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 24, 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 February 24, 2022, Y-mAbs Therapeutics, Inc., announced its financial results for the fiscal year ended December 31, 2021. 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 February 24, 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: February 24, 2022

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 2021 Financial Results and Recent Corporate Developments

- **Announced completion of pre-BLA meeting with the FDA for omburtamab BLA resubmission expected by the end of first quarter 2022**
- **DANYELZA® adoption drives sequential revenue increase**
- **Completed IND submission to the FDA for first SADA construct**
- **Appointed Sue Smith as Chief Commercial Officer**
- **Strong cash position with $181.6 million as of December 31, 2021, providing runway through the end of 2023**
- **The Company will host a conference call on Friday, February 25, 2022, at 9 a.m. EST**

New York, NY, February 24, 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 fourth quarter and the full year ended December 31, 2021 and provided recent corporate highlights.

"In recent months, we have achieved significant progress on the omburtamab BLA, which we expect to resubmit to the FDA by the end of the first quarter of 2022," said Dr. Claus Moller, Chief Executive Officer. "We believe we now have a clear regulatory path in place and are one step closer to our goal of delivering omburtamab to children suffering from high-risk neuroblastoma brain tumors. In parallel, we are continuing to advance SADA, our novel platform for targeted radioisotope delivery that can potentially be adapted to various tumor targets. We filed an IND for GD2-SADA, the first SADA construct for potential use in GD2 positive solid tumors and are now accelerating pre-clinical testing with plans to submit at least one IND per year for additional SADA targets. In the meantime, we are actively pursuing additional collaboration and partnership opportunities."

"We are very pleased with our 2021 financial results, especially with our continued execution of the DANYELZA commercial launch, which generated revenues of $32.9 million in its first year," said Thomas Gad, Founder, Chairman and President. "We continue to be focused on our oncology programs, supported by a strong balance sheet. We ended the year with $181.6 million in cash, that is anticipated to support us through multiple potentially value-creating catalysts by the end of 2023. We believe that we are well-positioned to elevate our business and we expect that 2022 will be another productive year for Y-mAbs."

Fourth Quarter 2021 and Recent Corporate Developments

- Subsequent to the end of the fourth quarter, on February 11, 2022, Y-mAbs announced the completion of a Pre-BLA Meeting with FDA for omburtamab and confirmed the timeline for resubmission of the omburtamab BLA by the end of the first quarter of 2022.
- On December 15, 2021, Y-mAbs announced a pipeline update, including compassionate use data from an investigational infusion protocol for naxitamab. It was observed that the protocol may help managing Grade 3 and Grade 4 adverse events.
- On December 14, 2021, Y-mAbs appointed Sue Smith to the role of Senior Vice-President, Chief Commercial Officer, effective January 1, 2022. Ms. Smith brings more than 25 years of extensive commercial experience including several successful product launches within cancer, rare diseases, and endocrinology.
- On October 7, 2021, Y-mAbs announced that the U.S. Food and Drug Administration ("FDA") had granted Rare Pediatric Disease Designation ("RPDD") for the Company's lutetium labeled omburtamab antibody program for the treatment of medulloblastoma.

Financial Results

Revenues

Y-mAbs reported net revenue of $34.9 million for the year ended December 31, 2021, which consisted of product revenues of $32.9 million, generated from sales of DANYELZA, our first FDA approved product, and licensing revenues of $2.0 million related to a licensing agreement in Latin America. The gross margin for product revenues was 93% in 2021. Y-mAbs reported net revenues of $20.8 million for the year ended December 31, 2020, related to its licensing agreements in China and Israel. Y-mAbs did not have product revenues for the year ended December 31, 2020, as DANYELZA was not approved by the FDA until late November 2020.

For the fourth quarter of 2021, Y-mAbs incurred net revenues of $9.6 million, which consisted of product revenues from the sales of DANYELZA. Sales were up 7.1% from the third quarter 2021, and we have now delivered DANYELZA to 28 centers across the nation, an increase of four centers since the third quarter 2021. Treatment centers outside MSK accounted for approximately 40% of the product revenues during the fourth quarter of 2021. Y-mAbs incurred net revenues of $20.8 million for the quarter ending December 31, 2020, related to its licensing agreements in China and Israel.

Operating Expenses

Research and Development

Y-mAbs is anticipating a BLA resubmission for omburtamab by the end of the first quarter 2022 and at the same time, the Company is advancing its antibody constructs through the clinic; predominantly DANYELZA, omburtamab, and the SADA constructs. Research and development expenses were $93.2 million for the twelve months ended December 31, 2021, compared to $93.7 million for the twelve months ended December 31, 2020. The $0.5 million decrease in research and development expenses primarily reflects the following main items:

- $4.8 million decrease in regulatory affairs expenses; and
- $13.3 million decrease in milestones and license acquisition costs.

