Merus Announces Financial Results for the First Quarter 2024 and Provides Business Update

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- *Petosemtamab in combination with pembrolizumab in 1L HNSCC initial interim clinical data at 2024 ASCO Annual Meeting; preparing for a potential phase 3 trial*
- *Zeno BLA accepted for priority review by the FDA for the treatment of NRG1+ NSCLC and PDAC*
- *Based on the Company's current operating plan, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2027*

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 08, 2024 (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 first quarter and provided a business update.

"At the upcoming 2024 ASCO meeting, we are looking forward to presenting multiple datasets including the first clinical data on safety and efficacy of petosemtamab in combination with pembrolizumab in previously untreated head and neck cancer. With petosemtamab, we continue to believe we have the opportunity to significantly improve the lives of patients with both previously treated, as well as newly diagnosed, head and neck cancer and thus, it remains the focus of the company's resources," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "Additionally, we are thrilled that Zeno's BLA has been accepted for priority review, a tremendous milestone for Merus representing our first Biclonics® advancing from discovery to marketing application."

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors
1L head & neck squamous cell carcinoma (HNSCC) in combination with pembrolizumab ongoing, presentation at 2024 ASCO; previously treated (2L+) HNSCC phase 3 registration trial planned to initiate mid-2024 and dose comparison of petosemtamab monotherapy 1100 vs 1500 mg in 2L+ HNSCC ongoing; planned initiation of 2L colorectal cancer (CRC) cohort in 2024

An abstract entitled: Petosemtamab (MCLA-158) with pembrolizumab as first-line (1L) treatment of recurrent/metastatic (r/m) head and neck squamous cell carcinoma (HNSCC): Phase 2 study was accepted for rapid oral session presentation at 2024 ASCO. Merus plans to report initial interim efficacy and safety data from this cohort.

Merus continues to evaluate patients with untreated advanced PD-L1+ HNSCC treated with petosemtamab 1500 mg in combination with pembrolizumab. Initial safety data from this single arm cohort may support the initiation of a 1L phase 3 trial with this combination. Among the initial patients dosed in the 1L combination cohort, the safety profile has been observed to be generally favorable.

Merus plans to initiate a phase 3 clinical trial in mid-2024 to evaluate petosemtamab monotherapy in 2L+ HNSCC. In the planned trial, patients will be randomized to petosemtamab monotherapy or investigators' choice of single agent chemotherapy or cetuximab. Merus believes a randomized registration trial in HNSCC with an overall response rate (ORR) endpoint could potentially support accelerated approval and the overall survival (OS) results from the same study could potentially verify its clinical benefit to support regular approval.

Merus continues to evaluate approximately 40 patients treated with petosemtamab monotherapy at either 1100 or 1500 mg dose levels to confirm a suitable dose for future potential phase 3 trials. Merus plans to share clinical data from this cohort in the second half of 2024.

At the American Association of Cancer Research (AACR) Annual Meeting 2023, Merus provided interim data on 49 2L+ HNSCC patients that were treated with petosemtamab at the recommended phase 2 dose of 1500 mg intravenous every two weeks. Merus plans to provide updated efficacy, durability and safety data of this cohort in the second half of 2024.

In 2024, Merus is planning to initiate the evaluation of petosemtamab with standard chemotherapy in 2L CRC.

Zenocutuzumab (Zeno or MCLA-128: HER2 x HER3 Biclonics®): NRG1 fusion-positive (NRG1+) lung, pancreatic and other solid tumors
Zeno BLA for treatment of NRG1+ NSCLC and PDAC accepted for priority review by the FDA

The U.S. Food and Drug Administration (FDA) has accepted for priority review a Biologics License Application (BLA) for the bispecific antibody zenocutuzumab (Zeno) in patients with NRG1+ non-small cell lung cancer (NSCLC) and pancreatic (PDAC) cancer. If approved, Zeno will be the first and only targeted therapy for patients with NRG1+ NSCLC and PDAC.

The Company is also conducting ongoing translational work on potential biomarkers outside of NRG1+ cancer which may support development opportunities for Zeno in additional areas of unmet need. Merus presented a pre-clinical poster: Zenocutuzumab, a HER2xHER3 bispecific antibody, is effective in cancer models with high NRG1 expression at the AACR Annual Meeting 2024.

Merus believes that obtaining a commercialization partnership agreement will be an essential step in bringing Zeno to patients with NRG1+ cancer, if approved.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Investigation of MCLA-129 continues in the MET ex14 NSCLC expansion cohort in the phase 1/2 trial; MCLA-129 in combination with chemotherapy in 2L+ EGFR mutant (EGFRm) NSCLC planned to start in 2024

An abstract entitled: Efficacy and safety of MCLA-129, an anti-EGFR/c-MET bispecific antibody, in non-small-cell lung cancer (NSCLC) with c-MET exon 14 skipping mutations (METex14) was accepted for poster presentation at 2024 ASCO.

