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

March 04, 2025

- *Reported Total Revenues of $26.5 million for the fourth quarter of 2024 and $87.7 million for the full year 2024*
- *The Company established two business units in January 2025 aimed to accelerate the clinical development of its Radiopharmaceuticals Platform and optimize the commercial potential of DANYELZA*
- *Cash and cash equivalents of $67.2 million held as of December 31, 2024, reflects $11.4 million Total Annual Cash Investment in the full year 2024*
- *Management announces Full Year 2025 guidance around Total Revenue, Operating Expenses, and Cash Investment and First Quarter 2025 guidance around Total Revenue*
- *The Company will host a conference call on Tuesday, March 4, 2025, at 8:00 a.m. ET*

NEW YORK, March 04, 2025 (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 fourth quarter and full year ended December 31, 2024.

“We delivered on the strategic priorities we set out to achieve in 2024 across our business,” said Michael Rossi, President and Chief Executive Officer. “In our DANYELZA business, we saw solid ex- U.S. growth in 2024 from our partners. In the U.S., while DANYELZA revenues stabilized in the face of increased competition from new market entrants and clinical trial activity, we remain committed to further penetrating high-volume centers and reaching more patients with high-risk relapsed/refractory neuroblastoma. In our Radiopharmaceutical business, we demonstrated the tolerability and validity of our SADA PRIT platform pre-targeting approach with the preliminary readout from Part A of our GD2-SADA Phase 1 trial, Trial 1001, in solid tumors, and we look forward to providing a complete data readout in the second quarter of this year. With our business realignment announced at the beginning of 2025, we expect to be in position to enhance our ability to execute on our business goals to drive future growth with DANYELZA while accelerating the preclinical and clinical advancement of our SADA PRIT platform and programs.”

Recent Corporate Highlights

- On January 10, 2025, Y-mAbs announced the internal realignment and establishment of two business units: DANYELZA and Radiopharmaceuticals. The business realignment is designed to support the optimization of internal resources and provide flexibility and agility to advance the Company’s novel Self-Assembly DisAssembly Pre-targeted Technology platform (SADA PRIT) programs through clinical development while simultaneously driving commercial growth of DANYELZA.
- In conjunction with the business realignment, Y-mAbs appointed Doug Gentilcore as Senior Vice President, Head of DANYELZA Business Unit. Mr. Gentilcore has over two decades of strategic leadership experience in the pharmaceutical industry.
- Y-mAbs presented translational pharmacokinetics data of GD2-SADA at the Society of Nuclear Medicine & Molecular Imaging (SNMMI) Mid-Winter and American College of Nuclear Medicine (ACNM) Annual Meeting on January 31, 2025. The poster titled “Preclinical and Translational Pharmacokinetics of GD2-SADA, a Self-Assembling and Disassembling (SADA) Bispecific Fusion Protein for Pre-targeted Radioimmunotherapy (PRIT)” characterizes the plasma levels of GD2-SADA in animal models over time and a range of doses, while also presenting the concentration- and time-dependent equilibrium between GD2-SADA tetramers and monomers *in vitro*. Incorporated within translational PK simulations, the data have provided insights into GD2-SADA tumor exposure and plasma elimination, key parameters for minimizing systemic exposure to ^{177}Lutetium-DOTA.
- Interim data from a Phase 2 clinical trial evaluating naxitamab with granulocyte-macrophage colony-stimulating factor (GM-CSF) in patients with relapsed/refractory high-risk neuroblastoma in the journal *Nature Communications*. The article, titled “The anti-GD2 monoclonal antibody naxitamab plus GM-CSF for relapsed or refractory high-risk neuroblastoma: a phase 2 clinical trial,” details the results of a single-arm, global Phase 2 trial (Trial 201, NCT03363373) of patients with relapsed/refractory high-risk neuroblastoma and residual disease in the bone/bone marrow who received naxitamab on days 1, 3, and 5 (3 mg/kg/day) with GM-CSF (days -4 to 5) every 4 weeks, until a complete response (CR) or partial response (PR) was achieved, followed by 5 additional cycles every 4 weeks. Overall, naxitamab demonstrated statistically significant efficacy with a manageable safety profile.

