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): November 7, 2022

Y-MABS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38650**	**47-4619612**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

230 Park Avenue
Suite 3350
New York, New York 10169
(Address of principal executive offices) (Zip Code)

(646) 885-8505
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading Symbol**	**Name of each exchange on which registered:**
Common Stock, $0.0001 par value	YMAB	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2022, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended September 30, 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 November 7, 2022.
104	Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Y-MABS THERAPEUTICS, INC.

Date: November 7, 2022

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

Exhibit 99.1

Y-mAbs Reports Third Quarter 2022 Financial Results and Recent Corporate Developments

- **Q3 2022 DANYELZA® record product revenues of $12.5 million, YoY growth of 40% and 28% sequential increase compared to Q2 2022**
- **DANYELZA marketing authorization granted in Israel; regulatory filing submitted in Brazil**
- **Management reiterates financial guidance, including anticipated 2022 full-year DANYELZA® revenue of $45-$50 million**
- **Cash position of $114.5 million as of September 30, 2022, anticipated runway into mid-2024**
- **The Company will host a conference call on Tuesday, November 8, 2022, at 4 p.m. EST**

New York, NY, November 7, 2022 (GLOBE NEWSWIRE) – Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB) a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer, today reported financial results for the third quarter of 2022.

"The third quarter marked significant progress for DANYELZA. We are thrilled to report record sales of $12.5 million, a 28% increase compared to the previous quarter. In addition, DANYELZA was approved in Israel and submitted for marketing authorization in Brazil, and we look forward to our partners' continued efforts to expand DANYELZA," said Thomas Gad, President and Interim Chief Executive Officer. "While we are truly disappointed by the outcome of the recent ODAC meeting for omburtamab after working tirelessly to receive breakthrough designation and submit the BLA to the FDA, we remain steadfast in our commitment to patients and caregivers who do not have access to an approved treatment, where there is a clear unmet need. However, while we await FDA's formal decision on the BLA, we remain confident knowing that that Y-mAbs has never been defined by a single program or technology. Our expertise spans multiple verticals and disciplines, and we continue to invest confidently in our future with the promise of SADA while looking to maximize DANYELZA as the cornerstone of a sustainable pediatric oncology franchise funded by a strong balance sheet with $114.5 million in cash that is sufficient to support our business operations as currently planned into mid-2024."

Third Quarter 2022 and Recent Corporate Developments

- On October 28, 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, 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
- On September 26, Y-mAbs announced a regulatory filing for DANYELZA for the treatment of neuroblastoma in Brazil by Adium Pharma
- On August 30, Y-mAbs announced that Takeda received marketing authorization for DANYELZA for the treatment of neuroblastoma in Israel
- On July 12, Y-mAbs announced clearance of the IND for GD2-SADA

Financial Results

Revenues

Y-mAbs reported net revenues of $12.5 million and $33.8 million for the third quarter 2022 and nine months ended September 30, 2022, which represented increases of 40% and 34%, respectively, over $9.0 million and $25.3 million in the comparable periods of 2021. Net revenues in the nine months ended September 30, 2022 included $1.0 million of license revenue, compared to $2.0 million of license revenue in the corresponding period in 2021.

DANYELZA product revenue for the third quarter 2022 and nine months ended September 30, 2022, was $12.5 million and $32.8 million, respectively, which represented increases of 40% and 41%, respectively, over the corresponding periods in 2021 and an increase of 28% compared to the second quarter of 2022 DANYELZA product revenues of $9.8 million. The increase was primarily driven by an increase in the number of new U.S. patients in treatment during the third quarter of 2022.

As of September 30, 2022, Y-mAbs has delivered DANYELZA to 43 centers across the United States, corresponding to an increase of more than 19% in the number of centers since the end of the second quarter of 2022. During the third quarter of 2022, approximately 40% of the vials sold in the United States were sold outside Memorial Sloan Kettering (“MSK”), a decrease from the prior quarter as a result of MSK’s growth of new patients outpacing the growth of new patients at institutions outside MSK.

