

Merus

Merus Announces Fourth Quarter and Full Year 2016 Financial Results and Corporate Developments

April 28, 2017

UTRECHT, The Netherlands, April 28, 2017 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, today announced financial results for the fourth quarter and full year ended December 31, 2016 and provided a corporate and clinical update.

"Last year was a transformative period for Merus marked by the signing of a global collaboration with Incyte, a deal that brings a world class collaborator to Merus and significant strength to our balance sheet, and that we believe will significantly advance our proprietary candidates into and through the clinic," said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. "We anticipate that 2017 will be distinguished by several important data points for our wholly owned clinical-stage pipeline, beginning with the presentation of data from lead compound MCLA-128, an ADCC-enhanced Biclomics® that binds to HER2 and HER3, at the upcoming ASCO annual meeting. We expect to follow this by the clinical advancement of MCLA-117, with initial phase 1 results in patients with AML expected in the second half of the year, then we anticipate submitting a Clinical Trial Application (CTA) for a planned Phase 1/2 clinical trial of MCLA-158 in patients with colorectal cancer by year end."

Recent Developments

- In March 2017, Merus announced that it was named BioCapital Europe Company of the Year for 2017. The Company of the Year Award is given to the organization that has undergone the most substantial transformation in the previous year and has experienced a breakthrough with respect to its technology, clinical development, partnering, IPO and/or M&A activities.
- In January 2017, Merus and the Institute for Research in Biomedicine (IRB) Barcelona, a research center devoted to understanding fundamental questions about human health and disease, entered into a research collaboration to jointly develop novel agents that target the tumor microenvironment. The research collaboration will combine Merus' Biclomics® technology platform for the discovery and development of therapeutic bispecific antibodies and IRB's unique cell and animal models to evaluate therapeutic targeting of stromal cells that support tumor growth and metastasis.
- In December 2016, Merus and Incyte (NASDAQ:INCY) announced a global, strategic collaboration agreement focused on the research, discovery and development of bispecific antibodies utilizing Merus' proprietary Biclomics® technology platform. The agreement grants Incyte certain exclusive rights for up to eleven bispecific antibody research programs, including two of Merus' current preclinical immuno-oncology discovery programs. Under the terms of the collaboration, which closed in January 2017, Incyte paid Merus an upfront payment of \$120 million and purchased 3.2 million common shares of Merus at \$25 per share, for a total equity investment of \$80 million. For one current preclinical program, Merus will retain all rights to develop and commercialize an approved product in the United States. Merus also has the option to co-fund development of product candidates arising from two other programs. For the other eight programs, Merus is eligible to receive potential development, regulatory and sales milestone payments of up to \$350 million per program, for an aggregate milestone opportunity of approximately \$2.8 billion if all milestones are achieved across all eight programs in all territories, in addition to tiered royalties ranging from 6 to 10 percent on global sales.
- In November 2016, Merus received favorable rulings for its European patent EP 2147594 B1 by the Opposition Division of the European Patent Office and by the Trial Board of the Japanese Patent Office for its Japanese counterpart JP 5749161. Both patents cover Merus' genetically-modified mice and their use to produce common light chain human monoclonal antibodies.
- In November 2016, Merus was awarded a grant of €0.5 million from EUREKA Eurostars with Aquila BioMedical Ltd. to jointly develop immunological assays supporting the selection of potent bispecific antibodies that positively modulate tumor immunity with superior potency and lower toxicity compared to existing drugs.

Anticipated 2017 Milestones

- Clinical data on MCLA-128 will be presented at the 2017 ASCO Annual Meeting taking place on June 2-6, 2017 in Chicago. The abstract is entitled, "*First in human phase 1/2 study of MCLA-128, a full length IgG1 bispecific antibody targeting HER2 and HER3; final phase 1 data and preliminary activity in HER2+ metastatic breast cancer (mBC).*"
- An Investigational New Drug application to the U.S. Food and Drug Administration of MCLA-117 for a Phase 1 trial is planned during the second half of 2017.

