Y-mAbs Reports First Quarter 2025 Financial Results and Recent Corporate Developments

May 13, 2025

- *Reported Net Product Revenues of $20.9 million for the first quarter of 2025, a year-over-year increase of approximately 8%*
- *National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for Neuroblastoma updated to include naxitamab-gqgk (DANYELZA®)*
- *Dosed first patient in Phase 1 clinical trial evaluating CD38-SADA pretargeted radioimmunotherapy in patients with Relapsed/Refractory non-Hodgkin Lymphoma (Trial 1201)*
- *The Company to host virtual Radiopharmaceutical R&D update discussing Part A clinical data from its Phase I GD2-SADA clinical trial (Trial 1001) and announcing radioimmunotherapy and pipeline strategy on May 28, 2025*
- *As of March 31, 2025, cash and cash equivalents were $60.3 million reflecting cash investments of $6.9 million in the first quarter, in-line with the Company's full year 2025 guidance*
- *Management reiterates Full Year 2025 guidance and provides second quarter 2025 Total Revenue guidance of between $17 million and $19 million*
- *The Company will host a conference call today, Tuesday, May 13, 2025, at 8:00 a.m. ET*

PRINCETON, N.J., May 13, 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 first quarter ended March 31, 2025.

"We closed the first quarter of 2025 demonstrating solid DANYELZA net product revenue, advancement of our novel SADA PRIT platform and programs, and prudent operational spending," said Michael Rossi, President and Chief Executive Officer. "We were pleased to have dosed the first patient in our Trial 1201 where our innovative approach to pretargeted radioimmunotherapy has the potential to improve outcomes for patients in the high-risk population with relapsed/refractory non-Hodgkin Lymphoma. Starting in the first quarter of 2025, we began operating as two separate business units, DANYELZA and Radiopharmaceuticals, and in doing so, our reporting highlights DANYELZA's segment profit in addition to the resource investments we are making to advance our radioimmunotherapy platform. We look forward to sharing updates on our radiopharmaceutical business strategy, including Part A clinical data from Trial 1001, new optimization data, and new planned target programs and anticipated timelines, during our virtual Radiopharmaceutical R&D update on May 28th."

Recent Corporate Highlights

- On May 7, 2025, Y-mAbs announced that naxitamab-gqgk (DANYELZA®) has been recommended by the National Comprehensive Cancer Network® ("NCCN") Clinical Practice Guidelines in Oncology (NCCN Guidelines ®) as a NCCN Category 2A treatment option for high-risk neuroblastoma.
- First patient has been dosed in the Company's CD38-SADA Phase 1 clinical trial (Trial 1201) evaluating Y-mAbs' Self-Assembly and Disassembly ("SADA") Pretargeted Radioimmunotherapy ("PRIT") platform for the treatment of patients with relapsed or refractory non-Hodgkin Lymphoma (r/r NHL). The patient was administered both the first protein dose and the 177Lu-DOTA imaging dose. Trial 1201 is a dose-escalation, open-label, single-arm, multi-center trial investigating the safety and tolerability of the CD38-SADA: 177Lu-DOTA Drug Complex in r/r NHL.
    - Trial 1201 is designed to investigate the pretargeted delivery of the CD38-SADA protein that binds with high affinity to lymphoma cells, followed by the administration of a radioactive 177Lu-DOTA payload to selectively target the tumor-bound CD38-SADA molecules while minimizing radiation to normal tissues. Part A of the clinical trial is CD38-SADA dose escalation with fixed 177Lu-DOTA payload doses to explore the optimal CD38-SADA protein dose and interval between the SADA protein administration and the payload. The primary endpoints of Part A include tumor imaging and occurrence of dose limiting toxicities ("DLT") in the DLT evaluation period.
- The Company presented preclinical and translational pharmacokinetics (PK) data of CD38-SADA in a poster at the 2025 American Association of Cancer Research ("AACR") Annual Meeting on April 27, 2025 in Chicago, IL. The poster titled *"Preclinical and translational pharmacokinetic (PK) modeling of the self-assembling and disassembling (SADA) bispecific fusion protein CD38-SADA for first-in-human (FIH) pretargeted radioimmunotherapy (PRIT)"* characterized the plasma concentrations of CD38-SADA in animal models over time and a range of doses. Utilizing *in vitro* binding kinetic parameters and PK data generated from three studies in mice, the study characterized the concentration- and time-dependent equilibrium between CD38-SADA tetramers and monomers. Using these data, Y-mAbs conducted a series of appropriately scaled human PK simulations, which informed the design and initial dosing regimen of Trial 1201, the Company's first-in-human Phase 1 clinical trial (Trial 1201) in patients with r/r NHL.
- Y-mAbs plans to host a virtual Radiopharmaceutical R&D update on Wednesday, May 28, 2025 where the Company will discuss:
    - Part A clinical data from ongoing Phase 1 GD2-SADA clinical trial (Trial 1001), including pharmacokinetic and dosimetry data;
    - Updates around the Company's nonclinical optimization studies for the GD2-SADA asset and plans for clinical implementation; and
    - Radiopharmaceutical pipeline strategy, including new planned target programs and anticipated timelines.
- Following the business realignment strategy announced in January 2025, the Company is now organized into two business

