

# Merus

## Merus Announces Recent Corporate Developments and Financial Results for the Fourth Quarter and Full Year 2017

April 26, 2018

- Phase 2 combination trial in two metastatic breast cancer (MBC) populations initiated for Merus' most advanced bispecific antibody candidate, MCLA-128 -
- Strategic collaboration announced with Simcere Pharmaceutical Group for multiple bispecific antibodies; expanded collaboration with Ono Pharmaceuticals for autoimmune diseases -
- \$55.8 million secured in private placement -
- Company to host conference call and webcast today at 8:30am -

UTRECHT, The Netherlands, April 26, 2018 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced financial results for the fourth quarter and full year ended December 31, 2017 and provided a corporate and clinical update.

"The momentum that we have built throughout 2017 continues to yield meaningful progress for our pipeline of potential best-in-class bispecific antibody candidates," said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. "We already have had a productive start to the year with the initiation of patient dosing in a Phase 2 combination trial of our most advanced bispecific antibody, MCLA-128, in two metastatic breast cancer (MBC) populations and we anticipate formulating a clinical development path for MCLA-128 in certain of our other solid tumor indications among gastric, ovarian, endometrial and non-small cell lung cancer (NSCLC). Additionally, we anticipate milestones for our other proprietary programs, MCLA-117 and MCLA-158, during the year."

"We also are committed to expanding the potential of our Biclonics® technology platform and leveraging our highly productive functional cell-based screening of numerous combinations of Biclonics®. Our functional screening has allowed Merus to forge strategic collaborations with leading biopharma companies, including Incyte Corporation and Simcere Pharmaceutical Group, as well as to expand our existing relationship with Ono Pharmaceuticals. These agreements highlight the broad potential application of Biclonics® in immuno-oncology and autoimmune diseases."

### Recent Clinical & Corporate Developments

- **Patient Dosing Commenced in a Phase 2 Clinical Trial of MCLA-128 in Two Metastatic Breast Cancer Populations** - Merus announced in January 2018 that the first patient was dosed in a Phase 2, open-label, multi-center international clinical trial to evaluate MCLA-128 in combination with current standards of care in two MBC populations, including HER2-positive MBC patients and hormone receptor positive/HER2-low MBC patients. MCLA-128 was advanced into Phase 2 following promising single-agent activity observed in heavily-pretreated patients treated in a Phase 1/2 trial.
- **Entered Strategic Collaboration with Simcere Pharmaceutical Group for Three Bispecific Antibodies** – In January 2018, Merus agreed to lead research and antibody generation of three bispecific antibodies utilizing Merus' proprietary Biclonics® technology platform and granted Simcere Pharmaceutical Group an exclusive license to develop and commercialize in China those bispecific antibodies in the area of immuno-oncology. Merus has retained all rights outside of China. Simcere is responsible for Investigational New Drug Application (IND)-enabling studies and manufacturing of clinical trial materials in China, which Merus intends to use to assist regulatory filing and early stage clinical development in the rest of the world.
- **Merus Entered into a New Global License with Ono Pharmaceuticals for Bispecific Antibodies Targeting Autoimmune Diseases** - Merus announced in March 2018 that Ono Pharmaceuticals Co., LTD. exercised its option under an agreement executed in April 2014 to enter into a new research and license agreement utilizing Merus' proprietary Biclonics® technology platform to generate a bispecific antibody that binds to a combination of targets designed for the treatment of autoimmune diseases.
- **Closed \$55.8 Million in Private Placement** - In February 2018, Merus closed a \$55.8 million private placement of 3.1 million common shares with a syndicate of new and existing investors, including Biotechnology Value Fund L.P. and certain of its affiliates, Aquilo Capital Management LLC, Sofinnova Venture Partners L.P., and LSP Life Sciences Fund N.V. Proceeds from the offering will be used to continue to fund Merus' product candidates in clinical and preclinical development, as well as for general corporate purposes.
- **IND Accepted by U.S. Food and Drug Administration (FDA) for MCLA-117 and Merus Obtains Patent Issuance on MCLA-117** - Merus received FDA acceptance of its IND for MCLA-117 in February 2018 and the Company plans to open trial sites in the U.S. for its ongoing Phase 1 trial in patients with acute myeloid leukemia (AML). In March, Merus also obtained issuance of its first U.S. patent

covering MCLA-117, and certain other Merus Biclomics® that engage T-cells with tumor cells by targeting CD3.

