Merus Announces Financial Results for the Fourth Quarter and Full Year 2022 and Provides Business Update

February 28, 2023

– Zenocutuzumab (Zeno) in NRG1+ cancer potential registrational path and timeline update planned for first half of 2023

– Petosemtamab clinical and regulatory update planned for first half of 2023

– MCLA-129 clinical update planned for second half of 2023

– Based on the Company's current operating plan, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into second half 2025

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Feb. 28, 2023 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) (Merus, the Company, we, or our), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclonics® and Triclonics®), today announced financial results for the fourth quarter and full year and provided a business update.

"We are making significant progress across our clinical pipeline of important and potentially clinically meaningful new cancer therapeutic candidates, all from our own Biclonics® antibody technologies," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "With continued enrollment to support a potential Zeno BLA submission in NRG1+ cancer, a clinical update on petosemtamab in the first half of the year and a planned MCLA-129 clinical update in the second half, 2023 promises to be a transformative year for Merus, as we strive to bring novel and highly innovative medicines to patients."

Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclonics®): NRG1+ cancer and other solid tumors
Enrollment continues in the eNRGy trial of Zeno monotherapy in NRG1+ cancer; and a phase 2 trial of Zeno in combination with androgen deprivation therapy (ADT) in castration resistant prostate cancer (CRPC), and in combination with afatinib in NRG1+ non-small cell lung cancer (NSCLC)

In October 2022, Merus met with the U.S. Food and Drug Administration (FDA) regarding a potential Biologics License Application (BLA) filing for Zeno in NRG1+ cancer. Based on the FDA feedback, Merus believes multiple registrational paths remain viable, and has decided the optimal approach is to sequence its development plan by first seeking a potential application for NRG1+ lung and/or pancreatic cancer, which could then be followed by a potential tissue agnostic filing. The Company believes Zeno has the potential to be both first in class and best in class, and a new standard of care for the treatment of NRG1+ cancer.

As of year end 2022, over 150 patients with NRG1+ cancer have been treated with Zeno monotherapy in our eNRGy trial and Early Access Program (EAP). Merus plans to provide an update on the potential registrational path and timeline in NRG1+ cancer in the first half of 2023 and a clinical update on Zeno in NRG1+ cancer at a major medical conference in 2023.

Further, Merus is evaluating Zeno in combination with an ADT (enzalutamide or abiraterone) in men with CRPC, irrespective of NRG1+ status. Merus plans to provide initial clinical data on Zeno in CRPC in the second half of 2023.

Merus is also evaluating Zeno in combination with afatinib in patients with NRG1+ NSCLC.

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors
Enrollment continues in dose expansion in the phase 1 trial; clinical update planned for 1H23

Petosemtamab is in clinical development in the expansion part of a phase 1 open-label, multicenter trial in advanced solid tumors, including previously treated head and neck squamous cell carcinoma (HNSCC). Merus previously reported early interim clinical data on petosemtamab in patients with advanced HNSCC at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics in October 2021. Among 10 patients, seven patients were evaluable for efficacy analysis by investigator assessment. Three of seven patients were observed to achieve a partial response, with one of these three observed to achieve complete response after the data cutoff date. Tumor reduction was observed in the target lesions of all seven patients.

Merus plans to provide a clinical update on petosemtamab in the first half of 2023 at a medical conference. The planned update will include data from approximately 40 patients with HNSCC with meaningful clinical follow up, and data from patients with gastro-esophageal cancer, to inform clinical development strategy.

Merus further plans to provide a regulatory path update on petosemtamab in the first half of 2023.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Enrollment continues in the expansion cohorts in the phase 1/2 trial; clinical update planned for 2H23

MCLA-129 is in clinical development in a phase 1/2, open-label clinical trial evaluating MCLA-129 monotherapy in patients with EGFRex20 NSCLC, MetEx14 NSCLC, and in HNSCC, as well as MCLA-129 in combination with Tagrisso (osimertinib), a third generation EGFR TKI, in patients with treatment-naïve EGFR mutant (m) NSCLC and in patients with EGFRm NSCLC that have progressed on Tagrisso.

