Y-mAbs Announces 2020 Financial Results and Recent Corporate Developments

February 25, 2021

NEW YORK, Feb. 25, 2021 (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 2020.

“We are pleased with our 2020 financial results, especially seen in conjunction with the approval of DANYELZA, and the sale of our Priority Review Voucher for $105 million. For omburtamab, we are working closely with the FDA to address the Agency’s request for additional data, and we believe we have made progress and continue to work very hard on resubmitting the BLA. We also entered into a licensing agreement for Greater China for DANYELZA and omburtamab including milestones of up to $120 million and distribution agreements for DANYELZA and omburtamab for Eastern Europe, Russia and Israel, and thereby secured expanded access for children around the world to this important immunotherapy,” stated Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, continued, “We successfully completed a follow-on offering with gross proceeds of approximately $115.0 million earlier this week, and in parallel, we are making good progress in the clinic and have continued to advance the earlier stage programs in our pipeline. Nivatrotamab, our leading bispecific antibody, recently received ODD and RPDD from the FDA and our INDs for nivatrotamab in Small Cell Lung Cancer (Phase 2) and ^{177}Lu-omburtamab-DTPA for medulloblastoma (Phase 1/2) and B7-H3 positive CNS/leptomeningeal metastasis in adults (Phase 1/2) were recently cleared by the FDA.”

Fourth Quarter 2020 and Recent Corporate Developments

- Subsequent to the end of the fourth quarter, on February 17, 2021, Y-mAbs announced the pricing of a follow-on shelf public offering, resulting in gross proceeds to the Company of approximately $115.0 million.
- On December 28, 2020 Y-mAbs announced that it entered into a definitive agreement to sell its DANYELZA Priority Review Voucher to United Therapeutics Corporation for $105 million. Under the terms of the license agreement with Memorial Sloan Kettering, Y-mAbs will retain 60% of the net proceeds received from the sale. The transaction closed in January 2021.
- On December 18, 2020, Y-mAbs announced that it had entered into a license agreement with SciClone Pharmaceuticals International Ltd to be the exclusive development and commercialization partner of DANYELZA and omburtamab for the treatment of pediatric patients in China, including upfront, approval and sales milestones of up to $120 million.
- On December 18, 2020, Y-mAbs announced that it had entered into a distribution agreement with Swixx BioPharma AG to be the exclusive distributor of DANYELZA and omburtamab for the treatment of pediatric patients in Eastern Europe and Russia.
- On December 9, 2020, Y-mAbs announced an update on DANYELZA data from the Company’s Study 201, which was presented at the ESMO Immunocology-Oncology Virtual Congress 2020.
- On December 4, 2020, Y-mAbs announced that it had entered into a license and distribution agreement with Takeda Israel for the registration and commercialization of DANYELZA and omburtamab for the treatment of pediatric patients in the State of Israel.
- On November 25, 2020, Y-mAbs announced that the FDA had approved DANYELZA for the treatment relapsed or primary refractory high-risk neuroblastoma.
- On November 19, 2020, Y-mAbs announced that a clinical update of omburtamab for the treatment of diffuse intrinsic pontine glioma was presented at the SNO Virtual Annual Meeting.
- On October 26, 2020, Y-mAbs announced that the FDA had 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.
- On October 14, 2020, Y-mAbs announced that the FDA had 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.

- 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.

- 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 has been in close dialog with the Agency to amend the BLA with the goal of resubmitting by the end of the second quarter or in the third quarter 2021.

Financial Results

Y-mAbs reported a net loss of $119.3 million, or ($2.97) per basic and diluted share, for the year ended December 31, 2020, compared to a net loss of $81.0 million, or ($2.30) per basic and diluted share, reported for the year ended December 31, 2019.

Revenues and Related Royalties Expense

Y-mAbs reported net revenues of $20.8 million for the year ended December 31, 2020 related to its licensing agreements in China and Israel. No revenues were reported for the year ended December 31, 2019.

Additionally, there were $2.2 million in royalties expense associated with the license revenue reported for the year ended December 31, 2020. No royalties expense was reported for the year ended December 31, 2019.

Operating Expenses

Research and Development
Research and development expenses were $93.7 million for the twelve months ended December 31, 2020, compared to $63.5 million for the twelve months ended December 31, 2019, an increase of $30.2 million. The increase in research and development expenses primarily reflects the following:

- $13.4 million increase in personnel costs;
- $13.2 million increase in milestones and license acquisition cost;
- $1.1 million increase in professional and consulting fees; and
- $1.6 million increase in outsourced services and supplies costs.

General and Administration
General and administrative expenses were $44.8 million for the twelve months ended December 31, 2020, compared to $19.5 million for the twelve months ended December 31, 2019, an increase of $25.3 million. The increase in general and administrative expenses primarily reflects the following:

- $12.7 million increase in commercial infrastructure costs;
- $8.9 million increase in personnel costs;
- $2.1 million increase in business insurance; and
- $2.1 million in professional fees.

Cash and Cash Equivalents

The Company had approximately $114.6 million in cash and cash equivalents as of December 31, 2020.

Webcast and Conference Call

The Company will host a conference call on Friday, February 26, 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 access code 13716724. A webcast will be available at: http://public.viavid.com/index.php?id=143629

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 novel 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.

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

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 114,634	$ 207,136
Other current assets	7,729	4,819
Total current assets	122,363	211,955
Property and equipment, net	1,825	2,052
Operating lease right-of-use assets	4,569	1,989
Other assets	3,290	370
TOTAL ASSETS	$ 132,047	$ 216,366
LIABILITIES AND STOCKHOLDERS’ EQUITY		
LIABILITIES		
Accounts payable	$ 9,372	$ 8,520
Accrued liabilities	8,197	4,550
Operating lease liabilities, current portion	1,966	516
Total current liabilities	19,535	13,586
Accrued milestone and royalty payments	2,695	1,921
Operating lease liabilities, long-term portion	2,013	1,714
Other liabilities	1,968	242
TOTAL LIABILITIES	26,211	17,463
STOCKHOLDERS’ EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized at December 31, 2020 and December 31, 2019; none issued at December 31, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2020 and December 31, 2019; 40,688,447 and 39,728,416 shares issued at December 31, 2020 and December 31, 2019, respectively	4	4
Additional paid in capital	391,558	364,712
Accumulated other comprehensive income / (loss)	(526)	50
Accumulated deficit	(285,200)	(165,863)
TOTAL STOCKHOLDERS’ EQUITY	105,836	198,903
TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY	$ 132,047	$ 216,366

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Net Loss and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	For the year ended December 31,	
	2020	2019
REVENUE		
License revenue	$ 20,750	$ —
OPERATING EXPENSES		
Research and development	93,697	63,492
General and administrative	44,785	19,512
Royalties	2,203	—
Total operating expenses	140,685	83,004
Loss from operations	(119,935)	(83,004)
OTHER INCOME		
Interest and other income, net	598	1,976
NET LOSS	$ (119,337)	$ (81,028)
Other comprehensive income / (loss)		
Foreign currency translation	(576)	43
COMPREHENSIVE LOSS	$ (119,913)	$ (80,985)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.97)	$ (2.30)
Weighted average common shares outstanding, basic and diluted	40,118,537	35,183,488

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