- **Merus Prevailed in its Patent Challenge against Regeneron** - In December 2017, the United States Court of Appeals for the Federal Circuit denied Regeneron Pharmaceutical Inc.'s request for a rehearing and rehearing en banc to reconsider its decision affirming that Regeneron engaged in inequitable conduct before the United States Patent and Trademark Office while prosecuting the U.S. Patent No. 8,502,018 (the '018 patent), which it had asserted against Merus. The decision to deny Regeneron's request further validated the thorough opinions previously issued by the trial court and Federal Circuit panel on matters related to the '018 patent.

#### **Anticipated 2018 Milestones**

##### ***MCLA-128, an antibody-dependent cell-mediated cytotoxicity (ADCC) enhanced Biclomics® that binds to HER2 and HER3-expressing solid tumor cells***

The Phase 1/2 study evaluating single agent activity for MCLA-128 in gastric, ovarian, endometrial and NSCLC patients is ongoing and Merus expects to formulate its clinical development plans for certain of these indications based on emerging data from this study in the second half of 2018.

##### ***MCLA-117, a Biclomics® that binds to CD3 and CLEC12A***

Merus is continuing its dose escalation of the Phase 1 clinical trial for MCLA-117 in Europe and the Company plans to open sites for the Phase 1 trial in the U.S. Safety and potential early activity data is expected in 2018.

##### ***MCLA-158, an ADCC-enhanced Biclomics® designed to bind to cancer stem cells expressing Lgr5 and EGFR***

Merus has received approval of a Clinical Trial Application (CTA) in several European countries for MCLA-158 for the potential treatment of metastatic colorectal cancer, including patients with the RAS-mutation, which represent a substantial unmet need. The Company expects to dose the first patient in the second quarter of 2018. Merus also filed an IND for MCLA-158 with the FDA in the first quarter of 2018 and plans to open trial sites in the U.S. in the second quarter of 2018.

##### ***MCLA-145, a Biclomics® designed to bind to PD-L1 and a second undisclosed immunomodulatory target***

IND-enabling studies for MCLA-145, the first drug candidate co-developed under the Merus and Incyte global research collaboration, are ongoing. 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.

#### **Fourth Quarter 2017 Financial Results**

Total revenue for the three months ended December 31, 2017 was €3.8 million compared to €(0.4) million for the same period in 2016. Revenue is comprised primarily of the amortization of the Company's upfront license payments from its collaboration agreements, research funding and income from research grants. The increase in revenue is primarily attributable to revenue associated with the Company's collaboration with Incyte which commenced in 2017. Revenue for the three months ended December 31, 2016 was negative because the Company reversed €0.7 million of revenue that had been previously recognized in a prior period related to a government grant.

Research and development expenses for the three months ended December 31, 2017 was €11.1 million compared to €6.5 million for the same period in 2016. The increase in research and development expenses reflects increases in clinical and preclinical development and manufacturing expenses.

Management and administration costs for the three months ended December 31, 2017 was €2.3 million compared to €2.7 million for the same period in 2016.

Other expenses for the three months ended December 31, 2017 was €2.8 million compared to €2.7 million for the same period in 2016.

For the three months ended December 31, 2017, Merus recorded a net loss of €14.2 million, or €(0.73) per share (basic and diluted), compared to €31.9 million, or €(1.99) per share (basic and diluted), for the same period in 2016. 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 2017 Financial Results**

Merus ended 2017 with cash, cash equivalents and investments of €190.8 million compared to €56.9 million at December 31, 2016. Net cash used in operating activities was €37.4 million in 2017 compared to €25.7 million in 2016.

Total revenue for the year ended December 31, 2017 was €13.6 million compared to €2.7 million for the year ended December 31, 2016. Revenue is comprised primarily of the amortization of our upfront license payments from collaborations, research funding and income from research grants. The increase in revenue is primarily attributable to the amortization of the upfront license payment and cost reimbursements associated with our collaboration with Incyte which began in January 2017.

Research and development costs for the year ended December 31, 2017 were €34.1 million compared to €18.4 million for the year ended December 31, 2016. The increase in research and development costs reflects higher enrollment in our clinical trials and expansion of research efforts to support our internal programs and collaboration with Incyte.

Management and administration costs for the year ended December 31, 2017 were €13.7 million compared to €4.3 million for the year ended December 31, 2016. The increase in management and administration costs is attributable to increases in management personnel and associated share-based payment expenses.

Other expenses for the year ended December 31, 2017 were €9.4 million compared to €7.7 million for the year ended December 31, 2016. The increase in other expenses is primarily related to increases in consulting, accounting, and higher insurance and facilities costs offset by a decrease in litigation costs.

For the year ended December 31, 2017, Merus reported a net loss of €73.0 million, or €(3.80) per share (basic and diluted), compared to a net loss of €47.2 million, or €(3.57) per share (basic and diluted) for the year ended December 31, 2016. The net loss for 2017 includes several significant non-cash charges, including €15.8 million of unrealized foreign exchange results, €12.8 million of share-based payment expenses, and €10.7 million for the accounting impact of a financial derivative related to the obligation to deliver shares to Incyte.