In October 2022, Merus presented initial clinical data on MCLA-129 at the 34th EORTC-NCI-AACR International Conference on Molecular Targets and Cancer Therapeutics. Twenty patients were treated across dose levels of 100 mg-1500 mg. As of an August 15, 2022 data cutoff date, in early interim data, 18 evaluable patients were observed to have clinical activity at a variety of dose levels with two confirmed partial responses and four additional patients with >20% target lesion tumor shrinkage based on investigator review. From this interim data, MCLA-129 was observed to be well tolerated with no dose limiting toxicities.

Merus plans to provide an initial clinical data update from the expansion cohorts, and a further clinical development strategy update in the second half of 2023.

MCLA-129 is subject to a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. (Betta), which permits Betta to develop MCLA-129 and potentially commercialize exclusively in China, while Merus retains global rights outside of China.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Enrollment continues in the phase 1 trial including in combination with Keytruda (pembrolizumab), a PD-1 inhibitor

MCLA-145 is in clinical development in a global, phase 1, open-label, clinical trial evaluating MCLA-145 in patients with solid tumors. The trial consists of a dose escalation phase, followed by a planned dose expansion phase. Merus is also evaluating the combination of MCLA-145 with Keytruda, with enrollment ongoing.

Collaborations

Incyte Corporation

Since 2017, Merus has been working together with Incyte Corporation (Incyte) under a global collaboration and license agreement focused on the research, discovery and development of bispecific antibodies utilizing Merus' proprietary Biclonics ® technology platform. The agreement grants Incyte certain exclusive rights for up to ten bispecific and monospecific antibody programs. The collaboration is progressing, with multiple programs in various stages of preclinical development. Further, Incyte announced, in 2023, that INCA32459, a novel Lag3xPD-1 bispecific antibody developed through the collaboration is currently being evaluated in clinical studies. In January 2023, Merus achieved a milestone payment of $2.5 million related to this program. For each program under the collaboration, Merus receives reimbursement for research activities and is eligible to receive potential development, regulatory and commercial milestones and sales royalties for any products, if approved.

Loxo Oncology at Lilly

In January 2021, Merus and Loxo Oncology at Lilly, a research and development group of Eli Lilly and Company (Lilly), announced a research collaboration and exclusive license agreement to develop up to three CD3-engaging T-cell re-directing bispecific antibody therapies utilizing Merus' Biclonics ® platform and proprietary CD3 panel along with the scientific and rational drug design expertise of Loxo Oncology at Lilly. The collaboration is progressing with multiple active research programs underway.

Ono Pharmaceutical

In March 2018, the Company granted Ono Pharmaceutical Co., Ltd. (Ono) an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market a limited number of bispecific antibody candidates based on Merus' Biclonics ® technology platform directed to a particular undisclosed target combination. In the fourth quarter of 2022, Merus achieved a milestone payment of €1.0 million from Ono for preclinical advancement of a lead candidate arising from this license.

Corporate Update

In January 2023, Merus announced the promotion of Peter B. Silverman as Chief Operating Officer. Mr. Silverman adds this title to his role as Executive Vice President, General Counsel. Mr. Silverman is an accomplished healthcare leader, with demonstrated success in progressing Merus across multiple business functions during his tenure at the company. Since Mr. Silverman joined Merus in 2017, he has made significant contributions to enhance the company's platform technology and intellectual property portfolio, advance our strategic collaborations, and has overseen the company's general and administrative functions, which have been instrumental in fostering the company's growth. We congratulate him on his well-deserved promotion and believe it will strengthen the organizational structure that will allow us to better maximize the exciting opportunities that lie ahead.

Cash Runway, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into second half 2025

As of December 31, 2022, Merus had $326.7 million cash, cash equivalents and marketable securities. Based on the Company's current operating plan, the existing cash, cash equivalents and marketable securities are expected to fund Merus' operations into second half 2025.

