

Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 77,806	$ 78,637
Accounts receivable, net	22,191	22,454
Inventories	8,498	5,065
Insurance recovery receivable related to legal settlement	16,025	—
Other current assets	2,243	4,955
Total current assets	126,763	111,111
Property and equipment, net	87	224
Operating lease right-of-use assets	1,271	1,412
Intangible assets, net	2,454	2,631
Other assets	13,460	12,491
TOTAL ASSETS	$ 144,035	$ 127,869
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 10,190	$ 6,060
Accrued liabilities	12,788	13,166
Accrued legal settlement	19,650	—
Operating lease liabilities, current portion	842	902
Total current liabilities	43,470	20,128
Accrued milestone and royalty payments	3,950	5,375
Operating lease liabilities, long-term portion	432	517
Other liabilities	847	864
TOTAL LIABILITIES	48,699	26,884
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at June 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at June 30, 2024 and December 31, 2023; 44,567,334 and 43,672,112 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	567,633	558,002
Accumulated other comprehensive income	1,047	449
Accumulated deficit	(473,348)	(457,470)
TOTAL STOCKHOLDERS' EQUITY	95,336	100,985
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 144,035	$ 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 June 30,		Six months ended June 30,	
	2024	2023	2024	2023
REVENUES				
Product revenue, net	$ 22,798	$ 20,751	$ 42,229	$ 41,002
License revenue	—	—	500	—
Total revenues	22,798	20,751	42,729	41,002
OPERATING COSTS AND EXPENSES				
Cost of goods sold	3,014	4,649	5,111	6,732
License royalties	—	—	50	—
Research and development	12,341	12,055	25,608	25,473
Selling, general, and administrative	17,232	11,270	28,657	23,521
Total operating costs and expenses	32,587	27,974	59,426	55,726
Loss from operations	(9,789)	(7,223)	(16,697)	(14,724)
OTHER INCOME, NET				
Interest and other income	640	1,100	1,079	2,211
LOSS BEFORE INCOME TAXES	(9,149)	(6,123)	(15,618)	(12,513)
Provision for income taxes	100	179	260	179
NET LOSS	$ (9,249)	$ (6,302)	$ (15,878)	$ (12,692)
Other comprehensive income/(loss)				
Foreign currency translation	199	18	598	(288)
COMPREHENSIVE LOSS	$ (9,050)	$ (6,284)	$ (15,280)	$ (12,980)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.21)	$ (0.14)	$ (0.36)	$ (0.29)
Weighted average common shares outstanding, basic and diluted	44,022,356	43,663,112	43,900,639	43,667,385

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Six months ended June 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (15,878)	$ (12,692)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	312	406
Stock-based compensation	7,285	8,920
Foreign currency and other transactions	724	(774)
Changes in assets and liabilities:		
Accounts receivable, net	263	(6,587)
Inventories	(3,433)	1,515
Insurance recovery receivable related to legal settlement	(16,025)	—
Other current assets	2,712	1,402
Other assets	(969)	(6,570)
Accounts payable	3,406	(6,149)
Accrued liabilities and other	(1,226)	2,671
Accrued legal settlement	19,650	—
NET CASH USED IN OPERATING ACTIVITIES	(3,179)	(17,858)
CASH FLOWS FROM INVESTING ACTIVITIES	—	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercised stock options	2,346	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	2,346	—
Effect of exchange rates on cash and cash equivalents	2	5
NET DECREASE IN CASH AND CASH EQUIVALENTS	(831)	(17,853)
Cash and cash equivalents at the beginning of period	78,637	105,762
Cash and cash equivalents at the end of period	$ 77,806	$ 87,909
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES		
Right-of-use assets obtained in exchange for lease obligations	$ 320	$ —
Acquisition of treasury shares upon repayment of secured promissory note	$ —	$ 480