Y-mAbs Announces 2019 Financial Results and Recent Corporate Developments

March 12, 2020

NEW YORK, March 12, 2020 (GLOBE NEWSWIRE) -- Y-mAbs Therapeutics, Inc. (the “Company” or “Y-mAbs”) (Nasdaq: YMAB) a late-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 2019.

“We are very pleased with our 2019 results, highlighted by notable progress in the preparation of our BLAs for naxitamab and omburtamab, as well as commercial ramp-up for the potential launch of both compounds. We start 2020 with $207 million in cash, and are excited to enter what we believe will be a truly transformational year for Y-mAbs,” stated Thomas Gad, Founder, Chairman, President and Head of Business Development and Strategy.

Dr. Claus Moller, Chief Executive Officer, continued, “During 2019, we have worked hard to make sure that naxitamab and omburtamab advance towards BLA submissions. We submitted the first portion of the rolling BLA for naxitamab in November 2019, and expect to complete the submission later this month. For omburtamab, we expect the rolling BLA submission to be completed in May.”

Fourth Quarter 2019 and Recent Corporate Developments

- After the close of the fourth quarter, on February 26, 2020, Y-mAbs announced a positive Pre-BLA meeting with FDA for omburtamab.
- On December 12, 2019, Y-mAbs announced that its GD2-GD3 Vaccine has been granted a Rare Pediatric Disease Designation by the FDA for the treatment of neuroblastoma.
- On December 11, 2019, Y-mAbs announced positive frontline data for naxitamab at the Company’s R&D event, which took place in New York City. Key opinion leaders discussed the current treatment landscape and unmet medical needs for high-risk neuroblastoma and other solid tumors.
- On December 5, 2019, the Company announced that the European Medicines Agency agreed to the Company’s proposed Pediatric Investigation Plan for omburtamab.
- On November 29, 2019, Y-mAbs announced that it had submitted to the FDA the first portion of its Biologics License Application for naxitamab for the treatment of patients with relapsed/refractory high-risk neuroblastoma under the FDA’s Rolling Review process.
- On November 15, 2019, Y-mAbs announced a clinical update on omburtamab for Desmoplastic Small Round Cell Tumor. The data was presented at the 2019 CTOS Annual Meeting in Tokyo, Japan.
- On November 1, 2019, Y-mAbs announced the pricing of a follow-on shelf public offering, resulting in gross proceeds to the Company of approximately $143.8 million.
- On October 28, 2019, Y-mAbs announced an update on omburtamab data, which was presented at the International Society of Pediatric Oncology conference.
- On October 25, 2019, Y-mAbs announced a naxitamab update, which was presented at the International Society of Pediatric Oncology conference.

Financial Results

Y-mAbs reported a net loss for the year ended December 31, 2019 of $81.0 million, or $2.30 per basic and diluted share, compared to a net loss of $43.3 million, or $1.50 per basic and diluted share, reported for the year ended December 31, 2018.

Operating Expenses

Research and Development
Research and development expenses were $63.5 million for the twelve months ended December 31, 2019, compared to $34.3 million for the twelve months ended December 31, 2018, an increase of $29.2 million. The increase in research and development expenses primarily reflects the following:

- $17.1 million increase in outsourced manufacturing for our two lead product candidates, naxitamab and omburtamab;
- $5.4 million increase in outsourced research and supplies to support expanding development activities;

- $3.3 million increase in personnel costs; and
- $2.5 million increase in clinical trials expenses.

General and Administration
General and administrative expenses were $19.5 million for the twelve months ended December 31, 2019, compared to $9.0 million for the twelve months ended December 31, 2018, an increase of $10.5 million. Such increase in general and administrative expenses primarily reflects the following:

- $5.1 million increase in personnel costs; and
- $2.8 million increase in commercial infrastructure costs;

Cash and Cash Equivalents
The Company had approximately $207.1 million in cash and cash equivalents as of December 31, 2019, compared to $147.8 million as of December 31, 2018. The increase of $59.3 million was primarily attributable to the $134.7 million net proceeds from the secondary public offering, completed in November 2019, which was partially offset by the net loss of $81.0 million for the fiscal year 2019 due to the increased costs of operation as the Company prepares for its submission of rolling BLAs for naxitamab and omburtamab, build-up of the Company's commercial infrastructure, and increased personnel costs.

Webcast and Conference Call

The Company will host a conference call today at 4:30 pm eastern time. To participate in the call, please dial 877-407-0792 (domestic) or 201-689-8263 (international) and reference the access code 13699294. A webcast will be available at: http://public.viavid.com/index.php?id=138170

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," "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)

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 207,136	$ 147,840
Restricted cash	—	31
Other current assets	4,819	3,661
Total current assets	211,955	151,532
Property and equipment, net	2,052	205

Operating lease right-of-use assets	1,989	—
Other assets	370	187
TOTAL ASSETS	$ 216,366	$ 151,924
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 8,520	$ 5,872
Accrued liabilities	4,550	3,251
Operating lease liabilities, current portion	516	—
Total current liabilities	13,586	9,123
Accrued milestone and royalty payments	1,921	2,050
Operating lease liabilities, long-term portion	1,714	—
Other liabilities	242	224
TOTAL LIABILITIES	17,463	11,397
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized at December 31, 2019 and December 31, 2018; none issued at December 31, 2019 and December 31, 2018	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2019 and December 31, 2018; 39,728,416 and 34,193,666 shares issued at December 31, 2019 and December 31, 2018, respectively	4	3
Additional paid in capital	364,712	225,352
Accumulated other comprehensive income	50	7
Accumulated deficit	(165,863)	(84,835)
TOTAL STOCKHOLDERS' EQUITY	198,903	140,527
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 216,366	$ 151,924

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,	
	2019	**2018**
OPERATING EXPENSES		
Research and development	$ 63,492	$ 34,269
General and administrative	19,512	8,961
Total operating expenses	83,004	43,230
Loss from operations	(83,004)	(43,230)
OTHER INCOME/(EXPENSES)		
Interest and other income/(expenses)	1,976	(44)
NET LOSS	$ (81,028)	$ (43,274)
Other comprehensive income		

Foreign currency translation	43	175
COMPREHENSIVE LOSS	$ (80,985)	$ (43,099)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.30)	$ (1.50)
Weighted average common shares outstanding, basic and diluted	35,183,488	28,772,384

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