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

November 08, 2024

- *Reported Total DANYELZA net product revenues of $18.5 million for the third quarter of 2024*
- *Entered into exclusive license and distribution agreement with Nobelpharma for DANYELZA in Japan recognizing an upfront payment of $2.0 million in the fourth quarter of 2024*
- *Achieved extension of primary DANYELZA U.S. patent through February 2034*
- *Continued geographic expansion of DANYELZA with new market revenues recorded in the third quarter from Turkey*
- *Management reiterates Full Year 2024 guidance around Total Net Revenue, Operating Expenses, and Cash Flow Investment*
- *The Company will host a conference call on Friday, November 8, 2024, at 8:00 a.m. ET*

NEW YORK, Nov. 08, 2024 (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 third quarter ended September 30, 2024.

“The third quarter of this year was one of continued focus and execution across our DANYELZA commercial business and our novel SADA PRIT radiopharmaceutical platform development pipeline,” said Michael Rossi, President and Chief Executive Officer. “Physician usage of DANYELZA in the U.S. continues to remain very strong for patients with relapsed/refractory high-risk neuroblastoma. In addition, we continue to drive ex-U.S. market expansion with our new exclusive license and distribution agreement with Nobelpharma in Japan and the launch of our named patient program in Turkey. From a SADA PRIT pipeline standpoint, we expect to complete Part A of our GD2-SADA Phase 1 trial this year and present that data in the first quarter of next year.”

Third Quarter 2024 and Recent Corporate Highlights

- Effective October 29, 2024, Y-mAbs entered into an exclusive license and distribution agreement with Nobelpharma for the development and commercialization of DANYELZA in Japan. Pursuant to the agreement, the Company recognized an upfront payment of $2.0 million in the fourth quarter of 2024. Y-mAbs is entitled to receive up to $31.0 million in product and commercial milestone payments in addition to profit sharing on the commercial sales of DANYELZA, if successfully approved and commercialized in Japan.
- Y-mAbs received notification of the accepted patent extension for DANYELZA, US 9,315,585, through February 2034.
- The Company’s named patient program for DANYELZA launched in Turkey with partner TRPharm İlaç Sanayi Ticaret A.Ş. and TRPharm FZ-LLC.
- Y-mAbs presented new clinical and preclinical data from studies evaluating anti-GD2 therapy naxitamab and the Company’s first program from its Self-Assembly DisAssembly Radioimmunotherapy Technology Platform (“SADA PRIT”), GD2-SADA, respectively, in neuroblastoma in poster presentations at the American Academy of Cancer Research Special Conference in the Advanced in Pediatric Cancer Research on September 6-7, 2024 in Toronto, Canada.
- The Company entered into a lease agreement for a term of ten years and nine months for office space in Princeton, New Jersey, where the Company plans to transition its headquarters in the first half of 2025 upon being provided access to the location.

Financial Results

Revenues

Total net revenues for the quarter ended September 30, 2024 were $18.5 million, a 10% decline over total net revenues for the quarter ended September 30, 2023 of $20.5 million, which included $0.5 million in license revenue, primarily driven by decreased net product revenues in both U.S. and ex-U.S. markets.

Total net revenues for the nine months ended September 30, 2024 were relatively flat compared to the nine months ended September 30, 2023, at $61.2 million and $61.5 million, respectively. The slight decrease was driven by a $0.7 million decrease in ex-U.S. DANYELZA net product revenues in the nine months ended September 30, 2024, which was partially offset by increased net product revenues in the U.S.

The Company’s U.S. DANYELZA net product revenues were $15.3 million and $16.1 million for the three months ended September 30, 2024 and 2023, respectively, representing a 5% decline, primarily due to an unfavorable price mix, partially offset by increased volume of 5% vial growth over the same time period.

Y-mAbs’ ex- U.S. DANYELZA net product revenues for the quarter ended September 30, 2024 were $3.1 million, a 19% decline from $3.9 million in the comparable period in 2023, primarily driven by decreased volume from Western Europe partially offset by volume increases in the remaining ex-U.S. territories.

As of September 30, 2024, Y-mAbs had delivered DANYELZA to 68 centers across the U.S. since initial launch, with three new accounts added in the U.S. in the third quarter of 2024. During the quarter ended September 30, 2024, approximately 65% of the vials sold in the U.S. were sold outside of Memorial Sloan Kettering Cancer Center (“MSK”), compared to 67% in the second quarter ended June 30, 2024.

