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

October 31, 2024 at 8:08 AM EDT

- *Phase 3 registrational trials evaluating petosemtamab in combination with pembrolizumab in 1L and petosemtamab monotherapy in 2/3L r/m HNSCC enrolling*
- *Petosemtamab in 2L+ r/m HNSCC interim clinical data accepted for rapid oral presentation at ESMO® Asia Congress 2024*
- *Based on the Company's current operating plan, existing cash, cash equivalents, and marketable securities expected to fund Merus' operations into 2028*

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Oct. 31, 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 third quarter and provided a business update.

"I'm encouraged by our continued operational effectiveness, with phase 3 trials accelerating for petosemtamab in both 1L and 2/3L recurrent/metastatic head and neck cancer. I believe petosemtamab has the potential to offer both a first and best in class chemo-free option for these patients," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "We look forward to providing an update on petosemtamab's monotherapy efficacy, duration and safety in 2L+ HNSCC this December at ESMO® Asia and, in the near future, providing more information on a number of important potential near term catalysts in 2025."

Petosemtamab (MCLA-158: EGFR x LGR5 Biclonics®): Solid Tumors
LiGeR-HN1 phase 3 trial in 1L head and neck squamous cell carcinoma (HNSCC) and LiGeR-HN2 phase 3 trial in 2/3L HNSCC enrolling; phase 2 trial in 2L metastatic colorectal cancer (mCRC) enrolling; clinical data update on 2L+ HNSCC planned for ESMO® Asia in December 2024

In the third quarter, Merus announced the first patient was dosed in LiGeR-HN1, a phase 3 trial evaluating the efficacy and safety of petosemtamab in combination with pembrolizumab in 1L HNSCC expressing PD-L1 (CPS≥1) compared to pembrolizumab. In this trial, patients will be randomized to petosemtamab plus pembrolizumab or pembrolizumab monotherapy. This was detailed in our press release, Merus Announces First Patient Dosed in LiGeR-HN1, a Phase 3 Trial Evaluating Petosemtamab in Combination with Pembrolizumab in 1L r/m HNSCC (September 30, 2024).

Merus provided an interim clinical update on petosemtamab with pembrolizumab in 1L r/m HNSCC at the American Society of Clinical Oncology® (ASCO) Annual Meeting 2024, demonstrating a 67% response rate among 24 evaluable patients. The oral presentation was detailed in our press release, Merus' Petosemtamab in Combination with Pembrolizumab Interim Data Demonstrates Robust Response Rate and Favorable Safety Profile in 1L r/m HNSCC (May 28, 2024).

Merus also provided an interim clinical update on petosemtamab monotherapy in 2L+ HNSCC at the American Association of Cancer Research® (AACR®) Annual Meeting 2023, demonstrating a 37% response rate among 43 evaluable patients. The oral presentation was detailed in our press release (April 17, 2023). Merus plans to provide updated efficacy, durability and safety data of this cohort along with clinical data from the dose optimization cohort evaluating petosemtamab monotherapy 1500 or 1100 mg dose levels in 2L+HNSCC. This was detailed in our press release, Merus Announces Abstract Accepted for Presentation at the ESMO Asia Congress 2024 (September 17, 2024).

Merus believes a randomized registration trial in HNSCC with an overall response rate endpoint could potentially support accelerated approval and the overall survival results from the same study could potentially verify its clinical benefit to support regular approval.

In the third quarter, Merus announced the first patient was dosed in a phase 2 trial evaluating petosemtamab in combination with standard chemotherapy in 2L mCRC. This was detailed in our press release, Merus Announces First Patient Dosed in Phase 2 Trial of Petosemtamab in 2L CRC (July 8, 2024).

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+ non-small cell lung cancer (NSCLC) and pancreatic cancer (PDAC) accepted for priority review by the FDA

The FDA has accepted for priority review a Biologics License Application (BLA) for the bispecific antibody Zeno in patients with NRG1+ NSCLC and PDAC cancer. This acceptance was detailed in our press release Merus Announces U.S. FDA Acceptance and Priority Review of Biologics License Application for Zeno for the Treatment of NRG1+ NSCLC and PDAC (May 6, 2024).

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

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Investigation of MCLA-129 is ongoing in METex14 NSCLC; phase 2 trial in combination with chemotherapy in 2L+ EGFR mutant (EGFRm) NSCLC enrolling

In the third quarter, Merus announced the first patients were dosed in the phase 2 trial evaluating MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC, with a cohort receiving MCLA-129 and paclitaxel and carboplatin, and another cohort receiving MCLA-129 and docetaxel. We also remain interested in partnering MCLA-129 to sufficiently resource the development of MCLA-129 and the 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.

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

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

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.

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.

Ono Pharmaceutical
In 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 an undisclosed target combination. During the third quarter of 2024, Merus achieved and received a milestone payment based on the filing of an Investigational New Drug (IND) application in Japan.

Cash Runway, existing cash, cash equivalents and marketable securities expected to fund Merus' operations into 2028

As of September 30, 2024, Merus had $782.9 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 2028.

Third Quarter 2024 Financial Results

Collaboration revenue for the three months ended September 30, 2024 increased by $0.8 million as compared to the three months ended September 30, 2023, primarily as a result of increases in amortization of upfront deferred revenue. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended September 30, 2024 increased by $26.5 million as compared to the three months ended September 30, 2023, primarily as a result of increases in external clinical services and drug manufacturing expenses.

