Y-mAbs Reports Third Quarter 2023 Financial Results and Recent Corporate Developments

November 13, 2023

- **Q3 2023 DANYELZA® net product revenues of $20.0 million represents YoY growth of 59%**
- **U.S. FDA clearance of IND for CD38-SADA for relapsed or refractory non-Hodgkin Lymphoma**
- **Cash and cash equivalents of $86.6 million as of September 30, 2023, with anticipated cash runway extended into 2027**
- **Management updates FY 2023 financial guidance by lowering anticipated operating expenses and use of cash**
- **The Company will host a conference call on Tuesday, November 14, 2023, at 9:00 a.m. ET**

NEW YORK, Nov. 13, 2023 (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 2023.

"We delivered $20 million in DANYELZA® (naxitamab-gqgk) net product sales in the third quarter of 2023, reflecting 59% growth compared to the same period in 2022, as sales continued trending upward since our initial launch," said Mike Rossi, President and Chief Executive Officer. "Our U.S. commercial team has made excellent progress by penetrating more high-volume Children's Oncology Group ("COG") sites while our ex- U.S. partners continue to gain further traction with physicians prescribing DANYELZA across Europe and China for relapsed or refractory high-risk neuroblastoma patients."

Mr. Rossi continued, "Supported by a solid financial foundation, we have advanced our novel SADA radioimmunotherapy platform with the continued execution of our Phase 1 GD2-SADA trial and the recent Investigational New Drug ("IND") clearance of our CD38-SADA program. With existing cash and cash equivalents anticipated to support our business operations as currently planned into 2027, a growing commercial product in DANYELZA, and a differentiated radioimmunotherapy platform in SADA, we believe Y-mAbs is on a path to potentially transform the treatment paradigm for a variety of cancers and improve patients' lives."

Third Quarter 2023 and Recent Corporate Developments

- On October 18, 2023, Y-mAbs announced that its Board of Directors appointed Mr. Rossi as President and Chief Executive Officer, effective November 6, 2023. Thomas Gad, who founded Y-mAbs in 2015 and has served as Interim Chief Executive Officer since 2022, has transitioned to the role of Vice Chairman of the Board of Directors and Chief Business Officer.
- On October 17, 2023, the U.S. Food & Drug Administration ("FDA") cleared Y-mAbs' IND for CD38-SADA, marking the second clinical development program utilizing the Company's novel SADA technology platform.
- On October 16, 2023, Y-mAbs announced the publication of the study of naxitamab-based chemoimmunotherapy in patients with chemoresistant high-risk neuroblastoma ("HR-NB") in the journal *Cancers*. The study investigated the HITS combination in patients with high-risk neuroblastoma who did not respond well to induction therapy. Patients who received HITS immediately after induction had higher response rates (47% vs. 18%) and superior estimated three-year overall survival (85% vs. 29%) compared with those who received the same combination regimen later in the course of treatment. The publication is entitled, "Early Salvage Chemo-Immunotherapy with Irinotecan, Temozolomide and Naxitamab Plus GM-CSF (HITS) for Patients with Primary Refractory High-Risk Neuroblastoma Provide the Best Chance for Long-Term Outcomes."
- On October 11, 2023, Y-mAbs showcased three poster presentations, in addition to an online publication, of DANYELZA at the 55th Congress of the International Society of Pediatric Oncology in Ottawa, Canada.
- On September 28, 2023, Y-mAbs received approval of its Mexican Marketing Authorization Application ("MAA") by COFEPRIS for DANYELZA, marking the Company's second approval in Latin American with its distribution partner Adium Pharma S.A.

Financial Results

Revenues

DANYELZA net product revenues were $20.0 million and $61.0 million for the third quarter and nine months ended September 30, 2023, which represented increases of 59% and 86%, respectively, over $12.5 million and $32.8 million in the comparable periods of 2022.

The DANYELZA net product revenues of $20.0 million in the third quarter of 2023, represented a marginal decline compared to the second quarter of 2023, primarily driven by modest unevenness in international revenues after a series of inventory stocking orders from the Company's international partners as reported in recent quarters.

As of September 30, 2023, Y-mAbs has delivered DANYELZA to 57 centers across the U.S. since initial launch, with nine new accounts added so far in 2023. During the third quarter ended September 30, 2023, approximately 63% of the vials sold in the U.S. were sold outside of Memorial Sloan Kettering Cancer Center ("MSK"), compared to 61% in the second quarter ended June 30, 2023.