- During the second half of 2017, Merus expects to report topline data from its Part 2 of Phase 1/2 monotherapy trial of MCLA-128 in patients with solid tumors in multiple indications.
- During the second half of 2017, Merus expects to report interim results from its Phase 1 clinical trial evaluating MCLA-117 in patients with AML.
- By the end of 2017, Merus expects to file a CTA for a planned Phase 1/2 clinical trial of MCLA-158 in patients with colorectal cancer.

Fourth Quarter 2016 Financial Results

(Euros in millions, except as indicated)

Total revenue for the three months ended December 31, 2016 was €1.1 million compared to €0.4 million for the same period in 2015. Revenue is comprised primarily of research funding, milestone payments and income from grants on research projects.

Research and development expenses for the three months ended December 31, 2016 were €7.5 million compared to €4.8 million for the same period in 2015.

For the three months ended December 31, 2016, Merus reported a net loss of €30.7 million, or €(1.91) per share (basic and diluted), compared to a net loss of €6.6 million, or €(0.77) per share (basic and diluted), for the same period in 2015. The net loss for the three months ended December 31, 2016 includes a non-cash charge of €19.2 million for the accounting impact of a financial derivative related to the obligation to deliver shares to Incyte in 2017.

Full Year 2016 Financial Results

(Euros in millions, except as indicated)

Total revenue for the full year 2016 was €2.7 million compared to €2.0 million for the full year 2015. Revenue is comprised primarily of research funding, milestone payments and income from grants on research projects.

Research and development expenses for the full year 2016 were €19.0 million compared to €16.4 million for the full year 2015.

For the full year 2016, Merus reported a loss of €47.2 million, or €(3.57) per share (basic and diluted), compared to a net loss of €23.2 million, or €(3.95) per share (basic and diluted) for the full year in 2015. The loss for the full year 2016 includes a non-cash charge of €19.2 million for the accounting impact of a financial derivative related to the obligation to deliver shares to Incyte in 2017.

Merus ended the 2016 full year with cash and cash equivalents of €56.9 million. On January 23, 2017, the Company closed its global strategic research collaboration with Incyte Corporation, which included an upfront payment of \$120 million and the purchase by Incyte of 3.2 million of Merus' common shares for \$80 million.

About MCLA-128

MCLA-128 is designed to block HER3/hereregulin dependent tumor growth and survival as well as enhance immune-mediated killing of tumors. MCLA-128 employs a 'dock and block' mechanism in which the mode of HER2 receptor binding orientates the HER3 binding arm to effectively block oncogenic signaling through the HER2:HER3 heterodimer even under high heregulin concentrations. In addition, MCLA-128 is engineered for enhanced ADCC in order to recruit and activate immune effector cells to directly kill the tumor.

About MCLA-117

MCLA-117 is a Biclomics® that is designed to bind to CD3 expressed by T-cells and CLEC12A expressed by acute myeloid leukemia (AML) tumor cells and stem cells. In preclinical studies, MCLA-117 has been shown to recruit and activate the immune system's own T-cells to kill AML tumor cells and stem cells.

About MCLA-158

MCLA-158 is an ADCC-enhanced Biclomics® being developed for the treatment of colorectal cancer and other solid tumors. MCLA-158 is designed to bind to Lgr5 and EGFR expressing cancer stem cells, block growth and survival pathways and enhance the recruitment of immune effector cells to directly kill cancer stem cells that persist in solid tumors causing relapse and metastasis.

About Merus N.V.

