Y-mAbs Announces Second Quarter Financial Results and Recent Corporate Developments

August 08, 2022

- **Omburtamab BLA Accepted by the FDA with November 2022 PDUFA date**
- **Announced IND Clearance for the first GD2-SADA construct**
- **YTD DANYELZA® product revenue $20.3 million**
- **Management reiterates financial guidance, including 2022 full-year DANYELZA® revenue of $45-$50 million**
- **Strong cash position with $133.7 million as of June 30, 2022, anticipated runway into mid-2024**
- **The Company will host a conference call on Tuesday, August 9, 2022, at 9 a.m. EST**

NEW YORK, Aug. 08, 2022 (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 2022.

"The highlight of the second quarter was FDA acceptance of our BLA filing for omburtamab,” said Thomas Gad, President, and Interim Chief Executive Officer. “We are excited about the upcoming PDUFA date, which we believe brings us closer to the potential approval and achieving our goal of delivering omburtamab to children suffering from high-risk neuroblastoma brain tumors. We were also thrilled to announce that the Phase 2 naxitamab chemo-immunotherapy trial met primary endpoints achieving an impressive response rate further underscoring DANYELZA potential in high-risk neuroblastoma. Our strong balance sheet with $133.7 million in cash is expected to support us through multiple potentially value-creating catalysts and into mid-2024.”

Second Quarter 2022 and Recent Corporate Developments

- On July 12, 2022, Y-mAbs announced clearance of the IND for GD2-SADA
- On May 31, 2022, Y-mAbs announced FDA acceptance of the Biologics License Application for OMBLASTYS® (omburtamab) for the treatment of neuroblastoma for priority review
- On May 26, 2022, Y-mAbs announced that the naxitamab chemoimmunotherapy investigational trial for High-Risk Neuroblastoma met its primary endpoint. The data was presented at the American Society of Clinical Oncology (ASCO).
- On April 27, 2022, Y-mAbs announced a management change. Dr. Claus Moller stepped down as Chief Executive Officer and Board Member, and the role of Interim Chief Executive Officer was assumed by Thomas Gad, the Company’s Founder and President, Interim Chief Executive Officer and Head of Business Development and Strategy, and Board Member. The Board, under the newly appointed Chairman, Dr. Jim Healy, has begun a search for Dr. Moller’s successor.
- On April 8, 2022, Y-mAbs presented pre-clinical data from the GD2-SADA construct at the American Association for Cancer Research (AACR) 2022 Annual Meeting.

Financial Results

Revenues

Y-mAbs reported net revenues of $10.8 million and $21.3 million for the quarter and six months ended June 30, 2022, which represented a decrease of 1% and an increase 30%, respectively, over $11.0 million and $16.3 million in the comparable periods of 2021. Net revenues in the quarter and six months ended June 30, 2022 included $1.0 million of license revenue, compared to $2.0 million of license revenue in the corresponding periods in 2021. DANYELZA product revenue for the quarter and six months ended June 30, 2022 was $9.8 million and $20.3 million, respectively, which represented increases of 9% and 42%, respectively, over the corresponding periods in 2021. DANYELZA product revenue of $9.8 million in the second quarter 2022 deceased 7% compared to the first quarter of 2022 DANYELZA product revenues of $10.5 million. The decline included a slight decrease in new US patients earlier in the second quarter 2022, followed by a rebound in June, while international revenues benefitted from increased royalty income from partner’s sales, offset by a decrease in volume due to the timing of partner orders.

We have now delivered DANYELZA to 36 centers across the U.S., corresponding to an increase of 6% in the number of centers since the end of the first quarter of 2022. During the second quarter of 2022, approximately 40% of the vials sold in the U.S. were sold outside Memorial Sloan Kettering (“MSK”), a decrease from the prior quarter as a result of a decreased number of new patients at institutions outside MSK earlier in the second quarter followed by a rebound in June, as noted above, all while new patients at MSK continued to grow.

