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

August 10, 2023

- **Q2 2023 DANYELZA® record net product revenues of $20.8 million, driving YoY growth of 112% and a 3% sequential increase compared to Q1 2023**
- **Management reiterates FY 2023 financial guidance**
- **DANYELZA marketing authorization granted in Brazil**
- **Ongoing patient recruitment in the Phase I GD2-SADA trial**
- **Cash and cash equivalents of $87.9 million as of June 30, 2023, anticipated cash runway into 2026**
- **The Company will host a conference call on Friday, August 11, 2023, at 9:00 a.m. EDT**

NEW YORK, Aug. 10, 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 second quarter of 2023.

"The second quarter of 2023 marked another period of progress for DANYELZA with continued revenue growth and international expansion with regulatory approval in Brazil,” said Thomas Gad, Founder, President, and Interim Chief Executive Officer. “As we continue patient enrollment in the Phase I GD2-SADA study, we are pleased to report that we have closed Cohort 1 and Cohort 2 and are now dosing Cohort 3, and we have administered a 200 mCi dose of 177Lu-DOTA and an interval between dosing of the protein and the payload of between two to five days. We look forward to presenting pk and imaging data from this study later this year at our R&D Day. Upon completion of our reorganization, we estimate our existing cash and cash equivalents to support our business operations as currently planned into 2026, positioning us well to deliver our therapies to more patients both in the U.S. and worldwide.”

Second Quarter 2023 and Recent Corporate Developments

- On July 2, 2023, the Company’s partner in China, SciClone Pharmaceuticals, announced that they had officially launched DANYELZA.
- On May 26, 2023, Y-mAbs announced interim clinical data from study 201 with naxitamab in combination with granulocyte-macrophage colony-stimulating factor (“GM-CSF”) in patients with relapsed or refractory high-risk neuroblastoma and presented such interim clinical data at the American Society of Clinical Oncology (“ASCO”) Annual Meeting on June 2-6, 2023.
- Also at ASCO, Y-mAbs presented the design of its Phase I clinical study evaluating the Company’s Self-Assembly DisAssembly Pre-targeted Radioimmunotherapy (“SADA Y-PRIT”) Theranostic Platform for the treatment of certain GD2-positive solid tumors, including small cell lung cancer, sarcoma, and malignant melanoma.
- On May 23, 2023, Y-mAbs announced that the Brazilian Health Regulatory Agency, Agência Nacional de Vigilância Sanitária (“ANVISA”) granted marketing authorization for DANYELZA (naxitamab-gqgk).
- On April 18, 2023, Y-mAbs announced that positive preclinical data had been presented on naxitamab in triple-negative breast cancer at the American Association for Cancer Research (“AACR”) Annual Meeting.
- On April 5, 2023, Y-mAbs announced that the first patient had been dosed in the Phase I clinical study evaluating the Company’s SADA Y-PRIT Theranostic Platform for the treatment of certain GD2-positive solid tumors.

Financial Results

Revenues

Y-mAbs reported DANYELZA net product revenues of $20.8 million and $41.0 million for the quarter and six months ended June 30, 2023, which represented increases of 112% and 102%, respectively, over $9.8 million and $20.3 million in the comparable periods of 2022.

The DANYELZA net product revenues for the quarter ended June 30, 2023 represents an increase of 3% compared to the first quarter of 2023. The $0.5 million sequential increase was driven by international revenues and related royalties, which included $3.5 million of revenues and related royalties for the China commercial launch inventory stocking order from SciClone, which Y-mAbs does not anticipate recurring at this level each quarter. This increase was partly offset by a softening in new U.S. patients in the second quarter and the Company’s $2.5 million inventory stocking order from WEP in the first quarter.

As of June 30, 2023, Y-mAbs has delivered DANYELZA to 56 centers across the U.S., a sequential increase of 6% in the number of centers since the first quarter of 2023. During the second quarter of 2023, approximately 61% of the vials sold in the U.S. were sold outside of Memorial Sloan Kettering Cancer Center (“MSKCC”), which is in line with the first quarter of 2023.

