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): March 30, 2023

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 March 30, 2023, Y-mAbs Therapeutics, Inc., announced its financial results for the fiscal year ended December 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 March 30, 2023.
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: March 30, 2023

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

Exhibit 99.1

Y-mAbs Reports Fourth Quarter and Full-Year 2022 Financial Results and Recent Corporate Developments

- **Q4 2022 DANYELZA® record net product revenues of $16.4 million, driving YoY growth of 71% and 31% sequential increase compared to Q3 2022**
- **DANYELZA conditional marketing authorization granted in China**
- **Management reiterates 2023 financial guidance**
- **First ever SADA Phase I trial opened**
- **Cash and cash equivalents of $105.8 million as of December 31, 2022, anticipated runway into the first quarter 2026**
- **The Company will host a conference call on Friday, March 31, 2023, at 9 a.m. EST**

New York, NY, March 30, 2023 (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 fourth quarter and full year 2022.

"The fourth quarter of 2022 marked another period of significant progress for DANYELZA and set up 2023 to be a very productive year,” said Thomas Gad, President and Interim Chief Executive Officer. “We are thrilled to report record DANYELZA net revenues of $16.4 million in the fourth quarter of 2022, a 31% sequential increase compared to the previous quarter. In addition, DANYELZA was conditionally approved in China, with a planned launch in the first half of 2023. We look forward to our partners’ continued efforts to expand DANYELZA globally to offer much-needed treatment for patients with relapsed/refractory high-risk neuroblastoma in the bone or bone marrow.”

Mr. Gad continued, “We recently implemented a restructuring plan to prioritize resources on the DANYELZA franchise and development of our SADA technology in the fight against cancer. With a 35% reduction in force and an anticipated 28% reduction in annual operating expenses for 2023, we emerge leaner and supported by a robust balance sheet with $105.8 million in cash and cash equivalents as of December 31, 2022, which we estimate should support our business operations as currently planned into the first quarter of 2026. We achieved a major milestone of getting our first unique SADA IND cleared by the FDA and opening up our first ever SADA Phase I trial late in 2022. We are actively screening patients initially for Small Cell Lung Cancer, Sarcoma and Melanoma and are eventually planning to screen more broadly for GD2 positive solid tumors.”

Fourth Quarter 2022 and Recent Corporate Developments

- On February 2, 2023, Y-mAbs announced that the European Medicines Agency agreed to the Company’s Pediatric Investigational Plan for naxitamab
- On January 4, 2023, Y-mAbs announced a restructuring plan including a 35% reduction in workforce and an anticipated 28% reduction in annual operating expenses for 2023
- On December 21, 2022, Y-mAbs announced a partnership with WEP Clinical regarding early access program for DANYELZA (naxitamab-gqgk) in Europe
- On December 14, 2022, Y-mAbs announced a new SADA construct, CD38-SADA against non-Hodgkin’s Lymphoma
- On December 8, 2022, Y-mAbs announced that DANYELZA (naxitamab-gqgk) for the treatment of high-risk neuroblastoma was conditionally approved in China

- On December 1, 2022, Y-mAbs announced that the Company had received a complete response letter for omburtamab BLA indicating that the FDA determined that it was unable to approve the BLA in its current form.

- On November 17, 2022, Y-mAbs activated its first ever SADA Phase I trial site and by March 11 Memorial Sloan Kettering was activated as the fourth clinical study site planned to enroll Small Cell Lung Cancer, Sarcoma and Melanoma patients

- On October 28, 2022, Y-mAbs announced the outcome of the FDA Oncologic Drugs Advisory Committee meeting, where the committee voted 16 to 0 that the Company had not provided sufficient evidence to conclude that omburtamab improves overall survival

- On October 3, 2022 Y-mAbs announced pivotal data from Study 101 for omburtamab in CNS/LM metastasis from neuroblastoma at the International Society of Pediatric Oncology ("SIOP") annual congress

Financial Results

Revenues

Y-mAbs reported net revenues of $31.5 million and $65.3 million for the fourth quarter 2022 and year ended December 31, 2022, which represented increases of 228% and 87%, respectively, over $9.6 million and $34.9 million in the comparable periods of 2021. Net revenues in the quarter and year ended December 31, 2022 included license revenue of $15.0 million and $16.0 million, respectively, compared to no license revenue in the fourth quarter ended December 31, 2021, and license revenue of $2.0 million for the year ended December 31, 2021. During the three months and year ended December 31, 2022, we recognized a regulatory-based milestone payment received of $15.0 million from SciClone Pharmaceuticals International Ltd. for the conditional approval of DANYELZA in China.

