

Y-mAbs Reports First Quarter 2023 Financial Results and Recent Corporate Developments and Updates 2023 Financial Guidance

May 08, 2023

- **Q1 2023 DANYELZA® record net product revenues of \$20.3 million, driving YoY growth of 93% and a 24% sequential increase compared to Q4 2022**
- **Management updates 2023 financial guidance, now anticipating higher DANYELZA net revenues of \$80-85 million and lower cash burn of \$40-50 million for FY 2023**
- **Ongoing patient recruitment in the Phase I SADA trial**
- **Cash and cash equivalents of \$92.6 million as of March 31, 2023, anticipated cash runway into the first quarter 2026**
- **The Company will host a conference call on Tuesday, May 9, 2023, at 9 a.m. EST**

NEW YORK, May 08, 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 first quarter of 2023.

"The first quarter of 2023 marked a period of significant progress for DANYELZA and we believe has set up 2023 to be a very productive year. We are thrilled to report record DANYELZA net revenues of \$20.3 million in the first quarter of 2023, a 24% sequential increase compared to the previous quarter and near doubling year-over-year. The increase allows us to update our FY 2023 DANYELZA revenue guidance from \$60-65 million to \$80-85 million," said Thomas Gad, President, and Interim Chief Executive Officer. "In Q1 2023, we implemented a restructuring plan to prioritize resources on the DANYELZA franchise and development of our SADA technology in the fight against cancer. With a 35% reduction in force and an anticipated 28% reduction in annual operating expenses for 2023, we emerge leaner and supported by a robust balance sheet with \$92.6 million in cash and cash equivalents as of March 31, 2023, which we estimate should support our business operations as currently planned into the first quarter of 2026. In addition, we achieved a major milestone of treating the first patient in our GD2-SADA trial in April 2023."

First Quarter 2023 and Recent Corporate Developments

- On April 18, 2023, Y-mAbs announced that positive preclinical data on naxitamab in triple-negative breast cancer was presented at the AACR Annual Meeting
- On April 5, 2023, Y-mAbs announced that the first patient had been dosed in the Phase 1 trial of GD2-SADA
- On February 2, 2023, Y-mAbs announced that the European Medicines Agency agreed to the Company's Pediatric Investigational Plan for naxitamab.
- On January 4, 2023, Y-mAbs announced a restructuring plan including a 35% reduction in workforce and an anticipated 28% reduction in annual operating expenses for 2023.

Financial Results

Revenues

Y-mAbs reported DANYELZA net product revenues of \$20.3 million for the quarter ended March 31, 2023, which reflects a 93% increase over \$10.5 million in the comparable quarter of 2022. The DANYELZA net product revenues of \$20.3 million for the quarter ended March 31, 2023 represents an increase of 24% compared to the fourth quarter 2022 DANYELZA net product revenues of \$16.4 million. The \$3.9 million sequential increase was primarily driven by an increase in new US patients and an incremental benefit from international revenues. Our net product revenues from other countries for the three months ended March 31, 2023 included \$2.5 million of product revenue from our distribution partner in connection with the early access program for DANYELZA in Europe. These sales reflected an initial inventory stocking and we do not anticipate recurring sales under this program to be as high in future quarters, which is reflected in our updated revenue guidance for 2023.

As of March 31, 2023, Y-mAbs has delivered DANYELZA to 53 centers across the United States, corresponding to a sequential increase of 10% in the number of centers since the fourth quarter of 2022. During the first quarter of 2023, approximately 62% of the vials sold in the United States were sold outside Memorial Sloan Kettering ("MSK"), an increase from the prior quarter as a result of growth in new patients at institutions outside MSK outpacing MSK's growth of new patients.

Operating Expenses

Research and Development

Research and development expenses were \$13.4 million for the three months ended March 31, 2023, compared to \$22.9 million for the three months ended March 31, 2022. The \$9.5 million decrease was primarily due to the decreased spending on deprioritized programs, which resulted in decreased costs for outsourced manufacturing services due to decreased clinical trial activities in 2023, outsourced research and supplies and spending for clinical trials, partially offset by increased personnel-related costs, inclusive of stock-based compensation, which includes an incremental impact for accrued severance related benefits of \$1.1 million and accelerated stock-based compensation expense of \$0.9 million associated with our first quarter of 2023 restructuring charge in connection with the implementation of our restructuring plan.

Selling, General, and Administration

Selling, general, and administrative expenses decreased by \$1.2 million to \$12.2 million for the three months ended March 31, 2023, compared to \$13.4 million for the three months ended March 31, 2022. The decrease in selling, general and administrative expenses was primarily the result of decreased personnel-related costs and insurance costs. The decrease in personnel-related costs is after \$0.8 million accelerated stock-based compensation expense related to our reduction in force.