Fourth Quarter 2024 Key Highlights

- Y-mAbs entered into an exclusive license and distribution agreement with Nobelpharma Co. Ltd. for the development and commercialization of DANYELZA in Japan. Y-mAbs received an upfront payment of $2.0 million in the fourth quarter of 2024. In addition, Y-mAbs is entitled to receive up to $31.0 million in regulatory-based and sales-based milestone payments in addition to royalty payments on commercial sales of DANYELZA by Nobelpharma, if successfully approved and commercialized in Japan.
- Continued commercial success with the named patient program for DANYELZA in Turkey with partner INPHARMUS (formerly named TRPharm İlaç Sanayi Ticaret A.Ş. and TRPharm FZ-LLC).
- Y-mAbs received notification of the accepted patent extension for DANYELZA, US 9,315,585, through February 2034.

Financial Results

Revenues

Total revenues for the quarter ended December 31, 2024 were $26.5 million, which was a 13% increase over the $23.4 million of total revenues for the quarter ended December 31, 2023, primarily driven by a $2.0 million increase in license revenue, and a $1.1 million increase in net product revenues.

Total revenues for the year ended December 31, 2024 were $87.7 million, a 3% increase over the total revenues for the year ended December 31, 2023 of $84.8 million. The $2.9 million increase was driven by a $2.0 million increase in license revenue, and a $0.9 million increase in net product revenues.

The Company's U.S. DANYELZA net product revenues for the quarter and year ended December 31, 2024 were $16.8 and $66.0 million, representing decreases of 12% and 3%, respectively, from the same periods in 2023. The decline in the U.S. DANYELZA net product revenues was driven by an unfavorable price mix for the quarter and year ended December 31, 2024, compared to 2023. The decline for the quarter ended December 31, 2024, was partially offset by slightly increased volume, compared to 2023.

The Company's international DANYELZA net product revenues for the quarter and year ended December 31, 2024 were $7.7 million and $19.2 million, representing increases of 78% and 16%, respectively, from the same periods in 2023. The increase in the international DANYELZA net product revenues was driven by the named patient program launch in Western Asia in 2024 and increased net product sales in the Eastern Asia, where our distribution partner purchased inventory in 2024 to avoid potential supply disruption in advance of a planned post-marketing labeling change in 2025, and Latin America regions, partially offset by decreased sales in Western Europe.

As of December 31, 2024, Y-mAbs had delivered DANYELZA to 69 centers across the U.S. since initial launch, with 11 new accounts added in the U.S. in 2024. During the quarter ended December 31, 2024, approximately 64% of the vials sold in the U.S. were sold outside of Memorial Sloan Kettering Cancer Center ("MSK"), compared to 65% in the third quarter ended September 30, 2024.

During the quarter and year ended December 31, 2024, the Company recognized license revenue of $2.0 million upon the execution of a license agreement with Nobelpharma in October 2024. The Company had license revenues totaling $2.5 million for the year ended December 31, 2024, which included license revenue from the Latin America distribution partner, Adium, related to price approval for DANYELZA in Brazil from the Brazilian Medicines Market Regulation Chamber, and from Nobelpharma, as noted above. The Company did not have any license revenue for the quarter ended December 31, 2023. The Company had license revenues of $0.5 million for the year ended December 31, 2023 from Adium, recognized upon the September 2023 achievement of marketing authorization for DANYELZA in Mexico.

Cost of Goods Sold

Cost of goods sold were $7.6 million and $2.0 million for the quarters ended December 31, 2024 and 2023, respectively, and were $15.0 million and $11.4 million for the years ended December 31, 2024 and 2023, respectively. Cost of goods sold included $0.6 million inventory write-off for the quarter and year ended December 31, 2024. The Company did not have any inventory write-off for the quarter ended December 31, 2023, and the Company had $0.8 million inventory write-downs in the year ended December 31, 2023.

Gross Profit

Gross profit was $18.9 million and $21.3 million for the quarters ended December 31, 2024 and 2023, respectively. Gross profit was $72.7 million and $73.5 million for the years ended December 31, 2024 and 2023, respectively. The decrease in gross profit was driven by the unfavorable price mix in connection with increased net product revenue from Eastern Asia, which generally has lower gross margins.

Operating Costs and Expenses

Research and Development

Research and development expenses were $12.2 million and $13.4 million for the quarters ended December 31, 2024 and 2023, respectively. The decrease in research and development expenses was primarily due to a $1.8 million decrease in outsourced manufacturing, a $0.4 million reduction of future milestone payments as the Company entered into an amendment with MSK to return the licensed patent rights related to omburtamab, and related drug substance inventory and regulatory work products, partially offset by a $1.0 million expense related to severance benefits and stock-based compensation charges associated with our business realignment.

