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

November 4, 2021

NEW YORK, Nov. 04, 2021 (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 2021.

"We are very pleased with our third quarter 2021 results. DANYELZA commercialization throughout the U.S continue to impress, as sales volume ex-MSK increased by 49% quarter over quarter. Resubmission of the omburtamab BLA is progressing as planned and we have requested a pre-BLA meeting with the aim of initiating a resubmission the BLA shortly thereafter. We ended the quarter with a cash balance of $215.7 million, so we believe we are well positioned to elevate our business to new levels," stated Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, continued, "We plan to submit the IND for our GD2-SADA construct in December, and we are truly excited to approach the clinic, which is a substantial milestone for the SADA technology. Going forward, we expect to submit at least one SADA IND per year, partly from our own pipeline of SADA constructs, and partly through one or more partnerships, which we expect to enter into during the next 6-12 months."

Recent Corporate Developments

- After the close of the quarter, on November 4, 2021, Y-mAbs announced that the Company has requested a pre-BLA meeting for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. The Company believes the pre-BLA meeting will be held in January 2022, and pending a positive meeting, the Company aims to initiate resubmission of the omburtamab BLA shortly thereafter.

- Also, after the close of the third quarter, on October 7, 2021, Y-mAbs announced that the U.S. Food and Drug Administration ("FDA") has granted Rare Pediatric Disease Designation ("RPDD") for the Company's lutetium labelled omburtamab antibody program for the treatment of medulloblastoma.

- On September 13, 2021, Y-mAbs announced that its partner in China, SciClone Pharmaceuticals had been granted priority review of the Biologics License Application for DANYELZA® (naxitamab-gqgk) for the treatment of patients with relapsed/refractory high-risk neuroblastoma by the Center for Drug Evaluation of China's National Medical Products Administration.

- On July 6, 2021, Y-mAbs announced that SciClone Pharmaceuticals had submitted the Biologics License Application for DANYELZA for the treatment of patients with relapsed/refractory high-risk neuroblastoma to the National Medical Products Administration ("NMPA") of China.

Financial Results

Y-mAbs reported a net loss of $28.9 million, or ($0.66) per basic and diluted share, for the quarter ended September 30, 2021, compared to a net loss of $32.8 million, or ($0.82) per basic and diluted share, reported for the quarter ended September 30, 2020. The decreased net loss was caused by the DANYELZA revenues in 2021, partially offset by increases in operating expenses related to the commercialization of DANYLEZA in the United States.

For the nine months ended September 30, 2021, Y-mAbs reported a net loss of $18.4 million, or ($0.43) per basic and diluted share, compared to the net loss of $99.4 million, or ($2.49) per basic and diluted share, reported for the nine months ended September 30, 2020. The decrease in net loss was primarily caused by the sale in January 2021 of the priority review voucher received upon the approval of DANYELZA and the DANYELZA revenues for the first nine months of 2021.

Revenues

Y-mAbs reported net revenues of $9.0 million for the quarter ended September 30, 2021 related to sales of DANYELZA.

Revenues were $25.3 million for the nine months ended September 30, 2021 and consisted of $23.3 million from the sales of DANYELZA and $2.0 million of licensing revenue.

No revenues were reported for the quarter ended and nine months ended September 30, 2020.

Operating Expenses

Research and Development
Research and development expenses were $23.1 million for the three months ended September 30, 2021, compared to $21.0 million for the three months ended September 30, 2020, an increase of $2.1 million. The increase in research and development expenses was primarily due to the following increases:

- $1.9 million in clinical trials; and
- $1.8 million in personnel costs.

These increases were partially offset by a reduction of $1.4 million in outsourced manufacturing costs.

Research and development expenses were $64.5 million for the nine months ended September 30, 2021, compared to $69.7 million for the nine months ended September 30, 2020, a decrease of $5.2 million. The decrease in research and development expenses was primarily due to:

- $13.3 million decrease in milestone payments and license acquisition costs driven by the SADA agreement executed in April 2020; and
- $4.4 million decrease in regulatory affairs costs.

These decreases were partially offset by increases of:

- $7.3 million in personnel costs;
- $2.5 million in clinical trials;
- $1.4 million in expenses related to our manufacturing and supply agreement with Spectron RX; and
- $1.0 million in external consulting and software expenses.

Selling, General, and Administration
Selling, general, and administrative expenses were $14.0 million for the three months ended September 30, 2021, compared to $11.6 million for the three months ended September 30, 2020, an increase of $2.4 million. The increase in selling, general and administrative expenses primarily reflects a $2.1 million increase in personnel costs due to the continued hiring of our commercialization team.