Operating Expenses

Research and Development

Research and development expenses were $26.4 million for the three months ended June 30, 2022, compared to $19.8 million for the three months ended June 30, 2021. The $6.6 million increase reflects an increase in outsourced manufacturing, inclusive of $2.9 million of naxitamab inventory vials that were designated for use in clinical trials during the three months ended June 30, 2022, our increased clinical trial activity and employee-related costs. Having completed the resubmission of the BLA for omburtamab in the first quarter 2022, we are focusing on pipeline development programs for

potential DANYELZA label expansion, omburtamab and advancing the SADA constructs into the clinic.

Research and development expenses increased by $8.0 million to $49.3 million during the six months ended June 30, 2022 compared to the prior year period. The $8.0 million increase reflects an increase in outsourced manufacturing, inclusive of $2.9 million of naxitamab inventory vials that were designated for clinical use during the six months ended June 30, 2022, and our increased clinical trial activity, with particular focus on the DANYELZA, omburtamab and SADA technologies.

Selling, General, and Administration

Selling, General, and Administrative expenses increased by $9.6 million and $11.1 million, to $23.1 million and $36.5 million, for the quarter and six months ended June 30, 2022, respectively, compared to the prior year periods. The increase in selling, general and administrative expenses in both periods was primarily the result of a $10.7 million charge related to contractual severance related benefits for our former Chief Executive Officer, which was inclusive of $9.3 million of non-cash share-based compensation expense, and, to a lesser extent, the launch and commercialization of DANYELZA, which include employee-related costs and commercial expenses.

Net Loss

We reported a net loss for the quarter ended June 30, 2022, of $41.1 million, or $0.94 per basic and diluted share, compared to net loss of $22.9 million, or $0.53 per basic and diluted share for the quarter ended June 30, 2021. The decrease in earnings was primarily driven by the $10.7 million charge for contractual severance related benefits for our former Chief Executive Officer and increased research and development expenses focused on pipeline development programs for DANYELZA label expansion, omburtamab, and advancing the SADA constructs into the clinic.

We reported a net loss for the six months ended June 30, 2022, of $69.2 million, or $1.58 per basic and diluted share, compared to a net income of $10.5 million, or $0.25 per basic share and $0.23 per diluted share, for the six months ended June 30, 2021. Net income in the six months ended June 30, 2021, included a $62.0 million net gain from the sale of our DANYELZA Priority Review Voucher, after sharing 40% of the net proceeds from the sale with MSK, pursuant to the terms of our license agreement with MSK. The decrease in earnings in the six months ended June 30, 2022 also reflects the unfavorable impact of a $10.7 million charge for contractual severance related benefits for our former Chief Executive Officer, and increased research and development expenses, both as noted above, partially offset by the favorable impact of DANYELZA's growing revenues.

Cash and Cash Equivalents

We had approximately $133.7 million in cash and cash equivalents as of June 30, 2022, and we continue to expect full year 2022 cash burn of $78-83 million. Our cash and cash equivalents balance of approximately $133.7 million as of June 30, 2022, which, when combined with forecasted DANYELZA revenue growth, is expected to be sufficient to fund our operations as currently planned into mid-2024. This estimate is based on our current business plan. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

This estimate does not include any assumption for net proceeds received on the anticipated priority review voucher, which we could sell upon the potential approval of omburtamab. In addition, no new partnerships or other new business development-related sources of income are included in the assumptions, potential omburtamab revenues upon approval are also excluded, and the DANYELZA revenues are only assumed to increase modestly each year for the purpose of this analysis of runway.

Financial Guidance

Management reiterates all elements of its financial guidance including:

- DANYELZA® 2022 revenues of $45-$50 million;
- Operating expenses of $162-167 million;
- Total cash burn of $78-83 million for 2022; and
- Cash position sufficient to fund current operations into mid-2024.

The revenue guidance includes an incremental benefit from international revenues.

Webcast and Conference Call

Y-mAbs will host a conference call on Tuesday, August 9, 2022, at 9 a.m. Eastern Time. To participate in the call, please dial 877-407-0792 (domestic) or 201-689-8263 (international) and reference the conference ID 13730680.