The Company did not have license revenue for the quarter ended September 30, 2024. The Company had license revenues of $0.5 million for the nine months ended September 30, 2024, from its Latin America distribution partner, Adium, related to price approval for DANYELZA in Brazil from the Brazilian Medicines Market Regulation Chamber. The Company had license revenues of $0.5 million for the quarter and nine months ended September 30, 2023 from Adium, recognized upon the September 2023 achievement of marketing authorization for DANYELZA in Mexico.

Operating Costs and Expenses

Cost of Goods Sold

Cost of goods sold were $2.3 million and $2.6 million for the quarter ended September 30, 2024 and 2023, respectively. Cost of goods sold were $7.4 million and $9.3 million for the nine months ended September 30, 2024 and 2023, respectively. Cost of goods sold included lower vial volumes of 1% and 37% in the three and nine months ended September 30, 2024, compared to the same periods in 2023, respectively. Cost of goods sold also included $0.4 million and $0.8 million inventory write-downs in the three and nine months ended September 30, 2023, respectively.

The Company defines gross margin as net product revenues less cost of goods sold divided by net product revenues. The Company's gross margins was relatively unchanged in the quarter ended September 30, 2024, compared to the comparable periods in 2023. The Company's gross margins increased in the nine months ended September 30, 2024, compared to the comparable period in 2023, due to a favorable gross profit mix from revenue in international regions, particularly Eastern Asia that had an inventory stocking order in the nine months ended September 30, 2024, and inventory write-downs during the comparable periods in 2023, as noted above.

Research and Development

Research and development expenses were $11.2 million for the quarter ended September 30, 2024, a decrease of $4.2 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 three months ended September 30, 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.

For the nine months ended September 30, 2024, research and development expenses were $36.8 million, a decrease of $4.0 million when compared with the same period in 2023. The decrease in the research and development expenses was primarily attributable to recognition of $4.1 million of milestone and license acquisition costs related to the Company's SADA license agreement during the nine months ended September 30, 2023, as noted above.

Selling, General, and Administrative

Selling, general, and administrative expenses were $13.6 million and $10.2 million for the quarters ended September 30, 2024 and 2023, respectively. The $3.4 million increase in the selling, general and administrative expenses was primarily attributable to a $1.2 million increase related to the Company's former Chief Financial Officer's separation and consulting agreements, $1.1 million increase in personnel cost, inclusive of stock-based compensation and $0.5 million in professional and consulting fees.

For the nine months ended September 30, 2024, selling, general, and administrative expenses were $42.3 million, an increase of $8.5 million compared with the same period in 2023. The increase was primarily attributable to a net impact of $3.6 million related to the settlement of a shareholder class-action lawsuit in the nine months ended September 30, 2024, and an additional legal settlement of $0.2 million in the nine months ended September 30, 2024. The increase also includes a $1.2 million increase related to our former Chief Financial Officer's separation and consulting agreements, a $1.1 million increase in personnel cost inclusive of stock-based compensation and $0.8 million in professional and consulting fees.

Interest and Other Income

Interest and other income were $1.9 million for the quarter ended September 30, 2024, as compared to $0.2 million for the quarter ended September 30, 2023. The increase of $1.7 million was primarily due to a $1.9 million of foreign currency transactional gains in the three months ended September 30, 2024, partially offset by a $0.2 million decrease in interest earned on the Company's cash and cash equivalents.

For the nine months ended September 30, 2024 and 2023, the interest and other income was $3.0 and $2.4 million, respectively. The increase of $0.6 million was primarily due to $1.1 million of foreign currency transactional gains, partially offset by a $0.3 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 September 30, 2024, of $7.0 million, or ($0.16) per basic and diluted share, compared to a net loss of $7.7 million, or ($0.18) per basic and diluted share, for the quarter ended September 30, 2023. The decrease in net loss for the quarter ended September 30, 2024 was primarily driven by decreased operating expenses and foreign currency transactional gains, partially offset by decreased net product revenue.

For the nine months ended September 30, 2024, the Company reported a net loss of $22.9 million, or ($0.52) per basic and diluted share, as compared to net loss of $20.4 million, or ($0.47) per basic and diluted share, for the nine months ended September 30, 2023. The increase in net loss for the nine months ended September 30, 2024 was primarily driven by the net $3.8 million in charges related to the Company's two legal settlements, as described above.

Cash and Cash Equivalents

As of September 30, 2024, Y-mAbs had approximately $68.1 million in cash and cash equivalents. Cash utilized in the first three quarters of 2024 was $10.5 million, which was favorable relative to the Company's internal forecasts, and is on track to meet its corporate guidance for the full year 2024.