Net Loss

We reported a net loss for the first quarter ended March 31, 2023, of (\$6.4) million, or (\$0.15) per basic and diluted share, compared to a net loss of (\$28.1) million, or (\$0.64) per basic and diluted share, for the quarter ended March 31, 2022. The favorable improvement in net loss compared to 2022 was primarily driven by increased DANYELZA revenues and decreased research and development expenses, partially offset by a \$2.8 million incremental impact of the restructuring charge in the first quarter of 2023.

Cash and Cash Equivalents

We had approximately \$92.6 million in cash and cash equivalents as of March 31, 2023, and we expect a full-year 2023 cash burn of \$40-50 million. Our existing cash and cash equivalents, when combined with anticipated DANYELZA revenues, which are assumed to increase by 10% for 2024 and 2025 for the purpose of our analysis of runway, is expected to be sufficient to fund our operations as currently planned into 2026. In terms of development activities, we have assumed that our prioritized programs will be advanced at our own expense and no new programs are assumed at this point. We assume no new partnerships or other new business development, and no further development of the omburtamab program. This estimate reflects our current business plan that is supported by assumptions that may prove to be inaccurate, such that we could use our available capital resources sooner than we currently expect.

Financial Guidance

We are updating our full-year 2023 financial guidance, which now reflects:

- Anticipated DANYELZA® net product revenues now expected to be \$80-85 million (previously \$60-65 million);
- Anticipated operating expenses continues to be expected to be \$115-120 million;
- Anticipated total annual cash burn now expected to be \$40-50 million (previously \$50-55 million); and
- Cash and cash equivalents anticipated to support operations as currently planned into the first quarter of 2026.

Webcast and Conference Call

Y-mAbs will host a conference call on Tuesday, May 9, 2023, at 9 a.m. Eastern Time. To participate in the call, please use the following dial-in information.

Investors (domestic): 888-886-7786

Investors
(international): 416-764-8658

Conference ID: 09065062

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-gqqk), 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; 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; the Company's plans and strategies, development, commercialization and product distribution plans; 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 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 potential application to GD2 positive solid tumors, and the timing thereof; expectations with respect to current and future clinical and pre-clinical studies and our research and development programs; 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, and future filings and reports by the Company including the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

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

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

	As of March 31, 2023	As of December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 92,629	\$ 105,762
Accounts receivable, net	18,702	12,531
Inventories	8,945	6,702
Other current assets	3,730	5,452
Total current assets	124,006	130,447
Property and equipment, net	511	604
Operating lease right-of-use assets	1,369	1,739
Intangible assets, net	2,898	2,986
Other assets	8,661	5,680
TOTAL ASSETS	\$ 137,445	\$ 141,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	\$ 8,843	\$ 14,175
Accrued liabilities	16,222	13,241
Operating lease liabilities, current portion	855	868
Total current liabilities	25,920	28,284
Accrued milestone and royalty payments	2,250	2,250
Operating lease liabilities, long-term portion	629	899
Other liabilities	817	802
TOTAL LIABILITIES	29,616	32,235
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.0001 par value, 5,500,000 shares authorized and none issued at March 31, 2023 and December 31, 2022	-	-
Common stock, \$0.0001 par value, 100,000,000 shares authorized at March 31, 2023 and December 31, 2022; 43,677,767 and 43,670,109 shares issued at March 31, 2023 and December 31, 2022, respectively	4	4
Additional paid in capital	549,233	543,929
Accumulated other comprehensive income	1,025	1,331
Accumulated deficit	(442,433)	(436,043)
TOTAL STOCKHOLDERS' EQUITY	107,829	109,221
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 137,445	\$ 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 March 31,	
	2023	2022
REVENUES		
Product revenue, net	\$ 20,251	\$ 10,486
Total revenues	<u>20,251</u>	<u>10,486</u>
OPERATING COSTS AND EXPENSES		
Cost of goods sold	2,083	1,831
Research and development	13,418	22,912
Selling, general, and administrative	12,251	13,438
Total operating costs and expenses	<u>27,752</u>	<u>38,181</u>
Loss from operations	<u>(7,501)</u>	<u>(27,695)</u>
OTHER INCOME / (LOSS), NET		
Interest and other income / (loss)	1,111	(373)
NET LOSS	\$ (6,390)	\$ (28,068)
Other comprehensive income / (loss)		
Foreign currency translation	(306)	311
COMPREHENSIVE LOSS	\$ (6,696)	\$ (27,757)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.15)	\$ (0.64)
Weighted average common shares outstanding, basic and diluted	<u>43,671,589</u>	<u>43,709,238</u>



Source: Y-mAbs Therapeutics, Inc