units: DANYELZA and Radiopharmaceuticals. The Company's business units are focused on different products and platforms. They are managed separately as each business unit requires different research and development, marketing and other operational investments. Their segment profit/(loss) from operations include certain non-cash costs.

First Quarter 2025 Key Highlights

- Enhanced collaboration with SciClone and other distribution partners with new commercial programs introduced in distribution partners' territories.
- 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) and expansion of agreement into new markets.

Financial Results

Revenues

Total revenues for the quarter ended March 31, 2025 were $20.9 million, which was a 5% increase over the $19.9 million of total revenues for the quarter ended March 31, 2024, primarily driven by a $6.7 million increase in Ex-U.S. DANYELZA revenue, partially offset by a $5.2 million decrease in U.S. DANYELZA revenue and $0.5 million decrease related to license revenue recognized in the three months ended March 31, 2024. Total DANYELZA net product revenues for the quarter ended March 31, 2025 were $20.9 million, which was an 8% increase over $19.4 million total DANYELZA net product revenues for the quarter ended March 31, 2024.

The Company's U.S. DANYELZA net product revenues for the quarter ended March 31, 2025 were $13.4 million, representing a decrease of 28% from the same period in 2024. The decline in the U.S. DANYELZA net product revenues was driven by enrollments in clinical studies and market dynamics.

The Company's Ex- U.S. DANYELZA net product revenues for the quarter ended March 31, 2025 were $7.5 million, representing an increase of $6.7 million from the same period in 2024. The increase in the Ex-U.S. DANYELZA net product revenues was driven by a $3.8 million increase in net product revenue in Western Asia, where the named patient program launched in late 2024, and increased net product sales in the Eastern Asia, where a new marketing initiative program was introduced in late 2024, and Latin America regions.

As of March 31, 2025, Y-mAbs had delivered DANYELZA to 70 centers across the U.S. since initial launch, with one new account added in the U.S. in the first quarter 2025. During the quarter ended March 31, 2025, approximately 72% of the vials sold in the U.S. were sold outside of Memorial Sloan Kettering Cancer Center ("MSK"), compared to 64% in the fourth quarter ended December 31, 2024.

There was no license revenue for the quarter ended March 31, 2025. During the quarter ended March 31, 2024, the Company had license revenues of $0.5 million, 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.

Cost of Goods Sold

Cost of goods sold was $3.0 million and $2.1 million for the three months ended March 31, 2025 and 2024, respectively. The increase in cost of goods sold in the three months ended March 31, 2025 compared to the same period in 2024, was driven by increased volumes in Ex-U.S. regions which carry a lower gross margin.

Gross Profit

Gross profit stayed consistent at $17.9 million and $17.8 million for the three months ended March 31, 2025 and 2024, respectively.

Gross margins are 86% and 89% for the three months ended March 31, 2025 and 2024, respectively. Gross margin from total revenues decreased in the three months ended March 31, 2025, which was mainly attributable to the decreased U.S. net product revenues, which are at higher margins compared to our Ex-U.S. regions.