#### **Financial Outlook**

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

#### **Conference Call Details**

Merus will hold a conference call to provide a full year update and discuss its financial results today, Thursday, April 26, 2018 at 8:30 a.m. ET. To listen to the conference call, please dial (877) 260-1463 (U.S.) or (706) 643-5907 (international) and reference conference ID 6184636. In addition, the presentation will be webcast live, and may be accessed for up to 90 days following the call, by visiting the "Investors" section of the Company's website, [www.merus.nl](http://www.merus.nl). An accompanying slide presentation also can be accessed via the "Investors" section of the website.

#### **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®,

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 Europe in gastric, ovarian, endometrial and NSCL cancers. Merus' second most advanced 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, as well as MCLA-145, which is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target, which is being developed in collaboration with Incyte Corporation.

#### 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 dosing, presentations, clinical data announcements, and regulatory filings, the advancement of the Phase 2 combination trial for MCLA-128, the expected use of proceeds from the private placement, the generation of a bispecific antibody that binds to a combination of targets designed for the treatment of autoimmune diseases under the agreement between Merus and Ono, the generation of three bispecific antibodies utilizing Merus' proprietary Biclomics® technology platform and Merus' use of Simcere's IND enabling studies and manufacturing of clinical trial materials in China to assist regulatory filing and early stage clinical development of Merus' product candidates under the agreement between Merus and Simcere, opening of trial sites in the United States for the Phase 1 trial of MCLA-117, 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 Biclomics® 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 Biclomics® 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 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 as of December 31, 2017

	December 31, 2017	December 31, 2016
	<b>(euros in thousands, unaudited)</b>	
<b>Non-current assets</b>		
Property, plant and equipment	1,168	648
Intangible assets	312	374
Restricted cash	-	167
Non-current investments	7,060	-
Other assets	129	109
	8,669	1,298
<b>Current assets</b>		
Financial asset	-	11,847
Trade and other receivables	4,413	2,248
Current investments	34,043	-
Cash and cash equivalents	149,678	56,917
	188,134	71,012
<b>Total assets</b>	196,803	72,310
<b>Shareholders' equity</b>		
Issued and paid-in capital	1,749	1,448
Share premium account	213,618	139,878
Accumulated loss	(167,480)	(107,295)
Total equity	47,887	34,031
<b>Non-current liabilities</b>		
Borrowings	-	319
Deferred revenue	130,195	30,206
<b>Current liabilities</b>		
Borrowings	-	167
Trade payables	2,855	2,298

Taxes and social security liabilities	243	29
Deferred revenue	6,996	1,610
Other liabilities and accruals	8,627	3,650
	18,721	7,754
<b>Total liabilities</b>	148,916	38,279
<b>Total equity and liabilities</b>	196,803	72,310

#### Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three months ended December 31,		Year ended December 31,		2016
	2017	2016	2017	2016	
<b>(euros in thousands, except per share data, unaudited)</b>					
<b>Revenue</b>	3,816	(408	)	13,600	2,719
Research and development costs	(11,050	)	(6,500	)	(18,424
Management and administration costs	(2,265	)	(2,698	)	(4,258
Other expenses	(2,807	)	(2,732	)	(7,709
<b>Total operating expenses</b>	(16,122	)	(11,930	)	(30,391
<b>Operating result</b>	(12,306	)	(12,338	)	(27,672
Finance income	248	14	1,112	88	
Finance costs	(2,120	)	(19,623	)	(19,644
<b>Total finance income (expenses)</b>	(1,872	)	(19,609	)	(19,556
<b>Result before tax</b>	(14,178	)	(31,947	)	(47,228
Income tax expense	(67	)	-	(249	-
<b>Result after taxation</b>	(14,245	)	(31,947	)	(47,228
Exchange differences from translation of foreign operations	38	5	89	8	
<b>Other comprehensive income</b>	38	5	89	8	
<b>Total comprehensive loss for the period</b>	(14,207	)	(31,942	)	(47,220
<b>Basic (and diluted) loss per share</b>	(0.73	)	(1.99	)	(3.57
<b>Basic (and diluted)</b>	19,423,027	16,085,851	19,196,440	13,236,649	

#### Contacts:

Investors:  
Kimberly Minarovich  
+1 646-368-8014  
[kimberly@argotpartners.com](mailto:kimberly@argotpartners.com)

Media:  
David Rosen  
+1 212-600-1902  
[david.rosen@argotpartners.com](mailto:david.rosen@argotpartners.com)

Source: Merus N.V.