Selling, general, and administrative expenses were $39.4 million for the nine months ended September 30, 2021, compared to $30.2 million for the nine months ended September 30, 2020, an increase of $9.2 million. The increase in selling, general and administrative expenses primarily reflects a $8.5 million increase in personnel costs due to the continued hiring of our commercialization team.

Cash and Cash Equivalents

The Company had $215.7 million in cash and cash equivalents as of September 30, 2021, compared to $114.6 million as of December 31, 2020. The increase of $101.1 million was primarily attributable to the following:

- The completion of the sale of our DANYELZA priority review voucher in January 2021. Y-mAbs netted $62.0 million after paying 40% of the net proceeds from the sale to MSK pursuant to the terms of the license agreement with MSK, and
- $107.7 million in net proceeds raised in our public offering in February 2021.

These increases were partially offset by the net cash used in operational activities of $68.7 million for the nine months ended September 2021.

Webcast and Conference Call

The Company will host a conference call on Friday, November 5, 2021 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 13724630.

A webcast will be available at: https://viavid.webcasts.com/starthere.jsp?ei=1507982&tp_key=2757523ca1

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. The Company has a broad and advanced product pipeline, including one FDA approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one pivotal-stage product candidate, 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; rate and degree of market acceptance and clinical utility as well as pricing and reimbursement levels; retaining and hiring key employees; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position and strategy; additional product candidates and technologies; collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of our cash and cash equivalents, and the need for, timing and amount of any future financing transaction; our financial performance, including our estimates regarding revenues, expenses, capital expenditure requirements; developments relating to our competitors and our industry; 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 pandemic caused by the coronavirus known as COVID-19 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 and in our other SEC filings. 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” 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 data)

	Septemer 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 215,730	$ 114,634
Accounts receivable, net	7,264	—
Inventories	4,787	—
Other current assets	2,799	7,729
Total current assets	230,580	122,363
Property and equipment, net	1,846	1,825
Operating lease right-of-use assets	2,802	4,569
Other assets	4,751	3,290
TOTAL ASSETS	$ 239,979	$ 132,047
LIABILITIES AND STOCKHOLDERS’ EQUITY		
LIABILITIES		
Accounts payable	$ 11,024	$ 9,372
Accrued liabilities	12,486	8,197
Operating lease liabilities, current portion	1,849	1,966
Total current liabilities	25,359	19,535
Accrued milestone and royalty payments	2,250	2,695
Operating lease liabilities, long-term portion	654	2,013
Other liabilities	871	1,968
TOTAL LIABILITIES	29,134	26,211
STOCKHOLDERS’ EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized at September 30, 2021 and December 31, 2020; none issued at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at September 30, 2021 and December 31, 2020; 43,643,916 and 40,688,447 shares issued at September 30, 2021 and December 31, 2020, respectively	4	4
Additional paid in capital	514,198	391,558

Accumulated other comprehensive income / (loss)	225	(526)
Accumulated deficit	(303,582)	(285,200)
TOTAL STOCKHOLDERS' EQUITY	210,845	105,836
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 239,979	$ 132,047

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 September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
REVENUE				
Product revenue, net	$ 8,965	$ —	$ 23,299	$ —
License revenue	—	—	2,000	—
Total revenue	8,965	—	25,299	—
OPERATING COSTS AND EXPENSES				
Cost of goods sold	550	—	843	—
Licensing royalties	—	—	210	—
Research and development	23,131	21,005	64,488	69,686
Selling, general, and administrative	13,988	11,636	39,433	30,155
Total operating costs and expenses	37,669	32,641	104,974	99,841
Loss from operations	(28,704)	(32,641)	(79,675)	(99,841)
OTHER INCOME, NET				
Gain from sale of priority review voucher	—	—	62,010	—
Interest and other income / (loss), net	(154)	(191)	(717)	437
NET LOSS	$ (28,858)	$ (32,832)	$ (18,382)	$ (99,404)
Other comprehensive income / (loss)				
Foreign currency translation	238	(12)	751	(78)
COMPREHENSIVE LOSS	$ (28,620)	$ (32,844)	$ (17,631)	$ (99,482)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.66)	$ (0.82)	$ (0.43)	$ (2.49)
Weighted average common shares outstanding, basic and diluted	43,598,350	40,187,173	43,019,217	39,971,766

Source: Y-mAbs Therapeutics, Inc