Full Year 2022 Financial Results

Collaboration revenue for the year ended December 31, 2022 decreased $7.5 million as compared to the year ended December 31, 2021, primarily as a result of decreases in Lilly revenue of $3.4 million and Incyte revenue of $3.2 million. The decrease in Lilly revenue was primarily due to a decrease in upfront payment amortization of $3.7 million, partially offset by an increase in reimbursement revenue of $0.3 million.

Research and development expense for the year ended December 31, 2022 increased $51.2 million as compared to the year ended December 31, 2021, primarily as a result of increases in external clinical services and drug manufacturing costs, including costs to fulfill our obligations under our collaboration agreements, related to our programs of $34.3 million, personnel related expenses including stock-based compensation of $11.3 million due to an increase in employee headcount, facilities cost of $2.6 million, and consultancy costs of $2.0 million.

General and administrative expense for the year ended December 31, 2022 increased $11.3 million as compared to the year ended December 31, 2021, primarily as a result increases in stock-based compensation of $4.0 million, consultancy costs of $3.6 million, and personnel related costs of $2.3 million.

Other income, net consists of interest earned on our cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange gains or losses on our foreign denominated cash, cash equivalents and marketable securities, and payables and receivables.

MERUS N.V.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands except per share data)

	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 147,749	$ 241,435
Marketable securities	142,480	168,990
Accounts receivable	4,051	1,697
Accounts receivable (related party)	—	4,609
Prepaid expenses and other current assets	12,163	7,448
Total current assets	306,443	424,179
Marketable securities	36,457	20,297
Property and equipment, net	12,222	3,549

Operating lease right-of-use assets	12,618	3,733
Intangible assets, net	1,950	2,347
Deferred tax assets	2,041	417
Other assets	4,811	2,078
Total assets	$ 376,542	$ 456,600
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,834	$ 13,237
Accrued expenses and other liabilities	35,590	22,506
Income taxes payable	2,400	—
Current portion of lease obligation	1,684	1,494
Current portion of deferred revenue	29,418	16,613
Current portion of deferred revenue (related party)	—	18,048
Total current liabilities	78,926	71,898
Lease obligation	11,790	2,257
Deferred revenue, net of current portion	38,771	10,962
Deferred revenue, net of current portion (related party)	—	55,282
Total liabilities	129,487	140,399
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 and 67,500,000 shares authorized as at December 31, 2022 and 2021, respectively; 46,310,589 and 43,467,052 shares issued and outstanding as at December 31, 2022 and 2021, respectively	4,751	4,481
Additional paid-in capital	870,874	787,869
Accumulated deficit	(598,122)	(466,928)
Accumulated other comprehensive (loss) income	(30,448)	(9,221)
Total stockholders' equity	247,055	316,201
Total liabilities and stockholders' equity	$ 376,542	$ 456,600

MERUS N.V.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands except per share data)

	Year Ended December 31,		
	2022	**2021**	**2020**
Collaboration revenue	$ 41,586	$ 19,503	$ 3,363
Collaboration revenue (related party)	—	29,604	26,580
Grant revenue	—	—	—
Total revenue	41,586	49,107	29,943
Operating expenses:			
Research and development	149,424	98,187	70,040
General and administrative	52,200	40,896	35,781
Total operating expenses	201,624	139,083	105,821
Operating loss	(160,038)	(89,976)	(75,878)
Other income (loss), net:			
Interest (expense) income, net	2,722	(129)	300
Foreign exchange (losses) gains, net	26,022	24,663	(9,432)
Other (losses) gains, net	1,059	(1,135)	—
Total other income (loss), net	29,803	23,399	(9,132)
Loss before income tax expense	(130,235)	(66,577)	(85,010)
Income tax expense	959	239	503
Net loss	$ (131,194)	$ (66,816)	$ (85,513)
Other comprehensive income (loss):			
Currency translation adjustment	(21,227)	(18,292)	7,485
Comprehensive loss	$ (152,421)	$ (85,108)	$ (78,028)
Net loss per share allocable to common stockholders:			
Basic and diluted	$ (2.92)	$ (1.73)	$ (2.92)
Weighted-average common shares outstanding:			
Basic and diluted	44,919,084	38,638,434	29,256,203

About Merus N.V.