We plan to start a cohort investigating MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC in 2024. We also remain interested in exploring partnering MCLA-129 to sufficiently resource the development of MCLA-129 and potential benefit it may have for patients.

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. An abstract sponsored by Betta entitled: Efficacy and safety of MCLA-129, an EGFR/c-MET bispecific antibody, in advanced non-small cell lung cancer (NSCLC) was accepted for poster presentation at 2024 ASCO.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors

Investigation continues of the phase 1 trial of MCLA-145 in combination with pembrolizumab

An abstract entitled: Phase I study of MCLA-145, a bispecific antibody targeting CD137 and PD-L1, in solid tumors, as monotherapy or in combination with pembrolizumab was accepted for rapid oral session presentation at 2024 ASCO.

Research
At the 20th Annual PEGS Boston meeting on May 14th, Merus plans to present preclinical validation of the compatibility and favorable pharmaceutical properties of Biclonics® conjugated with a range of linkers and payloads to generate antibody-drug conjugates (ADClonics™), demonstrating our platform and format holds the potential for improved binding selectivity, internalization and cancer cell killing activity.

Company News
Effective May 7, 2024, Jason Haddock was appointed to the Merus Board of Directors. Most recently, he served as Chief Financial Officer (CFO) at Archer Dx from May to August 2020 until it was acquired by Invitae Corporation. From 2016 to 2019, he served as CFO of Array BioPharma, Inc. and from 2015 to 2016, Mr. Haddock served as CFO and Chief Operating Officer (COO) of BERG. Mr. Haddock spent 15 years (2001-2015) at Bristol-Myers Squibb in a variety of finance, strategic, commercial and business development capacities, including CFO and COO roles for business units in Asia Pacific, Europe and the United States. He currently serves on the board of directors of PYC Therapeutics. Mr. Haddock holds a BS in accounting from Illinois State University and an Executive MBA from Washington University in St. Louis.

Collaborations

Incyte Corporation
Since 2017, Merus has been working 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. 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. During the first quarter of 2024, Merus achieved a milestone of $1 million for candidate nomination and expects to receive payment in the second quarter of 2024. This is the fifth program to obtain candidate nomination under the collaboration.

Eli Lilly and Company
In January 2021, Merus and 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 Lilly. The collaboration is progressing well with three programs ongoing at various stages of preclinical development.

Gilead Sciences
In March 2024, Merus and Gilead Sciences announced a collaboration to discover novel antibody based trispecific T-cell engagers using Merus' patented Triclonics® platform. Under the terms of the agreement, Merus will lead early-stage research activities for two programs, with an option to pursue a third. Gilead will have the right to exclusively license programs developed under the collaboration after the completion of select research activities. If Gilead exercises its option to license any such program from the collaboration, Gilead will be responsible for additional research, development and commercialization activities for such program. Merus received an equity investment by Gilead of $25 million in Merus common shares and an upfront payment of $56 million.

On April 9, 2024, Merus received U.S. Patent Number 11,952,424 covering our proprietary Triclonics® format, related to a trispecific antibody comprising a common light chain, capable of binding at least three different epitopes or antigens.

Cash Runway, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2027

As of March 31, 2024, Merus had $398.7 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 2027.

First Quarter 2024 Financial Results

We ended the first quarter with cash, cash equivalents and marketable securities of $398.7 million compared to $411.7 million at December 31, 2023. The decrease was primarily the result of cash used to fund the operations partially offset by equity investment from Gilead Sciences.

Collaboration revenue for the three months ended March 31, 2024 decreased by $5.6 million as compared to the three months ended March 31, 2023, primarily as a result of lower cost reimbursement revenue.

Research and development expense for the three months ended March 31, 2024 increased by $3.7 million as compared to the three months ended March 31, 2023, primarily as a result of an increase in clinical and manufacturing costs related to our programs.

General and administrative expense for the three months ended March 31, 2024 increased by $0.7 million as compared to the three months ended March 31, 2023, primarily as a result of increases in personnel related costs partially offset by decrease in facility and consulting costs.

Other income (loss), net consists of interest earned and fees paid on our cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange (losses) gains on our foreign denominated cash, cash equivalents and marketable securities. Other gains or losses relate to the issuance and settlement of financial instruments.