Research and development expenses were $49.0 million for the year ended December 31, 2024, a decrease of $5.2 million when compared with the same period in 2023. The decrease in research and development expenses was primarily attributable to the recognition of $4.1 million of milestone and license acquisition costs related to the Company's SADA license agreement during the year ended December 31, 2023, as certain time-based clinical milestones within the agreement were determined to be probable based on the availability of necessary data and the assessment of clinical progress in the third quarter of 2023.

Selling, General, and Administrative

Selling, general, and administrative expenses were $12.4 million and $11.1 million for the quarters ended December 31, 2024 and 2023, respectively. The $1.3 million increase in the selling, general and administrative expenses was primarily attributable to a $0.8 million increase in personnel cost, inclusive of stock-based compensation, and a $0.6 million expense related to severance benefits and stock-based compensation charges associated with our business realignment.

For the year ended December 31, 2024, selling, general, and administrative expenses were $54.6 million, an increase of $9.7 million compared with the same period in 2023. The increase was primarily attributable to a net impact of $3.8 million related to legal settlements, a $1.2 million charge related to separation and consulting agreements with a former executive and a $2.2 million increase in personnel cost, inclusive of stock-based compensation.

Interest and Other (Loss)/Income

The Company experienced interest and other loss of $1.6 million for the quarter ended December 31, 2024, as compared to interest and other income of $2.4 million for the quarter ended December 31, 2023. The decrease of $4.0 million was primarily due to a $3.7 million decrease in foreign currency transactional gains in the three months ended December 31, 2024, and a $0.3 million decrease in interest earned on the Company's cash and cash equivalents.

For the years ended December 31, 2024 and 2023, the interest and other income was $1.4 and $4.8 million, respectively. The decrease of $3.4 million was primarily due to $2.6 million decrease of foreign currency transactional gains, partially offset by a $0.7 million decrease in interest earned on the Company's cash and cash equivalents.

Net Loss

Y-mAbs reported a net loss for the quarter ended December 31, 2024, of $6.8 million, or ($0.15) per basic and diluted share, compared to a net loss of $1.0 million, or ($0.02) per basic and diluted share, for the quarter ended December 31, 2023. For the year ended December 31, 2024, the Company reported a net loss of $29.7 million, or ($0.67) per basic and diluted share, as compared to net loss of $21.4 million, or ($0.49) per basic and diluted share, for the year ended December 31, 2023. The increase in net loss for the quarter and year ended December 31, 2024 was primarily driven by increased operating expenses and decreased foreign currency transactional gains, partially offset by increased total revenues.

Cash and Cash Equivalents

As of December 31, 2024, Y-mAbs had approximately $67.2 million in cash and cash equivalents. Total annual cash investment in 2024 was $11.4 million, which was favorable relative to the Company's corporate guidance for the full year 2024, which was between $15 million and $20 million. The Company continues its efforts to be capital efficient in its operations.

2025 Financial Guidance

Management announces its guidance for the full year 2025:

- Anticipated Total Revenues expected to be between $75 million and $90 million;
- Anticipated Total Operating Costs and Expenses, excluding cost of goods sold, expected to be between $116 million and $121 million (Total Operating Costs and Expenses including cost of goods sold is anticipated to be between $129 million and $134 million);
- Anticipated Total Annual Cash Investment expected to be between $25 million and $30 million; and
- Cash and Cash Equivalents anticipated to be sufficient to fund operations as currently planned into 2027.

Management announces its guidance for the first quarter 2025:

- Anticipated Total Revenues expected to be between $18 million and $21 million.

Webcast and Conference Call

Y-mAbs will host a conference call on Tuesday, March 4, 2025, at 8:00 a.m. ET. To participate in the live conference call, register here:

https://register.vevent.com/register/Blc0434de7d34443d1a7e4c7635d2c9faa

To listen to 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") Pre-targeted 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 the first quarter and full year 2025 and beyond, including estimated operating expenses, estimated operating expenses excluding cost of goods sold, total annual cash investment and total revenues and sufficiency of cash resources and related assumptions; expectations with respect to the Company's future financial performance; expectations with respect to the business unit realignment, including the expected impacts and anticipated benefits thereof, including operational flexibility and speed, and acceleration of clinical development within the radiopharmaceutical platform and optimizing the commercial potential of DANYELZA and driving future DANYELZA growth; implied and express statements regarding the future of the Company's business, including with respect to expansion and its goals; expectations with respect to the Company's plans and strategies, development, regulatory, commercialization and product distribution plans, including the timing thereof; 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; 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 regarding collaborations or strategic partnerships and the potential benefits thereof; 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," "aim," 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 business unit realignment 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 or its partners' 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; risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture as well as regulatory submissions; the Company's ability to enter into new partnerships or to recognize the anticipated benefits from its existing partnerships; 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, 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, 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.