Operating Expenses

Cost of Goods Sold

Cost of goods sold was $4.6 million and $1.1 million for the three months ended June 30, 2023 and 2022, respectively. The increased cost of goods sold was driven by increased product revenue in the three months ended June 30, 2023 and an inventory write-down of $0.5 million in the three months ended June 30, 2023. Cost of goods sold was $6.7 million and $3.0 million for the six months ended June 30, 2023 and 2022, respectively. The increase in cost of goods sold was primarily driven by increased product revenue.

The Company's gross margin decreased in the three and six months ended June 30, 2023, compared to the same periods in 2022, as a result of increased revenues from geographic areas outside of the United States, which were at a lower gross margin. The Company's cost of goods sold includes amounts related to materials, third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, third-party royalties for approved products, and indirect overhead costs.

Research and Development

Research and development expenses were $12.1 million for the three months ended June 30, 2023, a reduction of 54% compared to $26.4 million for the three months ended June 30, 2022. The $14.3 million decrease was primarily due to decreased spending on deprioritized programs in connection with the Company's previously announced restructuring plan, resulting in a $6.6 million decrease related to outsourced manufacturing, a $3.2 million decrease in personnel-related costs, and a $2.5 million decrease in outsourced research and supplies.

For the six months ended June 30, 2023, research and development expenses were $25.5 million, a reduction of 48% compared to $49.3 million for the six months ended June 30, 2022. The $23.8 million decrease was primarily due to decreased spending on deprioritized programs as described above, resulting in a $12.3 million decrease related to outsourced manufacturing, a $4.8 million decrease in outsourced research and supplies, a $2.9 million decrease in clinical trials and a $2.1 million decrease in personnel-related costs.

Y-mAbs recorded a restructuring charge of $3.4 million in research and development expenses during the six months ended June 30, 2023, in connection with the restructuring plan.

Selling, General, and Administration

Selling, general, and administrative expenses were $11.3 million for the three months ended June 30, 2023, a reduction of 51.1% compared to $23.1 million for the three months ended June 30, 2022. The $11.8 million decrease in selling, general and administrative expenses was primarily attributable to a $10.9 million charge related to contractual severance related benefits for the Company's former Chief Executive Officer in connection with his departure in the second quarter of 2022.

For the six months ended June 30, 2023, selling, general, and administrative expenses were $23.5 million, a reduction of 35.6% compared to $36.5 million for the six months ended June 30, 2022. The $13.0 million decrease in SG&A expenses was primarily attributable to the contractual severance-related benefits described above.

Y-mAbs recorded a restructuring charge of $1.1 million in selling, general, and administrative expenses during the six months ended June 30, 2023, in connection with the restructuring plan.

Net Loss

Y-mAbs reported a net loss for the second quarter ended June 30, 2023, of $6.3 million, or ($0.14) per basic and diluted share, compared to a net loss of $41.1 million, or ($0.94) per basic and diluted share, for the quarter ended June 30, 2022. For the six months ended June 30, 2023, the Company reported a net loss of $12.7 million, or $0.29 per basic and diluted share, compared to a net loss of $69.2 million, or $1.58 per basic and diluted share, for the six months ended June 30, 2022. The favorable decrease in net loss was primarily driven by an increase in DANYELZA U.S. product revenues in the second quarter and six months ended June 30, 2023, an incremental benefit from expanding into international markets, decreased research and development cost, and decreased selling, general and administration cost, partially offset by the unfavorable impact of restructuring charges, all as noted above.

Cash and Cash Equivalents

As of June 30, 2023, Y-mAbs had approximately $87.9 million in cash and cash equivalents which, together with anticipated DANYELZA product revenues, is expected to support operations as currently planned into 2026. 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

Management reiterates its full year 2023 financial guidance, as updated on May 8, 2023:

- Anticipated DANYELZA® net product revenues expected to be between $80 million and $85 million;
- Anticipated operating expenses expected to be between $115 million and $120 million;
- Anticipated total annual cash burn expected to be between $40 million and $50 million; and
- Cash and cash equivalents anticipated to support operations as currently planned into 2026.

Webcast and Conference Call

Y-mAbs will host a conference call on Friday, August 11, 2023, at 9:00 a.m. EDT. To participate in the call, please use the following dial-in information.

