Y-mAbs Announces Third Quarter 2020 Financial Results and Recent Corporate Developments

November 5, 2020

NEW YORK, Nov. 05, 2020 (GLOBE NEWSWIRE) -- Y-mAbs Therapeutics, Inc. (the “Company” or “Y-mAbs”) (Nasdaq: YMAB) a development-stage clinical 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 2020.

“We are very pleased with our third quarter 2020 financial results, especially seen in conjunction with the upcoming PDUFA date for naxitamab later this month, and the planned resubmission of the omburtamab BLA. We believe that we are well positioned to transform Y-mAbs to a commercial-stage company,” stated Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, continued, “We are making good progress on the omburtamab BLA resubmission, and concurrently we’ve continued to advance many of the earlier stage programs in our pipeline. Nivatrotamab, our leading bispecific antibody, recently received ODD and RPDD from the FDA and our two INDs for ^{177}Lu-omburtamab-DTPA in medulloblastoma and B7-H3 positive CNS/leptomeningeal metastasis in adults were recently cleared by the FDA.”

Third Quarter 2020 and Recent Corporate Developments

- Subsequent to the end of the third quarter, on October 26, 2020 Y-mAbs announced that the FDA has cleared the Company’s IND for ^{177}Lu-omburtamab-DTPA for the treatment of B7-H3 positive CNS and Leptomeningeal Metastasis from tumors in adult patients
- Also subsequent to the end of the third quarter, on October 16, 2020, Y-mAbs announced updates on naxitamab and omburtamab data, which were presented at the International Society of Pediatric Oncology conference
- Also subsequent to the end of the third quarter, on October 14, 2020 Y-mAbs announced that the FDA has cleared the Company’s Investigational New Drug application for ^{177}Lu-omburtamab-DTPA for the treatment of medulloblastoma, which is the most common type of primary brain cancer in children
- Also subsequent to the end of the third quarter, on October 7, 2020, Y-mAbs announced that the FDA has granted Orphan Drug Designation and Rare Pediatric Disease Designation for its leading bispecific antibody product candidate nivatrotamab for the treatment of neuroblastoma
- After the close of the third quarter, on October 5, 2020, Y-mAbs announced that it had received a Refusal to File letter from the FDA for the omburtamab BLA for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. Subsequently, Y-mAbs requested and received what it believes to have been a positive Type A meeting with the FDA, and plans to work in close dialog with the Agency to amend the BLA with the goal of resubmitting by the end of 2020 or in early 2021. The BLA was originally submitted in August 2020
- On July 14, 2020, Y-mAbs announced an update on the SADA technology and presented B7-H3 as a new preclinical SADA construct with potential use in prostate cancer

Financial Results

Y-mAbs reported a net loss of $32.8 million, or ($0.82) per basic and diluted share, for the three months ended September 30, 2020, compared to a net loss of $23.9 million, or ($0.70) per basic and diluted share, reported for the three months ended September 30, 2019.

For the nine months ended September 30, 2020, Y-mAbs reported a net loss of $99.4 million, or ($2.49) per basic and diluted share, compared to the net loss of $57.9 million, or ($1.69) per basic and diluted share, reported for the nine months ended September 30, 2019.

Operating Expenses

Research and Development
Research and development expenses were $21.0 million for the three months ended September 30, 2020, compared to $19.7 million for the three months ended September 30, 2019, an increase of $1.3 million. The increase in research and development expenses primarily reflects the following:

- $2.4 million increase in personnel costs;
- $0.5 million increase in clinical trial expenses;
- $0.4 million increase in professional and consulting fees; and
- $2.0 million offsetting decrease in outsourced manufacturing cost

Research and development expenses were $69.7 million for the nine months ended September 30, 2020, compared to $46.7 million for the nine months ended September 30, 2019, an increase of $23.0 million. The increase in research and development expenses primarily reflects the following:

- $13.3 million increase in milestones and license fees related to the SADA upfront cash payment and stock issuances and accrued milestones;
- $6.3 million increase in personnel costs; and
- $1.9 million increase in outsourced research and supplies to support the expansion of our product development activities

General and Administration
General and administrative expenses were $11.6 million for the three months ended September 30, 2020, compared to $4.7 million for the three months ended September 30, 2019, an increase of $6.9 million. Such increase in general and administrative expenses primarily reflects the following:

- $3.2 million increase in commercial infrastructure costs;
- $2.2 million increase in personnel costs; and
- $1.6 million increase in business insurance and professional fees

General and administrative expenses were $30.2 million for the nine months ended September 30, 2020, compared to $12.6 million for the nine months ended September 30, 2019, an increase of $17.6 million. Such increase in general and administrative expenses primarily reflects the following:

- $8.7 million increase in commercial infrastructure costs;
- $5.8 million increase in personnel costs; and
- $3.1 million increase in business insurance and professional fees

Cash and Cash Equivalents

The Company had approximately $131.3 million in cash and cash equivalents as of September 30, 2020

Webcast and Conference Call

The Company will host a conference call on Friday, November 6, 2020 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 access code 13712633. A webcast will be available at: http://public.viavid.com/index.php?id=142256

About Y-mAbs

Y-mAbs is a late-stage clinical 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 two pivotal-stage product candidates naxitamab and omburtamab—which target tumors that express GD2 and B7-H3, respectively.

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 and commercialization plans; current and future clinical and pre-clinical studies and our research and development programs; 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," "appear," "believe," "contemplate," "continue," "could," "estimate," "expect," "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 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 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.

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

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 131,267	$ 207,136
Other current assets	1,942	4,819
Total current assets	133,209	211,955
Property and equipment, net	1,888	2,052
Operating lease right-of-use assets	5,123	1,989
Other assets	2,975	370
TOTAL ASSETS	$ 143,195	$ 216,366
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 10,320	$ 8,520
Accrued liabilities	7,570	4,550
Operating lease liabilities, current portion	1,887	516
Total current liabilities	19,777	13,586
Accrued milestone and royalty payments	2,466	1,921
Operating lease liabilities, long-term portion	2,517	1,714
Other liabilities	1,923	242
TOTAL LIABILITIES	26,683	17,463
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized at September 30, 2020 and December 31, 2019; none issued at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at September 30, 2020 and December 31, 2019; 40,472,435 and 39,728,416 shares issued at September 30, 2020 and December 31, 2019, respectively	4	4
Additional paid in capital	381,803	364,712
Accumulated other comprehensive income / (loss)	(28)	50
Accumulated deficit	(265,267)	(165,863)
TOTAL STOCKHOLDERS' EQUITY	116,512	198,903
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 143,195	$ 216,366

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	
	2020	2019	2020	2019
OPERATING EXPENSES				
Research and development	$ 21,005	$ 19,660	$ 69,686	$ 46,665
General and administrative	11,636	4,699	30,155	12,581
Total operating expenses	32,641	24,359	99,841	59,246
Loss from operations	(32,641)	(24,359)	(99,841)	(59,246)
OTHER INCOME				
Interest and other income, net	(191)	437	437	1,354
NET LOSS	$ (32,832)	$ (23,922)	$ (99,404)	$ (57,892)
Other comprehensive income / (loss)				
Foreign currency translation	(12)	134	(78)	124
COMPREHENSIVE LOSS	$ (32,844)	$ (23,788)	$ (99,482)	$ (57,768)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.82)	$ (0.70)	$ (2.49)	$ (1.69)
Weighted average common shares outstanding, basic and diluted	40,187,173	34,371,927	39,971,766	34,253,739

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