General and administrative expense for the three months ended September 30, 2024 increased by $8.2 million as compared to the three months ended September 30, 2023, primarily as a result of increases in personnel related expenses, facilities, depreciation expense and consulting expenses.

Collaboration revenue for the nine months ended September 30, 2024 decreased by $8.0 million as compared to the nine months ended September 30, 2023, primarily as a result of decreases in milestone revenue and amortization of deferred revenue.

Research and development expense for the nine months ended September 30, 2024 increased by $51.0 million as compared to the nine months ended September 30, 2023, primarily as a result of increases in external clinical services and drug manufacturing expenses.

General and administrative expense for the nine months ended September 30, 2024 increased by $15.5 million as compared to the nine months ended September 30, 2023, primarily as a result of increases in personnel related expenses and consulting expenses.

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)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 432,998	$ 204,246
Marketable securities	199,270	150,130
Accounts receivable	1,134	2,429
Prepaid expenses and other current assets	32,874	12,009
Total current assets	666,276	368,814
Marketable securities	150,620	57,312
Property and equipment, net	12,146	12,135
Operating lease right-of-use assets	10,312	11,362
Intangible assets, net	1,856	1,800
Deferred tax assets	838	1,199

Other assets	2,628	2,872
Total assets	$ 844,676	$ 455,494
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,185	$ 4,602
Accrued expenses and other liabilities	36,279	38,482
Income taxes payable	4,876	1,646
Current portion of lease obligation	1,762	1,674
Current portion of deferred revenue	30,974	22,685
Total current liabilities	80,076	69,089
Lease obligation	9,284	10,488
Deferred revenue, net of current portion	52,055	19,574
Total liabilities	141,415	99,151
Commitments and contingencies - Note 6		
Shareholders' equity:		
Common shares, €0.09 par value; 105,000,000 shares authorized at September 30, 2024 and December 31, 2023; 68,426,779 and 57,825,879 shares issued and outstanding as at September 30, 2024 and December 31, 2023, respectively	6,919	5,883
Additional paid-in capital	1,640,930	1,126,054
Accumulated other comprehensive income	(7,124)	(22,533)
Accumulated deficit	(937,464)	(753,061)
Total shareholders' equity	703,261	356,343
Total liabilities and shareholders' equity	$ 844,676	$ 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 11,772	$ 11,033	$ 26,993	$ 35,008
Total revenue	11,772	11,033	26,993	35,008
Operating expenses:				
Research and development	63,239	36,810	150,942	99,973
General and administrative	20,765	12,591	59,466	44,040
Total operating expenses	84,004	49,401	210,408	144,013
Operating loss	(72,232)	(38,368)	(183,415)	(109,005)
Other income, net:				
Interest income, net	10,254	4,522	22,301	9,312
Foreign exchange gains (loss)	(34,950)	11,952	(16,897)	7,062
Total other income (loss), net	(24,696)	16,474	5,404	16,374
Net loss before income taxes	(96,928)	(21,894)	(178,011)	(92,631)
Income tax expense	2,977	1,118	6,392	2,155
Net loss	$ (99,905)	$ (23,012)	$ (184,403)	$ (94,786)
Other comprehensive loss:				
Currency translation adjustment	31,775	(10,722)	15,409	(6,985)
Comprehensive loss	$ (68,130)	$ (33,734)	$ (168,994)	$ (101,771)
Net loss per share attributable to common stockholders: Basic and diluted	$ (1.46)	$ (0.43)	$ (2.94)	$ (1.91)
Weighted-average common shares outstanding: Basic and diluted	68,254,120	53,869,762	62,750,425	49,532,722

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 Zeno through the regulatory, BLA review and potential commercialization processes; our ongoing LiGeR-HN1, LiGeR-HN2 and phase 2 mCRC trials for petosemtamab, our planned update at ESMO Asia in December on the HNSCC 2L+ dose cohort and patients previously reported at AACR 2023; our belief that

petosemtamab has the potential to offer both a first and best in class chemo-free option for r/m HNSCC patients; our belief that a randomized registration trial in HNSCC with an overall response rate endpoint could potentially support accelerated approval and the overall survival results from the same study could potentially verify its clinical benefit to support regular approval; our belief that obtaining a commercialization partnership agreement is an important step in bringing Zeno to patients with NRG1+ cancer, if approved; statements regarding the sufficiency of our cash, cash equivalents and marketable securities, and expectation that it will fund the Company into 2028; the continued investigation of MCLA-145 in combination with pembrolizumab; the investigation of MCLA-129 in monotherapy in Met ex14 NSCLC, and enrolling of patients in the investigation of MCLA-129 in combination with chemotherapy in 2L+ EGFRm NSCLC; our interest in partnering MCLA-129 to sufficiently resource the development of MCLA-129 and the potential benefit it may have for patients; the benefits of the collaborations between Incyte and Merus, Lilly and Merus, Gilead and Merus, and license agreement between Ono and Merus; and the potential of those collaborations and license for future value generation, including whether and when Merus will receive any future payments, 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 September 30, 2024, filed with the Securities and Exchange Commission, or SEC, on October 31, 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.

Multiclonics®, Biclonics® and Triclonics® are registered trademarks of Merus N.V.

Investor and Media Inquiries:
Sherri Spear
Merus N.V.
SVP Investor Relations and Strategic Communications
617-821-3246
s.spear@merus.nl

Kathleen Farren
Merus N.V.
Associate Director Investor Relations and Corporate Communications
617-230-4165
k.farren@merus.nl

Source: Merus N.V.