2024 Financial Guidance

Management reiterates its full year 2024 guidance:

- Anticipated Total Net Revenues expected to be between $87 million and $95 million;
- Anticipated Operating Expenses expected to remain between $115 million and $120 million;
- Anticipated Total Annual Cash Investment expected to remain between $15 million and $20 million; and
- Cash and Cash Equivalents anticipated to continue to support operations as currently planned into 2027.

Webcast and Conference Call

Y-mAbs will host a conference call on Friday, November 8, 2024, at 8:00 a.m. ET. To participate in the call, please use the following dial-in information:

Investors (domestic): (877) 407-0792

Investors (international): (201) 689-8263

To access 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 2024 and beyond, including estimated operating expenses, use of cash and cash equivalents and DANYELZA product revenue and sufficiency of cash resources and related assumptions; expectations with respect to the Company's future financial performance; 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," 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 restructuring plan and revised business plan 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, the state of war between Israel and Hamas and the related risk of a larger regional conflict, 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, 2023, and the Company's Quarterly Report on Form 10-Q for the quarterly periods ended March 31, 2024, and September 30, 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.

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Y-MABS THERAPEUTICS, INC.

Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	September 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 68,122	$ 78,637
Accounts receivable, net	19,916	22,454
Inventories	9,557	5,065
Other current assets	1,462	4,955
Total current assets	99,057	111,111
Property and equipment, net	53	224

Operating lease right-of-use assets	1,075	1,412
Intangible assets, net	2,366	2,631
Other assets	18,366	12,491
TOTAL ASSETS	$ 120,917	$ 127,869
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 7,878	$ 6,060
Accrued liabilities	16,638	13,166
Operating lease liabilities, current portion	776	902
Total current liabilities	25,292	20,128
Accrued milestones	2,000	5,375
Operating lease liabilities, long-term portion	299	517
Other liabilities	897	864
TOTAL LIABILITIES	28,488	26,884
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at September 30, 2024 and December 31, 2023; 44,766,802 and 43,672,112 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	572,807	558,002
Accumulated other comprehensive income	(36)	449
Accumulated deficit	(480,346)	(457,470)
TOTAL STOCKHOLDERS' EQUITY	92,429	100,985
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 120,917	$ 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 September 30,		Nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
REVENUES				
Product revenue, net	$ 18,461	$ 19,954	$ 60,690	$ 60,956
License revenue	—	500	500	500
Total revenues	18,461	20,454	61,190	61,456
OPERATING COSTS AND EXPENSES				
Cost of goods sold	2,248	2,595	7,359	9,327
License royalties	—	50	50	50
Research and development	11,168	15,358	36,776	40,831
Selling, general, and administrative	13,613	10,200	42,270	33,721
Total operating costs and expenses	27,029	28,203	86,455	83,929
Loss from operations	(8,568)	(7,749)	(25,265)	(22,473)
OTHER INCOME, NET				
Interest and other income	1,916	189	2,995	2,400
LOSS BEFORE INCOME TAXES	(6,652)	(7,560)	(22,270)	(20,073)
Provision for income taxes	346	187	606	366
NET LOSS	$ (6,998)	$ (7,747)	$ (22,876)	$ (20,439)
Other comprehensive income/(loss)				
Foreign currency translation	(1,083)	806	(485)	518
COMPREHENSIVE LOSS	$ (8,081)	$ (6,941)	$ (23,361)	$ (19,921)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.16)	$ (0.18)	$ (0.52)	$ (0.47)
Weighted average common shares outstanding, basic and diluted	44,626,943	43,620,532	44,145,183	43,651,536

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Nine months ended September 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (22,876)	$ (20,439)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	433	574
Stock-based compensation	11,480	11,330
Foreign currency and other transactions	(456)	(369)
Changes in assets and liabilities:		
Accounts receivable, net	2,538	(6,343)
Inventories	(4,492)	(411)
Other current assets	3,493	2,671
Other assets	(5,875)	(3,735)
Accounts payable	2,274	(6,196)
Accrued liabilities and other	(363)	3,722
NET CASH USED IN OPERATING ACTIVITIES	(13,844)	(19,196)
CASH FLOWS FROM INVESTING ACTIVITIES	—	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercised stock options	3,325	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	3,325	—
Effect of exchange rates on cash and cash equivalents	4	5
NET DECREASE IN CASH AND CASH EQUIVALENTS	(10,515)	(19,191)
Cash and cash equivalents at the beginning of period	78,637	105,762
Cash and cash equivalents at the end of period	$ 68,122	$ 86,571
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

Y-mAbs Therapeutics, Inc.

Source: Y-mAbs Therapeutics, Inc.