A webcast will be available at: https://viavid.webcasts.com/starthere.jsp?ei=1555384&tp_key=db740a8735

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 The Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about our business model and development, commercialization and product distribution plans; 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 statements with respect to the potential approval of omburtamab, pipeline development programs, potential for DANYELZA label expansion, and advancement of SADA; retaining and hiring key employees, including the search for Dr. Moller's successor; additional product candidates and technologies; collaborations or strategic partnerships and the potential benefits thereof; expectations related our anticipated cash runway and the sufficiency of our cash resources, and the need for, timing

and amount of any future financing transaction; DANYELZA revenue guidance for 2022, and our financial performance, including our estimates regarding revenues, expenses and capital expenditure requirements; 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” 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; 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 the COVID-19 pandemic; risks associated with the conflict between Russia and Ukraine and sanctions related thereto, macroeconomic conditions, including inflation and global capital markets; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC and in our other SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 to be filed with the SEC. 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.

Contact:

Y-mAbs Therapeutics, Inc.
230 Park Avenue, Suite 3350
New York, NY 10169
USA

+1 646 885 8505

E-mail: info@ymabs.com

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

	June30, 2022	December31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 133,665	$ 181,564
Accounts receivable, net	7,208	7,712
Inventories	6,794	5,512
Other current assets	6,253	7,473
Total current assets	153,920	202,261
Property and equipment, net	1,554	1,847
Operating lease right-of-use assets	2,381	3,842
Intangible assets, net	1,574	1,663
Other assets	5,749	3,170
TOTAL ASSETS	$ 165,178	$ 212,783
LIABILITIES AND STOCKHOLDERS’ EQUITY		
LIABILITIES		
Accounts payable	$ 11,291	$ 13,552
Accrued liabilities	17,067	12,540
Operating lease liabilities, current portion	1,092	1,783
Total current liabilities	29,450	27,875
Accrued milestone and royalty payments	2,250	2,100
Operating lease liabilities, long-term portion	1,302	1,851
Other liabilities	780	851
TOTAL LIABILITIES	33,782	32,677
STOCKHOLDERS’ EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at June 30, 2022 and December 31, 2021; 43,720,038 and 43,694,716 shares issued at June 30, 2022 and December 31, 2021, respectively	4	4

Additional paid in capital	537,962	519,206
Accumulated other comprehensive income	3,104	1,371
Accumulated deficit	(409,674)	(340,475)
TOTAL STOCKHOLDERS' EQUITY	131,396	180,106
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 165,178	$ 212,783

Y-MABS THERAPEUTICS, INC.
Consolidated Statements of Net Income / (Loss) and Comprehensive Income / (Loss)
(unaudited)
(in thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
REVENUES				
Product revenue, net	$ 9,797	$ 8,951	$ 20,283	$ 14,334
License revenue	1,000	2,000	1,000	2,000
Total revenues	10,797	10,951	21,283	16,334
OPERATING COSTS AND EXPENSES				
Cost of goods sold	1,140	200	2,972	293
License royalties	100	210	100	210
Research and development	26,420	19,778	49,332	41,357
Selling, general, and administrative	23,082	13,475	36,520	25,445
Total operating costs and expenses	50,742	33,663	88,924	67,305
Loss from operations	(39,945)	(22,712)	(67,641)	(50,971)
OTHER INCOME / (LOSS), NET				
Gain from sale of priority review voucher, net	—	—	—	62,010
Interest and other loss	(1,186)	(225)	(1,558)	(563)
NET INCOME / (LOSS)	$ (41,131)	$ (22,937)	$ (69,199)	$ 10,476
Other comprehensive income				
Foreign currency translation	1,422	78	1,733	513
COMPREHENSIVE INCOME / (LOSS)	$ (39,709)	$ (22,859)	$ (67,466)	$ 10,989
Net income / (loss) per share attributable to common stockholders, basic	$ (0.94)	$ (0.53)	$ (1.58)	$ 0.25
Weighted average common shares outstanding, basic	43,718,748	$ 43,569,482	43,713,967	42,724,813
Net income / (loss) per share attributable to common stockholders, diluted	$ (0.94)	$ (0.53)	$ (1.58)	$ 0.23
Weighted average common shares outstanding, diluted	43,718,748	43,569,482	43,713,967	45,080,419

Source: Y-mAbs Therapeutics, Inc