Merus Announces Financial Results for the Second Quarter 2018 & Mid-year Operating Results

August 10, 2018

MCLA-128 Phase 1/2 clinical data from the gastric cancer cohort will be presented at the European Society for Medical Oncology Congress in October 2018

UTRECHT, The Netherlands, Aug. 10, 2018 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS) ("Merus", "we", "our" or the "Company"), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced financial results for the second quarter ended June 30, 2018 and provided a corporate and clinical update.

"Merus continues to make progress on the advancement of our pipeline of bispecific antibody candidates derived from our Biclonics® technology platform," said Ton Logtenberg, Ph.D., President and Chief Executive Officer of Merus. "Our clinical trials for MCLA-128, MCLA-117 and MCLA-158 are ongoing. We plan to report data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at the European Society for Medical Oncology Congress (ESMO) in October 2018. In addition, we plan to provide an update in the fourth quarter of 2018 on the ovarian, endometrial and non-small cell lung cancer cohorts of the single-agent trial of MCLA-128, as well as the MCLA-117 trial in acute myeloid leukemia (AML), which will help shape the future clinical plans for both programs."

Anticipated 2018 Milestones

MCLA-128, an antibody-dependent cell-mediated cytotoxicity (ADCC)-enhanced Biclonics® that binds to HER2 and HER3-expressing solid tumor cells that employs a unique mechanism, DOCK & BLOCK®, for the selective and potent inhibition of the heregulin/HER3 tumor-signaling pathway
The Phase 2, open-label, multi-center international clinical trial evaluating MCLA-128 in combination treatments in two metastatic breast cancer (MBC) populations is ongoing. The trial is enrolling HER2-positive MBC patients and hormone receptor positive/HER2-low MBC patients at sites in the U.S. and Europe.

The Phase 1/2 study evaluating single-agent activity for MCLA-128 in various solid tumor indications is ongoing and Merus will present data on the gastric cohort at ESMO in October 2018.

MCLA-117, a Biclonics® that binds to CD3 and CLEC12A
Dose escalation in the Phase 1 clinical trial of MCLA-117 is ongoing in Europe and the U.S. A clinical update is planned for fourth quarter of 2018.

MCLA-158, an ADCC-enhanced Biclonics® designed to bind to cancer initiating cells expressing Lgr5 and EGFR
Recruitment for the Phase 1 clinical trial of MCLA-158 in patients with solid tumors is ongoing. The trial is being conducted in Europe and the U.S.

MCLA-145, a Biclonics® designed to bind to PD-L1 and a second undisclosed immunomodulatory target
MCLA-145, the first drug candidate co-developed under the Merus and Incyte global research collaboration, continues to progress in IND-enabling studies. Merus has full rights to develop and commercialize MCLA-145 in the U.S. and Incyte is responsible for its development and commercialization outside the U.S.

Second Quarter 2018 Financial Results

Merus ended the second quarter of 2018 with cash, cash equivalents and investments of €224.1 million compared to €190.8 million at December 31, 2017, the increase primarily being the result of the closing of a $55.8 million (€44.8 million) private placement of 3.1 million common shares completed in February 2018.

Total revenue for the three months ended June 30, 2018 was €6.5 million compared to €6.2 million for the same period in 2017. Revenue for the three months ended June 30, 2017 has been restated for the adoption of IFRS 15, a new accounting standard related to revenue recognition. Under IFRS 15, Merus reduced the period that it amortizes revenue for the upfront license payment received from Incyte from 21 years to 9 years which resulted in €2.2 million of additional revenue for the three months ended June 30, 2017. Revenue is comprised primarily of the amortization of upfront license payments from Merus' collaboration agreements and collaboration income related to cost reimbursements and research milestones for performance of research and development services under the respective agreements. The increase in revenue for the period is attributable to €0.3 million of amortization of upfront license payments, €0.7 million of collaboration income for expense reimbursements, offset, by lower income from grants on research projects of €(0.7) million.

Research and development costs for the three months ended June 30, 2018 were €12.5 million compared to €8.4 million for the same period in 2017. The increase in research and development costs reflects the increase in manufacturing costs, higher research and development headcount and related costs, as well as additional spending in support of the Company's clinical development programs.

Management and administration costs for the three months ended June 30, 2018 were €2.6 million compared to €3.5 million for the same period in 2017. The decrease relates primarily to lower share-based compensation expenses.

Other expenses for the three months ended June 30, 2018 were €3.3 million compared to €2.3 million for the same period in 2017. The increase in other expenses was the result of higher consulting, accounting and professional fees.

For the three months ended June 30, 2018, Merus reported a net loss of €4.6 million, or €(0.20) per share (basic and diluted), compared to a net loss of €19.6 million, or €(1.01) per share (basic and diluted), for the same period in 2017. Net loss for the three months ended June 30, 2017 has been restated for the adoption of IFRS 15 which resulted in a reduction of net loss of €2.2 million or €0.11 per share (basic and diluted). The net loss for the three months ended June 30, 2018 includes approximately €6.9 million of unrealized foreign currency gains as compared to €(12.0) million of unrealized foreign currency losses in the same period 2017.

Financial Outlook

Based on the Company's current operating plan, Merus expects that its existing cash, cash equivalents and investments will be sufficient to fund its operations through the end of 2020.