Y-mAbs reported total revenues of $20.5 million and $61.5 million for the third quarter and nine months ended September 30, 2023, which represented increases of 63% and 82%, respectively, over $12.5 million and $33.8 million in the comparable periods of 2022. Total revenues in the third quarter and nine months ended September 30, 2023 included $0.5 million of license revenue recognized upon the September 2023 achievement of marketing authorization for DANYELZA in Mexico under the Company's sublicense agreement with Adium. There was no license revenue in the third quarter ended September 30, 2022, and license revenue for the nine months ended September 30, 2022 was $1.0 million.

Operating Costs and Expenses

Cost of Goods Sold

Cost of goods sold was $2.6 million and $2.5 million for the third quarter ended September 30, 2023 and 2022, respectively. Cost of goods sold was $9.3 million and $5.4 million for the nine months ended September 30, 2023 and 2022, respectively. The increase in cost of goods sold in both periods was primarily driven by increased product revenue in the three and nine months ended September 30, 2023, and inventory write-downs of $0.4 million and $0.8 million in the three and nine months ended September 30, 2023, respectively, partially offset by a $1.2 million charge related to an inventory batch that did not meet the Company's quality specifications during the three and nine months ended September 30, 2022.

Excluding the above inventory charges, the Company's gross margin decreased slightly in the three and nine months ended September 30, 2023, compared to the same periods in 2022, due to an increase in ex-U.S. revenues, which were at lower gross margins.

Research and Development

Research and development expenses were $15.4 million for the third quarter ended September 30, 2023, a reduction of 32% compared to $22.5 million for the third quarter ended September 30, 2022. The $7.1 million decrease was primarily due to decreased spending on deprioritized programs, which resulted in a $5.7 million decrease in outsourced manufacturing, decreased personnel-related costs, inclusive of stock-based compensation, of $2.0 million, a $2.0 million decrease in outsourced research and supplies, and a $0.3 million decrease in clinical trials, partially offset by a $4.1 million increase in milestones and license acquisition costs related to the Company's SADA License Agreement, as the Company determined that certain time-based clinical milestones within the agreement are probable of achievement 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, 2023, research and development expenses were $40.8 million, a reduction of 43% compared to $71.8 million for the nine months ended September 30, 2022. The $31.0 million decrease was primarily due to decreased spending on deprioritized programs as described above, resulting in a $17.9 million decrease related to outsourced manufacturing, a $6.8 million decrease in outsourced research and supplies, a $3.1 million decrease in clinical trials and a $4.1 million decrease in personnel-related costs, partially offset by a $4.1 million increase in milestones and license acquisition costs related to the Company's SADA License Agreement, as the Company determined that certain time-based clinical milestones within the agreement are probable of achievement based on the availability of necessary data and the assessment of clinical progress in the third quarter of 2023.

The $2.0 million and $4.1 million decreases in personnel-related costs during the three and nine months ended September 30, 2023, respectively, were driven by the headcount reduction as part of Company's restructuring plan announced in January 2023, partially offset by severance charges recognized in conjunction with the restructuring plan.

Selling, General, and Administration

Selling, general, and administrative expenses were $10.2 million for the third quarter ended September 30, 2023, a reduction of 25% compared to $13.6 million for the third quarter ended September 30, 2022. The $3.4 million decrease in selling, general and administrative expenses was primarily attributable to a $1.9 million decrease in commercialization expenses, incurred in 2022 in anticipation of the potential omburtamab launch.

For the nine months ended September 30, 2023, selling, general, and administrative expenses were $33.7 million, a reduction of 33% compared to $50.1 million for the nine months ended September 30, 2022. The $16.4 million decrease in selling, general and administrative expenses was primarily attributable to a $10.9 million charge in the nine months ended September 30, 2022 related to contractual severance-related benefits for the Company's former Chief Executive Officer, and, to a lesser extent, a $2.9 million decrease in commercialization expenses, incurred in 2022 in anticipation of a potential omburtamab launch.

Net Loss

Y-mAbs reported a net loss for the third quarter ended September 30, 2023, of $7.7 million, or ($0.18) per basic and diluted share, compared to a net loss of $27.5 million, or ($0.63) per basic and diluted share, for the quarter ended September 30, 2022. For the nine months ended September 30, 2023, the Company reported a net loss of $20.4 million, or ($0.47) per basic and diluted share, compared to a net loss of $96.7 million, or ($2.21) per basic and diluted share, for the nine months ended September 30, 2022. The favorable decrease in net loss was primarily driven by an increase in DANYELZA U.S. and international product revenues in the third quarter and nine months ended September 30, 2023, decreased research and development cost, and decreased selling, general and administration cost.

Cash and Cash Equivalents

As of September 30, 2023, Y-mAbs had approximately $86.6 million in cash and cash equivalents which, together with anticipated DANYELZA product revenues, is expected to support operations as currently planned into 2027. 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.