DANYELZA® and Y-mAbs® are registered trademarks of Y-mAbs Therapeutics, Inc.

YMABS THERAPEUTICS, INC.

Consolidated Balance Sheets
(unaudited)

(In thousands, except share and per share data)

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 67,234	$ 78,637
Accounts receivable, net	19,688	22,454
Inventories	7,214	5,065
Other current assets	4,373	4,955
Total current assets	98,509	111,111
Property and equipment, net	42	224
Operating lease right-of-use assets	817	1,412
Intangible assets, net	2,276	2,631
Other assets	488	543
Inventories, long-term	17,772	11,948
TOTAL ASSETS	$ 119,904	$ 127,869
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 6,662	$ 6,060
Accrued liabilities	16,406	13,166
Operating lease liabilities, current portion	630	902
Total current liabilities	23,698	20,128
Accrued milestones	3,200	5,375
Operating lease liabilities, long-term portion	190	517
Other liabilities	812	864
TOTAL LIABILITIES	27,900	26,884
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at December 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2024 and December 31, 2023; 44,988,313 and 43,672,112 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	576,872	558,002
Accumulated other comprehensive income	2,264	449
Accumulated deficit	(487,136)	(457,470)
TOTAL STOCKHOLDERS' EQUITY	92,004	100,985
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 119,904	$ 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 December 31,		Year ended December 31,	
	2024	2023	2024	2023
REVENUES				
Net product revenue	$ 24,495	$ 23,363	$ 85,185	$ 84,319
License revenue	2,000	—	2,500	500

Total revenues	26,495	23,363	87,685	84,819
COST OF GOODS SOLD	7,642	2,039	15,001	11,366
GROSS PROFIT	18,853	21,324	72,684	73,453
OPERATING COSTS AND EXPENSES				
License royalties	200	—	250	50
Research and development	12,214	13,388	48,990	54,219
Selling, general, and administrative	12,375	11,135	54,645	44,856
Total operating costs and expenses	24,789	24,523	103,885	99,125
Loss from operations	(5,936)	(3,199)	(31,201)	(25,672)
OTHER (LOSS)/INCOME, NET				
Interest and other (loss)/income	(1,606)	2,406	1,389	4,806
LOSS BEFORE INCOME TAXES	(7,542)	(793)	(29,812)	(20,866)
(Benefits)/provision for income taxes	(752)	195	(146)	561
NET LOSS	$ (6,790)	$ (988)	$ (29,666)	$ (21,427)
Other comprehensive income/(loss)				
Foreign currency translation	2,300	(1,400)	1,815	(882)
COMPREHENSIVE LOSS	$ (4,490)	$ (2,388)	$ (27,851)	$ (22,309)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.15)	$ (0.02)	$ (0.67)	$ (0.49)
Weighted average common shares outstanding, basic and diluted	44,875,489	43,627,270	44,328,962	43,645,388

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Year ended December 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (29,666)	$ (21,427)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	535	735
Stock-based compensation	14,559	14,453
Foreign currency and other transactions	1,987	(1,259)
Provision for bad debt	520	—
Changes in assets and liabilities:		
Accounts receivable, net	2,246	(9,923)
Inventories	(2,149)	1,637
Other current assets	582	17
Inventories, long-term	(5,824)	(6,667)
Other assets	55	(145)
Accounts payable	(1,385)	(6,856)
Accrued liabilities and other	2,826	2,203
NET CASH USED IN OPERATING ACTIVITIES	(15,714)	(27,232)
CASH FLOWS FROM INVESTING ACTIVITIES	—	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercised stock options	4,311	100
NET CASH PROVIDED BY FINANCING ACTIVITIES	4,311	100
Effect of exchange rates on cash and cash equivalents	—	7
NET DECREASE IN CASH AND CASH EQUIVALENTS	(11,403)	(27,125)
Cash and cash equivalents at the beginning of period	78,637	105,762
Cash and cash equivalents at the end of period	$ 67,234	$ 78,637
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for income taxes	$ 713	$ 367
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES		
Right-of-use assets obtained in exchange for lease obligations	$ 320	$ 636
Acquisition of treasury shares upon repayment of secured promissory note	$ —	$ 480

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Source: Y-mAbs Therapeutics, Inc.