Operating Expenses

Research and Development

Research and development expenses were $22.4 million for the three months ended September 30, 2022, compared to $23.1 million for the three months ended September 30, 2021. The $0.7 million decrease reflects decreased spending for clinical trials, partially offset by increased costs for outsourced manufacturing services. Having completed the resubmission of the BLA for omburtamab in the first quarter of 2022, we are focusing on pipeline development programs for potential DANYELZA label expansion and advancing SADA constructs into the clinic.

Research and development expenses increased by $7.3 million to $71.8 million during the nine months ended September 30, 2022, compared to the prior year period. The $7.3 million increase mainly reflects an increase in outsourced manufacturing services and increased personnel costs dedicated to our advancement of DANYELZA, omburtamab, and the SADA constructs.

Selling, General, and Administration

Selling, general, and administrative expenses decreased by $0.4 million to $13.6 million for the three months ended September 30, 2022, compared to $14.0 million for the three months ended September 30, 2021. The decrease in selling, general and administrative expenses was primarily the result of a $2.1 million decrease in salary and stock-based compensation expense, partially offset by increased costs related to the commercialization of DANYELZA.

Selling, general, and administrative expenses increased by $10.7 million to $50.1 million for the nine months ended September 30, 2022, compared to $39.4 million for the nine months ended September 30, 2021. The increase in selling, general, and administrative expenses was primarily attributable to an $8.9 million increase in severance and share-based compensation expense related to our former chief executive officer in the nine months ended September 30, 2022, and to a lesser extent, the commercialization of DANYELZA.

Net Loss

We reported a net loss for the quarter ended September 30, 2022 of $27.5 million, or $0.63 per basic and diluted share, compared to a net loss of $28.9 million, or $0.66 per basic and diluted share for the quarter ended September 30, 2021. The decrease in net loss was primarily driven by the positive gross profit impact from increased revenues.

We reported a net loss for the nine months ended September 30, 2022 of $96.7 million, or $2.21 per basic and diluted share, compared to a net loss of $18.4 million, or $0.43 per basic and diluted share, for the nine months ended September 30, 2021. Net loss in the nine months ended September 30, 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 in the nine months ended September 30, 2022 also reflects the impact of contractual severance-related benefits for our former chief executive officer, and increased research and development expenses, both as noted above, partially offset by the gross profit impact of DANYELZA's revenue growth.

Cash and Cash Equivalents

We had approximately $114.5 million in cash and cash equivalents as of September 30, 2022, and we continue to expect a full-year 2022 cash burn of $78-83 million. Our cash and cash equivalents balance, when combined with anticipated DANYELZA revenues, is expected to be sufficient to fund our operations as currently planned into mid-2024. This estimate is based on our current business plan, and we have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

This estimate does not include any potential product revenues for omburtamab, if approved, or any potential net proceeds from the potential receipt and sale of any priority review voucher, which we expect would be awarded to us if we receive approval of omburtamab. The estimate assumes receipt of a regulatory milestone payment for DANYELZA approval in China, but no new partnerships or other new business development-related sources of income.

Financial Guidance

Management reiterates all elements of its 2022 financial guidance including, anticipated:

- DANYELZA® product revenues of $45-$50 million;
- Operating expenses of $162-167 million;
- Total cash burn of $78-83 million; and
- Cash position sufficient to fund current operations as planned into mid-2024.

The DANYELZA revenue guidance includes an incremental benefit from international revenues. We will review operating expenses based on final FDA feedback on the omburtamab BLA but expect no adverse impact on cash runway.

Webcast and Conference Call

Y-mAbs will host a conference call on Tuesday, November 8, 2022, at 4 p.m. Eastern Time. To participate in the call, please dial 877-300-8521 (domestic) or 412-317-6026 (international) and reference the conference ID 10172741.