Financial Guidance

The Company is updating and reiterating its full-year 2023 financial guidance, as follows:

- Reiterating anticipated DANYELZA® net product revenues of between $80 million and $85 million;
- Lowering anticipated operating expenses to between $110 million and $115 million from previous guidance of between $115 million and $120 million;
- Lowering anticipated total annual cash burn to between $27 million and $32 million from previous guidance of between $40 million and $50 million; and
- Cash and cash equivalents now anticipated to support operations as currently planned into 2027 compared to previous cash runway guidance into 2026.

Webcast and Conference Call

Y-mAbs will host a conference call on Tuesday, November 14, 2023, at 9:00 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
Conference ID: 13741478

To access a live webcast of the update, please use this link. Prior to the call and webcast, a slide presentation pertaining to Y-mAbs' quarterly earnings will be made available in the investor relations section of the Company's 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, 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 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 2023 and beyond, including estimated operating expenses, cash burn and DANYELZA product revenue and sufficiency of cash resources and related assumptions; implied and express statements regarding the future of the Company's business, including with respect to expansion and its goals; the Company's plans and strategies, development, commercialization and product distribution plans, including potential partnerships; 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 Technology and potential benefits and applications thereof; statements with respect to DANYELZA as a growing commercial product and SADA as a differentiated radioimmunotherapy platform positioning the Company on a path to potentially transform the treatment paradigm for a variety of cancers and improve patients' lives; expectations relating to key anticipated development milestones, including potential expansion of international commercialization efforts with respect to DANYELZA development efforts and the SADA Technology, including potential indications and applications, 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 related to the timing of the initiation and completion of regulatory submissions; additional product candidates and technologies; expectations regarding collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of cash and cash equivalents, and the need for, timing and amount of any future financing transaction; expectations with respect to the Company's future financial performance; 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," 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 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; the risks related to the Company's dependence on third parties including for conduct of clinical testing and product manufacture; the Company's inability to enter into partnerships; the 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, 2022, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 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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Investor Contact:

Courtney Dugan
VP, Head of Investor Relations
cdu@ymabs.com

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

	As of September 30, 2023	As of December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 86,571	$ 105,762
Accounts receivable, net	18,874	12,531
Inventories	7,113	6,702
Other current assets	2,302	5,452
Total current assets	114,860	130,447
Property and equipment, net	296	604

Operating lease right-of-use assets	1,593	1,739
Intangible assets, net	2,720	2,986
Other assets	9,415	5,680
TOTAL ASSETS	$ 128,884	$ 141,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 7,610	$ 14,175
Accrued liabilities	13,304	13,241
Operating lease liabilities, current portion	898	868
Total current liabilities	21,812	28,284
Accrued milestone payments	5,375	2,250
Operating lease liabilities, long-term portion	725	899
Other liabilities	822	802
TOTAL LIABILITIES	28,734	32,235
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at September 30, 2023 and December 31, 2022	-	-
Common stock, $0.0001 par value, 100,000,000 shares authorized at September 30, 2023 and December 31, 2022; 43,621,618 and 43,670,109 shares issued at September 30, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	554,779	543,929
Accumulated other comprehensive income	1,849	1,331
Accumulated deficit	(456,482)	(436,043)
TOTAL STOCKHOLDERS' EQUITY	100,150	109,221
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 128,884	$ 141,456

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,	
	2023	**2022**	**2023**	**2022**
REVENUES				
Product revenue, net	$ 19,954	$ 12,537	$ 60,956	$ 32,820
License revenue	500	—	500	1,000
Total revenues	20,454	12,537	61,456	33,820
OPERATING COSTS AND EXPENSES				
Cost of goods sold	2,595	2,475	9,327	5,447
License royalties	50	—	50	100
Research and development	15,358	22,453	40,831	71,785
Selling, general, and administrative	10,200	13,626	33,721	50,146
Total operating costs and expenses	28,203	38,554	83,929	127,478
Loss from operations	(7,749)	(26,017)	(22,473)	(93,658)
OTHER INCOME/(LOSS), NET				
Interest and other income/(loss)	189	(1,509)	2,400	(3,067)
LOSS BEFORE INCOME TAXES	(7,560)	(27,526)	(20,073)	(96,725)
Provision for income taxes	187	—	366	—
NET LOSS	$ (7,747)	$ (27,526)	$ (20,439)	$ (96,725)
Other comprehensive income				
Foreign currency translation	806	1,598	518	3,331
COMPREHENSIVE LOSS	$ (6,941)	$ (25,928)	$ (19,921)	$ (93,394)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.63)	$ (0.47)	$ (2.21)
Weighted average common shares outstanding, basic and diluted	43,620,532	43,718,351	43,651,536	43,715,451

Source: Y-mAbs Therapeutics, Inc