Merus is a clinical-stage immuno-oncology company developing innovative full length human bispecific antibody therapeutics, referred to as Biclomics®. Biclomics® are based on the full-length IgG format, are manufactured using industry standard processes and have been observed in preclinical studies to have several of the same features of conventional monoclonal antibodies, such as long half-life and low immunogenicity. Merus' lead bispecific antibody candidate, MCLA-128, is being evaluated in a Phase 1/2 clinical trial in Europe as a potential treatment for HER2-expressing solid tumors. Merus' second bispecific antibody candidate, MCLA-117, is being developed in a Phase 1 clinical trial in patients with acute myeloid leukemia. The Company also has a pipeline of proprietary bispecific antibody candidates in preclinical development, including MCLA-158, which is designed to bind to cancer stem cells and is being developed as a potential treatment for colorectal cancer and other solid tumors, and Biclomics® designed to bind to various combinations of immunomodulatory molecules, including PD-1 and PD-L1.

Forward Looking Statement

Except for the historical information set forth herein, this press release contains predictions, estimates and other forward-looking statements, including without limitation statements regarding: the impact of our collaboration with Incyte on the clinical development of our bispecific antibody candidates, anticipated clinical data points for 2017, the timing of presentations, clinical data announcements, and regulatory filings, the potential payments under our collaboration agreement with Incyte, each statement under "Anticipated Milestones," and the treatment potential of our bispecific antibody candidates.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our need for additional funding, which may not be available and which may require us to restrict our operations or require us to relinquish rights to our technologies or bispecific antibody candidates; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; the unpredictable nature of our early stage development efforts for marketable drugs; potential delays in enrollment of patients, which could affect the receipt of necessary regulatory approvals; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; we may not identify suitable bispecific antibody candidates under our collaboration with Incyte or Incyte may fail to perform adequately under our collaboration; and our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, on April 28, 2017, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change, except as required under applicable law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this

press release.

Consolidated Statement of Financial Position

	December 31, 2016	December 31, 2015
	(euros in thousands, unaudited)	
Non-current assets		
Property, plant and equipment	648	325
Intangible assets	374	435
Restricted cash	167	218
	1,189	978
Current assets		
Financial asset	11,847	-
Trade and other receivables	2,357	1,665
Cash and cash equivalents	56,917	32,851
	71,120	34,516
Total assets	72,310	35,494
Shareholders' equity		
Issued and paid-in capital	1,448	775
Share premium account	139,878	90,909
Accumulated loss	(107,295)	(63,382)
Total equity	34,031	28,302
Non-current liabilities		
Borrowings	319	486
Deferred revenue	30,206	390
Current liabilities		
Borrowings	167	167
Trade payables	2,298	2,419
Taxes and social security liabilities	29	142
Deferred revenue	1,610	223
Other liabilities and accruals	3,650	3,365
	7,754	6,316
Total liabilities	38,280	7,192
Total equity and liabilities	72,310	35,494

Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three months ended		Year ended	
	December 31, 2016	December 31, 2015	December 31, 2016	December 31, 2015
	(euros in thousands, except per share data, unaudited)			
Revenue	1,115	373	2,719	1,977
Research and development costs	(7,485)	(4,844)	(18,991)	(16,350)
Management and administration costs	(3,858)	(368)	(4,258)	(768)
Other expenses	(1,079)	(1,835)	(7,142)	(7,898)
Total operating expenses	(12,422)	(7,047)	(30,391)	(25,016)
Operating result	(11,307)	(6,674)	(27,672)	(23,039)
Finance income	74	36	88	50
Finance costs	(19,457)	(8)	(19,644)	(195)
Total finance income (expenses)	(19,383)	28	(19,556)	(145)
Result before tax	(30,691)	(6,646)	(47,228)	(23,184)
Income tax expense	—	—	—	—

Result after taxation	(30,691)	(6,646)	(47,228)	(23,184)
Exchange differences from translation of foreign operations	8		—		8		—	
Other comprehensive income	8		—		8		—	
Total comprehensive loss	(30,683)	(6,646)	(47,220)	(23,184)
Basic (and diluted) loss per share	(1.91)	(0.77)	(3.57)	(3.95)

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