A webcast will be available at: https://viavid.webcasts.com/starthere.jsp?ei=1579270&tp_key=92279e61e6

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 The Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about our business model and development, commercialization and product distribution plans; current and future clinical and pre-clinical studies and our research and development programs; expectations related to the timing of the initiation and completion of regulatory submissions; regulatory, marketing and reimbursement approvals, including statements with respect to the potential approval and utility of omburtamab, pipeline development programs, potential for DANYELZA territory expansion, and advancement of SADA; collaborations or strategic partnerships and the potential benefits thereof; potential for receipt and sale of a PRV voucher relating to omurtamab, if approved, and potential net proceeds therefrom; expectations related to our anticipated cash runway and the sufficiency of our cash resources; DANYELZA revenue guidance and other guidance for 2022 and future years, and our financial performance, including our estimates regarding revenues, expenses and capital expenditure requirements; and other statements that are not historical facts. Words such as ''anticipate,'' ''believe,'' "contemplate," ''continue,'' ''could,'' ''estimate,'' ''expect,'' "hope," ''intend,'' ''may,'' ''might,'' ''plan,'' ''potential,'' ''predict,'' ''project,'' ''should,'' ''target,'' "will", ''would'' and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including but not limited to: risks associated with our financial condition and need for additional capital; risks associated with our development work; cost and success of our product development activities and clinical trials; the risks of delay in the timing of our regulatory submissions or failure to receive approval of our drug candidates; the risks related to commercializing any approved pharmaceutical product, including the rate and degree of market acceptance of our product candidates; development of our sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for our products; the risks related to our dependence on third parties, including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; the risks related to government regulation; risks related to market approval; risks associated with protection of our intellectual property rights; risks related to employee matters and managing growth; risks related to our common stock; risks associated with the COVID-19 pandemic; risks associated with the conflict between Russia and Ukraine and sanctions related thereto, macroeconomic conditions, including inflation and volatile global capital markets; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC and in our other SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 to be filed with the SEC. 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 data)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 114,526	$ 181,564
Accounts receivable, net	9,251	7,712
Inventories	6,242	5,512
Other current assets	3,225	7,473
Total current assets	133,244	202,261
Property and equipment, net	1,372	1,847
Operating lease right-of-use assets	2,169	3,842
Intangible assets, net	1,530	1,663
Other assets	5,600	3,170
TOTAL ASSETS	$ 143,915	$ 212,783
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 13,723	$ 13,552
Accrued liabilities	17,092	12,540
Operating lease liabilities, current portion	1,200	1,783
Total current liabilities	32,015	27,875
Accrued milestone payments	2,250	2,100
Operating lease liabilities, long-term portion	1,019	1,851
Other liabilities	733	851
TOTAL LIABILITIES	36,017	32,677
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at September 30, 2022 and December 31, 2021; 43,668,130 and 43,694,716 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	4	4
Additional paid in capital	540,392	519,206
Accumulated other comprehensive income	4,702	1,371
Accumulated deficit	(437,200)	(340,475)
TOTAL STOCKHOLDERS' EQUITY	107,898	180,106
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 143,915	$ 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 September 30,		Nine months ended September 30,	
	2022	**2021**	**2022**	**2021**
REVENUES				
Product revenue, net	$ 12,537	$ 8,965	$ 32,820	$ 23,299
License revenue	—	—	1,000	2,000
Total revenues	12,537	8,965	33,820	25,299
OPERATING COSTS AND EXPENSES				
Cost of goods sold	2,475	550	5,447	843
License royalties	—	—	100	210
Research and development	22,453	23,131	71,785	64,488
Selling, general, and administrative	13,626	13,988	50,146	39,433
Total operating costs and expenses	38,554	37,669	127,478	104,974
Loss from operations	(26,017)	(28,704)	(93,658)	(79,675)
OTHER INCOME / (LOSS), NET				
Gain from sale of priority review voucher, net	—	—	—	62,010
Interest and other loss	(1,509)	(154)	(3,067)	(717)
NET LOSS	$ (27,526)	$ (28,858)	$ (96,725)	$ (18,382)
Other comprehensive income				
Foreign currency translation	1,598	238	3,331	751
COMPREHENSIVE LOSS	$ (25,928)	$ (28,620)	$ (93,394)	$ (17,631)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.63)	$ (0.66)	$ (2.21)	$ (0.43)
Weighted average common shares outstanding, basic and diluted	43,718,351	43,598,350	43,715,451	43,019,217