DANYELZA net product revenue for the fourth quarter of 2022 and year ended December 31, 2022, was $16.4 million and $49.3 million, respectively, which represented increases of 71% and 50%, respectively, over the corresponding periods in 2021 and an increase of 31% compared to the third quarter 2022 DANYELZA net product revenues of $12.5 million. The increase was primarily driven by an increase in the number of new U.S. patients in treatment during the fourth quarter of 2022.

As of December 31, 2022, Y-mAbs has delivered DANYELZA to 48 centers across the United States, corresponding to an increase of 12% in the number of centers since the third quarter of 2022. During the fourth quarter of 2022, approximately 53% of the vials sold in the United States were sold outside Memorial Sloan Kettering ("MSK"), an increase from the prior quarter as a result of the growth of new patients at institutions outside MSK outpacing MSK's growth of new patients.

Operating Expenses

Research and Development

Research and development expenses were $19.8 million for the three months ended December 31, 2022, compared to $28.7 million for the three months ended December 31, 2021. The $8.9 million decrease reflects decreased spending for clinical trials, outsourced research and supplies, and costs for outsourced manufacturing services due to decreased clinical trial activities in 2022. Having completed the resubmission of the BLA for omburtamab in the first quarter of 2022, we are now focused on pipeline development programs for potential DANYELZA label expansion and advancing SADA constructs into the clinic.

Research and development expenses decreased by $1.6 million to $91.6 million during the year ended December 31, 2022, compared to the prior year period. The decrease mainly reflects decreased clinical trial activities in 2022.

Selling, General, and Administration

Selling, general, and administrative expenses decreased by $4.3 million to $10.8 million for the three months ended December 31, 2022, compared to $15.1 million for the three months ended December 31, 2021. The decrease in selling, general and administrative expenses was primarily the result of a $1.8 million decrease in costs related to the commercialization of DANYELZA as there were heavy launch costs in the fourth quarter of 2021.

Selling, general, and administrative expenses increased by $6.3 million to $60.9 million for the year ended December 31, 2022, compared to $54.6 million for the year ended December 31, 2021. The increase in selling, general, and administrative expenses was primarily attributable to a $7.8 million increase in severance and share-based compensation expense related to the termination of our former chief executive officer.

Net Loss

We reported net income for the fourth quarter ended December 31, 2022, of $1.2 million, or $0.03 per basic and diluted share, compared to a net loss of $36.9 million, or $0.85 per basic and diluted share, for the quarter ended December 31, 2021. The favorable change to net income in 2022 was primarily driven by the license revenues of $15.0 million, the positive gross profit impact from increased DANYELZA revenues and the decreased research and development expenses in 2022.

We reported a net loss for the year ended December 31, 2022, of $95.6 million, or $2.19 per basic and diluted share, compared to a net loss of $55.3 million, or $1.28 per basic and diluted share, for the year ended December 31, 2021. Net loss in the year ended December 31, 2021, included a $62.0 million net gain from the sale of our DANYELZA Priority Review Voucher, after sharing 40% of the net proceeds from the sale with MSK, pursuant to the terms of our license agreement with MSK. The increase in net loss for the year ended December 31, 2022, also reflects the impact of contractual severance-related benefits for our former chief executive officer, as noted above, partially offset by the gross profit impact of DANYELZA's revenue growth and 2022 license revenues.

Cash and Cash Equivalents

We had approximately $105.8 million in cash and cash equivalents as of December 31, 2022, and we expect a full-year 2023 cash burn of $50-55 million. Our existing cash and cash equivalents, when combined with anticipated DANYELZA revenues, which are assumed to increase by 10% each year for the purpose of our analysis of runway, is expected to be sufficient to fund our operations into the first quarter of 2026. In terms of development activities, we have assumed that our prioritized programs will be advanced at our own expense and no new programs are assumed at this point. We assume no new partnerships or other new business development, and no further development of the omburtamab program.

This estimate reflects our current business plan that is supported by assumptions that may prove to be inaccurate, such that we could use our available capital resources sooner than we currently expect.

Financial Guidance

Management reiterated its 2023 financial guidance including:

- Anticipated DANYELZA® net product revenues of $60-$65 million;
- Anticipated operating expenses of $115-120 million;
- Anticipated total annual cash burn of $50-55 million; and
- Cash and cash equivalents anticipated to support operations as currently planned into the first quarter of 2026.