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

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 178,168	$ 204,246
Marketable securities	159,328	150,130
Accounts receivable	58,726	2,429
Prepaid expenses and other current assets	14,038	12,009
Total current assets	410,260	368,814
Marketable securities	61,167	57,312
Property and equipment, net	11,336	12,135
Operating lease right-of-use assets	10,767	11,362
Intangible assets, net	1,716	1,800
Deferred tax assets	277	1,199
Other assets	2,560	2,872
Total assets	$ 498,083	$ 455,494
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,488	$ 4,602
Accrued expenses and other liabilities	33,361	38,482
Income taxes payable	1,822	1,646
Current portion of lease obligation	1,674	1,674
Current portion of deferred revenue	34,142	22,685
Total current liabilities	78,487	69,089
Lease obligation	9,853	10,488
Deferred revenue, net of current portion	60,295	19,574
Total liabilities	148,635	99,151
Commitments and contingencies - Note 6		
Shareholders' equity:		
Common shares, €0.09 par value; 67,500,000 shares authorized at March 31, 2024 and December 31, 2023; 58,687,551 and 57,825,879 shares issued and outstanding as at March 31, 2024 and December 31, 2023, respectively	5,968	5,883
Additional paid-in capital	1,160,918	1,126,054
Accumulated other comprehensive income	(29,921)	(22,533)
Accumulated deficit	(787,517)	(753,061)
Total shareholders' equity	349,448	356,343
Total liabilities and shareholders' equity	$ 498,083	$ 455,494

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

	Three Months Ended March 31,	
	2024	2023
Collaboration revenue	$ 7,889	$ 13,499
Total revenue	7,889	13,499
Operating expenses:		
Research and development	38,584	34,865
General and administrative	16,114	15,386
Total operating expenses	54,698	50,251
Operating loss	(46,809)	(36,752)
Other income, net:		
Interest income, net	4,917	1,995
Foreign exchange gains (loss)	8,534	(5,441)
Total other income (loss), net	13,451	(3,446)
Net loss before income taxes	(33,358)	(40,198)
Income tax expense	1,098	(457)
Net loss	$ (34,456)	$ (39,741)
Other comprehensive loss:		
Currency translation adjustment	(7,388)	4,242
Comprehensive loss	$ (41,844)	$ (35,499)

Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.59)	$ (0.86)
Weighted-average common shares outstanding:		
Basic and diluted	58,085,416	46,323,772

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, and LinkedIn.

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; our ability to successfully advance our Zeno through the regulatory, BLA review and potential commercialization processes; our upcoming presentations of multiple datasets at ASCO 2024, including the first clinical data on safety and efficacy of petosemtamab in combination with pembrolizumab in previously untreated head and neck cancer; our belief we have the opportunity to significantly improve the lives of patients with both previously treated, as well as newly diagnosed, head and neck cancer by administration of petosemtamab, and it being a focus of the Company's resources; our plan to start a phase 3 registration trial in 2L+ HNSCC in mid-2024; our plan to provide initial interim efficacy and safety data on the combination with pembrolizumab in the second quarter of 2024; our preparation for a potential first-line phase 3 trial of petosemtamab in combination with pembrolizumab in untreated advanced PD-L1+ HNSCC; our plan to initiate investigation of petosemtamab with standard chemotherapy in 2L colorectal cancer patients; the potential design and details of our planned phase 3 trial investigating monotherapy petosemtamab in 2L HNSCC; the enrollment of approximately 40 patients in previously treated HNSCC with petosemtamab monotherapy at the 1100 or 1500 mg dose levels to confirm a suitable dose for future randomized trials and plan to share the clinical data form this cohort in the second half of 2024; our plan to provide updated efficacy, durability and safety data in the second half of 2024 of the cohort disclosed at the AACR Annual Meeting 2023; our belief that obtaining a commercialization partnership agreement will be an essential step in bringing Zeno to patients with NRG1+ cancer, if approved; our conduct of ongoing translational work on potential biomarkers outside of NRG1+ tumors, which may support development opportunities for Zeno in additional areas of unmet need; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into 2027; the ongoing monitoring and evaluation of patients the phase 1 trial of MCLA-145 in combination with pembrolizumab; the advancement of the phase 1/2 trial for MCLA-129 in the dose expansion phase, in monotherapy in Met ex14 NSCLC; our plan to initiate a cohort of MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC in 2024; the benefits of the collaborations between Incyte and Merus, Lilly and Merus, Gilead and Merus, and the potential of those collaboration for future value generation, including whether and when Merus will receive any future payment under the collaborations, including milestones or royalties, and the amounts of such payments; whether any programs under the collaboration will be successful; and 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, including any future clinical development by Betta of MCLA-129. 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 volatility in the global economy, including global instability, including the ongoing conflicts in Europe and the Middle East; 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; 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 Quarterly Report on Form 10-Q for the period ended March 31, 2024, filed with the Securities and Exchange Commission, or SEC, on May 8, 2024, 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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