Investors (domestic):	877-407-0792
Investors (international):	201-689-8263
Conference ID:	13739908

To access a live webcast of the update, please use this link.

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, total cash burn and DANYELZA product revenue and sufficiency of cash resources and related assumptions; the restructuring, including the reduction in workforce and revised business plan, and the expected impacts, expenses and benefits thereof, including potential cost-savings from the reduction in force, expected reduction of operating expenses and any expectations with respect to cost savings to be derived therefrom; 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 omburtamab; expectations with respect to our 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, including the development of the first tumor binding dataset, and potential benefits and applications thereof; 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 our research and development programs, including with respect to timing and results; expectations related to the timing of the initiation and completion of regulatory submissions; regulatory, marketing and reimbursement approvals; including satisfaction of conditions to approvals; 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 our financial condition and need for additional capital; the risks that actual results of our restructuring plan and revised business plan will not be as expected; risks associated with our development work; cost and success of our product development activities and clinical trials; the risks of delay in the timing of our regulatory submissions or failure to receive approval of our drug candidates; the risks related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of our product candidates; development of our sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for our products; the risks related to our dependence on third parties including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; the risks related to government regulation; risks related to market approval, risks associated with protection of our intellectual property rights; risks related to employee matters and managing growth; risks related to our common stock, risks associated with 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 ending December 31, 2022, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 and future filings and reports by the Company including the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023. 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)

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 87,909	$ 105,762
Accounts receivable, net	19,118	12,531
Inventories	5,187	6,702
Other current assets	3,570	5,452
Total current assets	115,784	130,447
Property and equipment, net	375	604
Operating lease right-of-use assets	1,178	1,739
Intangible assets, net	2,809	2,986
Other assets	12,250	5,680
TOTAL ASSETS	$ 132,396	$ 141,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 7,252	$ 14,175
Accrued liabilities	16,152	13,241
Operating lease liabilities, current portion	829	868
Total current liabilities	24,233	28,284
Accrued milestones and royalty payments	2,250	2,250
Operating lease liabilities, long-term portion	416	899
Other liabilities	816	802
TOTAL LIABILITIES	27,715	32,235

STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at June 30, 2023 and December 31, 2022	-	-
Common stock, $0.0001 par value, 100,000,000 shares authorized at June 30, 2023 and December 31, 2022; 43,620,192 and 43,670,109 shares issued at June 30, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	552,369	543,929
Accumulated other comprehensive income	1,043	1,331
Accumulated deficit	(448,735)	(436,043)
TOTAL STOCKHOLDERS' EQUITY	104,681	109,221
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 132,396	$ 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 June 30,		Six months ended June 30,	
	2023	**2022**	**2023**	**2022**
REVENUES				
Product revenue, net	$ 20,751	$ 9,797	$ 41,002	$ 20,283
License revenue	—	1,000	—	1,000
Total revenues	20,751	10,797	41,002	21,283
OPERATING COSTS AND EXPENSES				
Cost of goods sold	4,649	1,140	6,732	2,972
License royalties	—	100	—	100
Research and development	12,055	26,420	25,473	49,332
Selling, general, and administrative	11,270	23,082	23,521	36,520
Total operating costs and expenses	27,974	50,742	55,726	88,924
Loss from operations	(7,223)	(39,945)	(14,724)	(67,641)
OTHER INCOME/(LOSS), NET				
Interest and other income/(loss)	1,100	(1,186)	2,211	(1,558)
LOSS BEFORE INCOME TAXES	(6,123)	(41,131)	(12,513)	(69,199)
Provision for income taxes	179	—	179	—
NET LOSS	$ (6,302)	$ (41,131)	$ (12,692)	$ (69,199)
Other comprehensive income/(loss)				
Foreign currency translation	18	1,422	(288)	1,733
COMPREHENSIVE LOSS	$ (6,284)	$ (39,709)	$ (12,980)	$ (67,466)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.14)	$ (0.94)	$ (0.29)	$ (1.58)
Weighted average common shares outstanding, basic and diluted	43,663,112	43,718,748	43,667,385	43,713,967

Y-mAbs Therapeutics, Inc.

Source: Y-mAbs Therapeutics, Inc