Webcast and Conference Call

Y-mAbs will host a conference call on Friday, March 31, 2023, at 9 a.m. Eastern Time. To participate in the call, please use the following dial-in information.

Investors (domestic):	877-407-0792
Investors (international):	201-689-8263
Conference ID:	13736579

To access a live webcast of the update, please use this link.

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, OMBLASTYS® (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 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 2023, including estimated operating expenses, total cash burn and DANYELZA product revenue and sufficiency of cash resources; the restructuring, including the reduction in workforce and revised business plan, and the expected impacts, expenses and benefits thereof, including potential cost-savings from the reduction in force, expected reduction of operating expenses and any expectations with respect to cost savings to be derived therefrom; implied and express statements regarding the future of the Company's business; the Company's plans and strategies, development, commercialization and product distribution plans; expectations with respect to omburtamab; expectations with respect to our 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 Technology, including the development of the first tumor binding dataset and potential benefits thereof; 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 potential application to [a broad set of][all] GD2 positive solid tumors, and the timing thereof; expectations with respect to 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; including satisfaction of conditions to approvals; 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'' 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; the risks that actual results of our restructuring plan and revised business plan will not be as expected; 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 COVID-19 pandemic; risks associated with the conflict between Russia and Ukraine and sanctions related thereto; including inflation and uncertain global credit and capital markets; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2022, and future filings and reports by the Company including the Company's Annual Report on Form 10-K for the year ended December 31, 2022. 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®, OMBLASTYS® and Y-mAbs® are registered trademarks of Y-mAbs Therapeutics, Inc.

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

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 105,762	$ 181,564
Accounts receivable, net	12,531	7,712
Inventories	6,702	5,512
Other current assets	5,452	7,473
Total current assets	130,447	202,261
Property and equipment, net	604	1,847
Operating lease right-of-use assets	1,739	3,842
Intangible assets, net	2,986	1,663
Other assets	5,680	3,170
TOTAL ASSETS	$ 141,456	$ 212,783
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 14,175	$ 13,552
Accrued liabilities	13,241	12,540
Operating lease liabilities, current portion	868	1,783
Total current liabilities	28,284	27,875
Accrued milestones	2,250	2,100
Operating lease liabilities, long-term portion	899	1,851
Other liabilities	802	851
TOTAL LIABILITIES	32,235	32,677
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at December 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2022 and December 31, 2021; 43,670,109 and 43,694,716 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	4	4
Additional paid in capital	543,929	519,206
Accumulated other comprehensive income	1,331	1,371
Accumulated deficit	(436,043)	(340,475)
TOTAL STOCKHOLDERS' EQUITY	109,221	180,106
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 141,456	$ 212,783

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,	
	2022	2021	2022	2021
REVENUES				
Product revenue, net	$ 16,447	$ 9,598	$ 49,267	$ 32,897
License revenue	15,000	—	16,000	2,000
Total revenues	31,447	9,598	65,267	34,897
OPERATING COSTS AND EXPENSES				
Cost of goods sold	2,020	1,461	7,467	2,304
License royalties	—	—	100	210
Research and development	19,787	28,757	91,572	93,245
Selling, general, and administrative	10,793	15,138	60,939	54,571
Total operating costs and expenses	32,600	45,356	160,078	150,330
Loss from operations	(1,153)	(35,758)	(94,811)	(115,433)
OTHER INCOME / (LOSS), NET				
Gain from sale of priority review voucher, net	—	—	—	62,010
Interest and other income/(loss), net	2,310	(1,135)	(757)	(1,852)
NET INCOME/(LOSS)	$ 1,157	$ (36,893)	$ (95,568)	$ (55,275)
Other comprehensive income				
Foreign currency translation	(3,371)	1,146	(40)	1,897
COMPREHENSIVE LOSS	$ (2,214)	$ (35,747)	$ (95,608)	$ (53,378)
Net income/(loss) per share attributable to common stockholders, basic	$ 0.03	$ (0.84)	$ (2.19)	$ (1.28)
Weighted average common shares outstanding, basic	43,668,690	43,664,277	43,703,663	43,181,808
Net income / (loss) per share attributable to common stockholders, diluted	$ 0.03	$ (0.84)	$ (2.19)	$ (1.28)
Weighted average common shares outstanding, diluted	44,692,485	43,664,277	43,703,663	43,181,808