The decreases mentioned above were partially offset by the following increases:

- $6.2 million increase in outsourced manufacturing expenses;
- $4.1 million increase in personnel costs associated with research and development activities; and
- $3.9 million increase in clinical trial expenses.

Selling, General, and Administration

Selling, general, and administrative expenses were $54.6 million for the twelve months ended December 31, 2021, compared to $44.8 million for the twelve months ended December 31, 2020, corresponding to an increase of $9.8 million. The increase in selling, general, and administrative expenses was primarily due to a $8.9 million increase in personnel costs, partly associated with the expansion of our commercial team that is poised to drive further adoption of DANYELZA in 2022.

Net Result

Y-mAbs reported a net loss of $55.3 million, or ($1.28) per basic and diluted share, for the year ended December 31, 2021, compared to a net loss of $119.3 million, or ($2.97) per basic and diluted share, reported for the year ended December 31, 2020. The decrease in net loss was primarily caused by the sale in January 2021 of the priority review voucher received upon the approval of DANYELZA and the DANYELZA revenues generated in 2021, partially offset by increases in operating expenses related to the commercialization of DANYELZA in the United States.

For the quarter ended December 31, 2021, Y-mAbs incurred a net loss of $36.9 million, or ($0.85) per basic and diluted share, which compares to a net loss of $19.9 million, or ($0.48) per basic and diluted share, incurred for the quarter ended December 31, 2020. The increase in net loss was primarily caused by the DANYELZA revenues in 2021 not fully offsetting the licensing income in the fourth quarter of 2020.

Cash and Cash Equivalents

The Company had approximately $181.6 million in cash and cash equivalents as of December 31, 2021.

Webcast and Conference Call

The Company will host a conference call on Friday, February 25, 2022, at 9 a.m. Eastern Time. To participate in the call, please dial 877-407-0792 (domestic) or 201-689-8263 (international) and reference the conference ID 13726652.

A webcast will be available at: https://viavid.webcasts.com/starthere.jsp?ei=1526062&tp_key=59e1f9cc51

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, 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; rate and degree of market acceptance and clinical utility as well as pricing and reimbursement levels; retaining and hiring key employees; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position and strategy; additional product candidates and technologies; collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of our cash and cash equivalents, and the need for, timing and amount of any future financing transaction; our financial performance, including our estimates regarding revenues, expenses, capital expenditure requirements; developments relating to our competitors and our industry; 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 pandemic caused by the coronavirus known as COVID-19 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 and in our other SEC filings. 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.

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

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 181,564	$ 114,634
Accounts receivable, net	7,712	—
Inventories	5,512	—
Other current assets	7,473	7,729
Total current assets	202,261	122,363
Property and equipment, net	1,847	1,825
Operating lease right-of-use assets	3,842	4,569
Intangible assets, net	1,663	—
Other assets	3,170	3,290
TOTAL ASSETS	$ 212,783	$ 132,047
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 13,552	$ 9,372
Accrued liabilities	12,540	8,197
Operating lease liabilities, current portion	1,783	1,966
Total current liabilities	27,875	19,535
Accrued milestone and royalty payments	2,100	2,695
Operating lease liabilities, long-term portion	1,851	2,013
Other liabilities	851	1,968
TOTAL LIABILITIES	32,677	26,211
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at December 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2021 and December 31, 2020; 43,694,716 and 40,688,447 shares issued at December 31, 2021 and December 31, 2020, respectively	4	4
Additional paid in capital	519,206	391,558
Accumulated other comprehensive income / (loss)	1,371	(526)
Accumulated deficit	(340,475)	(285,200)
TOTAL STOCKHOLDERS' EQUITY	180,106	105,836
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 212,783	$ 132,047

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

	For the year ended December 31,	
	2021	2020
REVENUES		
Product revenue, net	$ 32,897	$ —
License revenue	2,000	20,750
Total revenues	34,897	20,750
OPERATING COSTS AND EXPENSES		
Cost of goods sold	2,304	—
Licensing royalties	210	2,203
Research and development	93,245	93,697
Selling, general, and administrative	54,571	44,785
Total operating costs and expenses	150,330	140,685
Loss from operations	(115,433)	(119,935)
OTHER INCOME, NET		
Gain from sale of priority review voucher, net	62,010	—
Interest and other income / (loss), net	(1,852)	598
NET LOSS	$ (55,275)	$ (119,337)
Other comprehensive income / (loss)		
Foreign currency translation	1,897	(576)
COMPREHENSIVE LOSS	$ (53,378)	$ (119,913)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.28)	$ (2.97)
Weighted average common shares outstanding, basic and diluted	43,181,808	40,118,537