Operating Costs and Expenses

Research and Development

Research and development expenses were $11.4 million and $13.3 million for the three months ended March 31, 2025 and 2024, respectively. The $1.9 million decrease in research and development expenses was primarily attributable to a decrease of $0.7 million in clinical trials due to the timing of completion in the Company's GD2-SADA program, investment in its ongoing SADA PRIT programs, and a $0.9 million decrease in personnel and stock-based compensation costs, partially offset by $0.6 million increase in outsourced manufacturing for investment in the Company's naxitamab program.

Selling, General, and Administrative

Selling, general, and administrative expenses were $13.1 million for the three months ended March 31, 2025, as compared to $11.4 million for the three months ended March 31, 2024. The $1.7 million increase in selling, general, and administrative expenses was primarily attributable to a $0.8 million increase in personnel and stock-based compensation costs, a $0.5 million charge related to the business realignment expense and $0.4 million in legal expenses recorded in the three months ended March 31, 2025.

Interest and Other Income

Interest and other income for the three months ended March 31, 2025 was $1.4 million compared to $0.4 million for the three months ended March 31, 2024. Interest and other income increased by $1.0 million primarily due to a $1.3 million increase in foreign currency transaction gains, partially offset by a $0.3 million decrease in interest earned from money market fund investments.

Net Loss

Y-mAbs reported a net loss for the quarter ended March 31, 2025, of $5.2 million, or ($0.12) per basic and diluted share, compared to a net loss of $6.6 million, or ($0.15) per basic and diluted share, for the quarter ended March 31, 2024. The decrease in net loss for the quarter ended March 31, 2025 was primarily driven by increased total revenues and increased foreign currency transactional gains, partially offset by increased operating costs and expenses.

Cash and Cash Equivalents

As of March 31, 2025, Y-mAbs had approximately $60.3 million in cash and cash equivalents which, together with anticipated DANYELZA product revenues, is expected to support operations as currently planned into 2027. The Company is currently operating below its anticipated cash investment guidance for the full year 2025. This estimate reflects the Company's current business plan that is supported by assumptions that may prove to be inaccurate, such that Y-mAbs could use its available capital resources sooner than it currently expects. The Company continues its efforts to be capital efficient in its operations.

2025 Financial Guidance

Management reiterates 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 anticipated cost of goods sold of between $13 million and $15 million 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 second quarter 2025:

- The Company anticipates Total Revenues to be between $17 million and $19 million.

Webcast and Conference Call

Y-mAbs will host a conference call on Tuesday, May 13, 2025, at 8:00 a.m. ET. 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") 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 the second 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 realignment, including the expected impacts and anticipated benefits thereof, including acceleration of clinical development within the radiopharmaceutical platform and optimizing the commercial potential of DANYELZA and driving future DANYELZA growth; the potential of the Company's approach to pretargeted radioimmunotherapy to improve outcomes for patients in the high-risk population for relapsed/refractory non-Hogdkin Lymphoma, if approved; 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 anticipated 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, results, strategy and regulatory matters; 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 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 Israel and Hamas and sanctions related thereto, international trade policies, including tariffs and trade restrictions, 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, as supplemented by the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2025, 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.

Non-GAAP Financial Measures

To supplement the Company's financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP),

Y-mAbs uses certain non-GAAP financial measures in this press release. In particular, the Company references Total Operating Costs and Expenses, including anticipated cost of goods sold in relation to the Company's financial guidance. Y-mAbs defines Total Operating Costs and Expenses including anticipated cost of goods sold as total operating costs and expenses plus cost of goods sold. Y-mAbs has included this additional metric in relation to the financial guidance as the Company previously presented this metric on the Consolidated Statements of Net Loss and Comprehensive Loss and used this metric for the 2024 financial guidance. Subsequently the Company has switched to not including cost of goods sold in total operating costs and expenses on the Consolidated Statements of Net Loss and Comprehensive Loss and the Company's financial guidance.

Y-MABS THERAPEUTICS, INC.

Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	March 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 60,310	$ 67,234
Accounts receivable, net	17,740	19,688
Inventories	7,995	7,214
Other current assets	4,403	4,373
Total current assets	90,448	98,509
Property and equipment, net	161	42
Operating lease right-of-use assets	601	817
Intangible assets, net	2,213	2,276
Inventories, long-term	18,472	17,772
Other assets	718	488
TOTAL ASSETS	$ 112,613	$ 119,904
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 4,627	$ 6,662
Accrued liabilities	13,875	16,406
Operating lease liabilities, current portion	455	630
Total current liabilities	18,957	23,698
Accrued milestones	3,200	3,200
Operating lease liabilities, long-term portion	148	190
Other liabilities	851	812
TOTAL LIABILITIES	23,156	27,900
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at March 31, 2025 and December 31, 2024; 45,250,794 and 44,988,313 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	5	4
Additional paid-in capital	580,383	576,872
Accumulated other comprehensive income	1,401	2,264
Accumulated deficit	(492,332)	(487,136)
TOTAL STOCKHOLDERS' EQUITY	89,457	92,004
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 112,613	$ 119,904

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Net Loss and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three months ended March 31,	
	2025	2024
REVENUES		
Net product revenue	$ 20,904	$ 19,431

License revenue	—	500
Total revenues	20,904	19,931
COST OF GOODS SOLD	3,001	2,097
GROSS PROFIT	17,903	17,834
OPERATING COSTS AND EXPENSES		
License royalties	—	50
Research and development	11,359	13,267
Selling, general, and administrative	13,087	11,425
Total operating costs and expenses	24,446	24,742
Loss from operations	(6,543)	(6,908)
OTHER INCOME, NET		
Interest and other income	1,352	439
LOSS BEFORE INCOME TAXES	(5,191)	(6,469)
Provision for income taxes	5	160
NET LOSS	$ (5,196)	$ (6,629)
Other comprehensive income/(loss)		
Foreign currency translation	(863)	399
COMPREHENSIVE LOSS	$ (6,059)	$ (6,230)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.12)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	45,104,476	43,779,456

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Three months ended March 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (5,196)	$ (6,629)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	71	159
Stock-based compensation	3,341	3,846
Foreign currency transactions	(812)	492
Changes in assets and liabilities:		
Accounts receivable, net	1,948	1,866
Inventories	(724)	(3,383)
Other current assets	(30)	1,473
Inventories, long-term	(700)	1,207
Other assets	(230)	111
Accounts payable	(1,223)	176
Accrued liabilities and other	(3,356)	(2,795)
NET CASH USED IN OPERATING ACTIVITIES	(6,911)	(3,477)
NET CASH USED IN INVESTING ACTIVITIES		
Purchase of property and equipment	(127)	—
NET CASH USED IN INVESTING ACTIVITIES	(127)	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercised stock options	114	588
NET CASH PROVIDED BY FINANCING ACTIVITIES	114	588
Effect of exchange rates on cash and cash equivalents	—	1
NET DECREASE IN CASH AND CASH EQUIVALENTS	(6,924)	(2,888)
Cash and cash equivalents at the beginning of period	67,234	78,637
Cash and cash equivalents at the end of period	$ 60,310	$ 75,749

Y-MABS THERAPEUTICS, INC.

Selected Financial Information by Reportable Segment

(unaudited)

(In thousands)

	Three Months Ended March 31,					
	2025			2024		
	DANYELZA	RIT	Total	DANYELZA	RIT	Total
REVENUES						
Net product revenue	$ 20,904	$ —	$ 20,904	$ 19,431	$ —	$ 19,431
License revenue	—	—	—	500	—	500
Total revenues	20,904	—	20,904	19,931	—	19,931
COST OF GOODS SOLD	3,001	—	3,001	2,097	—	2,097
OPERATING COSTS AND EXPENSES						
License royalties	—	—	—	50	—	50
Research and development	4,926	5,696	10,622	5,409	6,041	11,450
Selling, general, and administrative	4,156	411	4,567	3,699	—	3,699
Segment profit/(loss) from operations	$ 8,821	$ (6,107)	$ 2,714	$ 8,676	$ (6,041)	$ 2,635
Corporate and unallocated expenses - Research and development			737			1,817
Corporate and unallocated expenses - Selling, general, and administrative			8,520			7,726
Consolidated Loss from Operations			(6,543)			(6,908)
OTHER INCOME, NET						
Corporate and unallocated expenses - Interest and other income			1,352			439
CONSOLIDATED LOSS BEFORE INCOME TAXES			$ (5,191)			$ (6,469)

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Y-mAbs Therapeutics, Inc.

Source: Y-mAbs Therapeutics, Inc.