Merus is a clinical-stage oncology company developing innovative full-length human bispecific and trispecific antibody therapeutics, referred to as Multiclonics®. Multiclonics® 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. For additional information, please visit Merus' website, www.merus.nl and https://twitter.com/MerusNV.

Forward-Looking Statements

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, statements regarding the content and timing of clinical trials, data readouts and clinical, regulatory, strategy and development updates for our product candidates, including with respect to enrollment and timing of data in our eNRGy trial and EAP, the treatment potential of Zeno and to be potentially first and best in class for NRG1+ cancer; our belief that multiple registrational paths remain viable, and that the optimal approach is to sequence its development plan by first seeking a potential application for NRG1+ lung and/or pancreatic cancer, which could then be followed by a potential tissue agnostic filing; our understanding of the recent FDA draft guidance; our potential filing of a BLA for Zeno in NRG1+ cancer; the continuation of enrollment of patients in the eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers; our clinical trial evaluating Zeno in combination with afatinib for NRG1+ NSCLC; our clinical trial evaluating Zeno in combination with an ADT as a treatment for CRPC; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into the second half of 2025; the advancement of the phase 1 trial of MCLA-145, as monotherapy and in combination with Keytruda; the advancement of the phase 1 trial for MCLA-158 and the planned update at a medical conference in the first half of 2023 and opportunity to present an update including approximately 40 patients with HNSCC with meaningful clinical follow up, and an update on patients with gastro-esophageal cancer, and planned a regulatory path update on petosemtamab in the first half of 2023; the advancement of the phase 1/2 trial for MCLA-129 in the dose expansion phase, in monotherapy in MetEx14 NSCLC, EGFRex20 NSCLC, and in HNSCC, as well as in combination with Tagrisso in treatment naïve EGFRm NSCLC and in patients with EGFRm NSCLC that have progressed on Tagrisso; the design and treatment potential of our bispecific antibody candidates and impact of their preclinical data; the benefits of the collaboration between Loxo Oncology at Lilly and Merus, its potential for future value generation, including whether and when Merus will receive any future payment under the collaboration, including milestones or royalties, and the amounts of such payments; whether any programs under the collaboration will be successful; Merus' and Lilly's activities under the agreement; our global collaboration and license agreement with Incyte, its progress and potential development and commercialization of up to ten bispecific and monospecific antibodies from our Biclonics® platform and Incyte's clinical study of INCA32459 developed in collaboration with us, including whether and when Merus will receive any future payment under the collaboration, including milestones or royalties, and the amounts of such payments; whether any programs under the collaboration will be successful; our collaboration and license agreement with Betta, which permits Betta to develop MCLA-129 and potentially commercialize exclusively in China, while Merus retains full ex-China rights; our license agreement with Ono any potential future advancement of a lead candidate arising from this license or potential future payments to Merus from this license; and any developments that may arise from these agreements; statements concerning the progress across our clinical pipeline; statements concerning the potential of our therapeutic candidates to be meaningful; statements concerning 2023 promising to be a transformative year for Merus; and Mr. Silverman's anticipated contribution to the organizational structure and ability to better maximize the exciting opportunities that lie ahead. 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 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; impacts of the COVID-19 pandemic; we may not identify suitable Biclonics® or bispecific antibody candidates under our collaborations or our collaborators may fail to perform adequately under our collaborations; 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 potential lawsuits for infringement of third-party intellectual property; our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks; and risks related to our ceasing to qualify as an emerging growth company and a smaller reporting company after December 31, 2021.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the period ended December 31, 2022, filed with the Securities and Exchange Commission, or SEC, on February 28, 2023, 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.

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