About Merus N.V.

Merus is a clinical-stage immuno-oncology company developing innovative full-length human bispecific antibody therapeutics, referred to as Biclonics®. Biclonics®, which are based on the full-length IgG format, are manufactured using industry standard processes and have been observed in preclinical and clinical studies to have several of the same features of conventional human monoclonal antibodies, such as long half-life and low immunogenicity. Merus' most advanced bispecific antibody candidate, MCLA-128, is being evaluated in a Phase 2 combination trial in two metastatic breast cancer populations. MCLA-128 is also being evaluated in a Phase 1/2 clinical trial in gastric, ovarian, endometrial and non-small cell lung cancers. Additional pipeline programs include MCLA-117, which is currently being studied in a Phase 1 clinical trial in patients with acute myeloid leukemia, and MCLA-158, a Biclonics® being studied in a Phase 1 clinical trial in patients with solid tumors with an initial focus on metastatic colorectal cancer. Through its collaboration with Incyte Corporation, Merus is also developing a preclinical bispecific antibody designed to bind to PD-L1 and a non-disclosed second immunomodulatory target. For additional information, please visit Merus' website, www.merus.nl.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation the formulation of clinical development plans and clinical development of our bispecific antibody candidates, anticipated clinical data points for 2018, the timing of expected patient recruitment and dosing, presentations, clinical updates and announcements, and the advancement of the Phase 2 combination trial for MCLA-128 each statement under "Anticipated Milestones," the sufficiency of our cash, cash equivalents and investments, and the design and treatment potential of our bispecific antibody candidates including MCLA-128, MCLA-117, MCLA-158 and MCLA-145.

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 Biclonics® and bispecific antibody candidates; potential delays in regulatory approval, which would impact our 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 Biclonics® or bispecific antibody candidates under our collaboration with Incyte or Incyte may fail to perform adequately under our collaboration; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; protection of our proprietary technology; our patents may be found invalid, unenforceable, circumvented by competitors and our patent applications may be found not to comply with the rules and regulations of patentability; we may fail to prevail in existing and potential lawsuits for infringement of third-party intellectual property; and our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks.

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 30, 2018, 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.

Unaudited Condensed Consolidated Statement of Financial Position

	June 30, 2018	December 31, 2017 Restated*
	(euros in thousands)	
Non-current assets		
Property, plant and equipment	1,876	1,168
Intangible assets	381	312
Non-current investments	16,650	7,060
Other assets	167	129
	19,074	8,669
Current assets		
Trade and other receivables	5,477	4,413
Current investments	37,077	34,043
Cash and cash equivalents	170,327	149,678
	212,881	188,134
Total assets	231,955	196,803
Shareholders' equity		
Issued and paid-in capital	2,037	1,749
Share premium account	258,061	213,618
Accumulated loss	(167,226)	(158,775)

Total equity	92,872	56,592
Non-current liabilities		
Deferred revenue, net of current portion	105,718	112,551
Current liabilities		
Trade payables	5,433	2,855
Taxes and social security liabilities	100	243
Deferred revenue	16,972	15,935
Other liabilities and accruals	10,860	8,627
	33,365	27,660
Total liabilities	139,083	140,211
Total equity and liabilities	231,955	196,803

*Accumulated loss and deferred revenue (current and non-current) have been restated for the impact of the adoption of IFRS 15, an accounting standard related to revenue recognition, by decreasing accumulated loss and net deferred revenue by a total of €8.7 million at December 31, 2017.

Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three months ended June 30,		**Six months ended June 30,**	
	(euros in thousands, except per share data)			
	2018	**2017** Restated**	**2018**	**2017** Restated**
Revenue	6,543	6,237	16,464	10,121
Research and development costs	(12,523)	(8,420)	(22,821)	(15,427)
Management and administration costs	(2,639)	(3,492)	(5,491)	(7,694)
Other expenses	(3,297)	(2,277)	(5,983)	(4,120)
Total operating expenses	(18,459)	(14,189)	(34,295)	(27,241)
Operating result	(11,916)	(7,952)	(17,831)	(17,120)
Finance income	7,411	420	4,945	610
Finance cost	(1)	(11,962)	(1)	(22,696)
Total finance income / (expense)	7,410	(11,542	4,944	(22,086
Result before taxation	(4,506)	(19,494)	(12,887)	(39,206)
Income tax expense	(87)	(107)	(139)	(118)
Result after taxation	(4,593)	(19,601)	(13,026)	(39,324)
Other comprehensive income				
Exchange differences on the translation of foreign operations	36	13	21	18
Total other comprehensive income for the period	36	13	21	18
Total comprehensive loss for the period	(4,557)	(19,588)	(13,005)	(39,306)
Basic (and diluted) loss per share	(0.20)	(1.01)	(0.60)	(2.07)
Weighted average shares outstanding				
Basic (and diluted)	22,628,611	19,392,495	21,809,950	18,976,446

** Revenue for the three and six months ended June 30, 2017 has been restated to reflect additional revenue of €2.2 million, or €0.11 per share, and €3.8 million, or €0.20 per share, respectively, related to the amortization of the up-front license payment received from Incyte due to the impact of the adoption of IFRS 15, an accounting standard related to revenue recognition.

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