

# Merus

## Merus Announces Financial Results for the First Quarter 2022 and Provides Business Update

May 9, 2022

- Zenocutuzumab clinical abstract selected for oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting
- Company to host investor call on Sunday, June 5 at 6:00 p.m. CT
- Clinical data update of petosemtamab (Peto) and MCLA-129 planned for second half of 2022

UTRECHT, The Netherlands and CAMBRIDGE, Mass., May 09, 2022 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq: MRUS) ("Merus", the "Company," "we", or "our"), a clinical-stage oncology company developing innovative, full-length multispecific antibodies (Biclomics® and Triclomics®), today announced financial results for the first quarter that ended March 31, 2022, and provided a business update.

"We continue to be encouraged by the ongoing trial of Zeno in patients with NRG1 fusion cancer and we are excited to be presenting a robust clinical update including safety, efficacy and duration of response in an oral presentation at ASCO on June 5<sup>th</sup>," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "We are also looking forward to sharing clinical updates of Peto and MCLA-129 in the second half of 2022 at medical conferences."

### Clinical Programs

#### **Zenocutuzumab (Zeno or MCLA-128: HER3 x HER2 Biclomics®)**

Oral presentation at the 2022 ASCO Annual Meeting

#### **ASCO presentation details:**

**Title:** Efficacy and safety of zenocutuzumab, a HER2 x HER3 bispecific antibody, across advanced NRG1 fusion (NRG1+) cancers

**Lead Author:** Alison Schram, MD, Memorial Sloan Kettering Cancer Center, NY

**Abstract #:** 105

**Session Title:** Clinical Science Symposium/ Bispecifics: Are Two Better Than One?

**Session Date and Time:** June 5, 2022, 9:45 -11:15 a.m. CT

We plan to present updated interim efficacy and safety data from the eNRGy trial and Early Access Program (EAP) of Zeno in patients with NRG1+ cancer. As of February 2022, more than 100 patients with NRG1+ cancer have been treated with Zeno monotherapy in our phase 1/2 eNRGy trial and EAP, with enrollment ongoing. We continue to be encouraged by the observed clinical activity and safety profile in the ongoing trial and look forward to sharing an interim clinical data update at ASCO on June 5.

Details of the eNRGy trial can be found at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and Merus' trial website at [www.nrg1.com](http://www.nrg1.com), or by calling 1-833-NRG-1234.

#### **Company Conference Call and Webcast Information**

Merus will host a conference call and webcast for investors on Sunday, June 5, 2022 at 6:00 p.m. CT. A replay will be available after the completion of the call in the [Investors and Media](#) section of our website for a limited time.

#### **Petosemtamab (Peto or MCLA-158: Lgr5 x EGFR Biclomics®): Solid Tumors**

Dose expansion continues in the phase 1 trial: clinical update planned for second half of 2022

Peto is currently enrolling patients with advanced solid tumors in the expansion phase of a phase 1 open-label, multicenter study. A clinical update is planned for the second half of 2022 at a medical conference.

On April 25, 2022, we announced the publication of a preclinical report of Peto in the journal *Nature Cancer*. The report describes the use of the Company's Biclomics® platform to perform a large-scale functional screen of bispecific antibodies resulting in selection of Peto, a bispecific antibody targeting the epidermal growth factor receptor (EGFR) and the leucine-rich repeat containing G protein-coupled receptor (LGR5). Peto displayed potent growth inhibition of colorectal cancer (CRC) organoids and blockade of metastasis initiation and tumor outgrowth in preclinical models of different tumor types. Peto specifically triggered EGFR degradation in organoids expressing LGR5, while showing minimal toxicity towards normal LGR5-expressing organoids.

#### **MCLA-145 (CD137 x PD-L1 Biclomics®): Solid Tumors**

MCLA-145 is currently enrolling a global, phase 1, open-label, single-agent 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 planning to evaluate the combination of MCLA-145 with a PD-1 blocking antibody.

In January 2022, we announced that Incyte (Nasdaq: INCY) elected to opt-out of its ex-U.S. development of MCLA-145, restoring full global rights to Merus. Under the terms of a 2017 Collaboration and License Agreement ("Agreement") between Merus and Incyte, Incyte's opt-out of ex- U.S. rights to MCLA-145 provides Merus the exclusive right to develop and commercialize potential MCLA-145 products globally. As part of the Agreement, Incyte will continue to support the program for a limited time while ex-U.S. activities are transitioned to Merus, and Incyte will also retain a right to a residual royalty of up to 4% on sales of future commercialization of MCLA-145, if approved.

#### **MCLA-129 (EGFR x c-MET Biclomics®): Solid Tumors**

Dose escalation continues in the phase 1 trial: clinical update planned for the second half of 2022

MCLA-129 is currently enrolling patients in a phase 1/2, open-label clinical trial consisting of dose escalation followed by a planned dose expansion. MCLA-129 is subject to a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. (Betta), which permits Betta to exclusively develop MCLA-129 in China, while Merus retains global rights outside of China. In October 2021, Betta announced that the first patient was dosed in a phase 1/2 trial in China sponsored by Betta, of MCLA-129 in patients with advanced solid tumors. A clinical update is planned for the second half of 2022.

At the American Association for Cancer Research 2022 Annual Meeting, we presented data demonstrating that MCLA-129 promotes antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cell-mediated phagocytosis (ADCP) of non-small cell lung cancer (NSCLC) cells. The data also show MCLA-129 significantly inhibits growth of a patient-derived tumor harboring an EGFR exon20 insertion (exon20ins) mutation, in a preclinical xenograft model.

The poster can be found on our [website](#).

#### Corporate Activities

##### Shannon Campbell Appointed as Chief Commercial Officer

In January 2022, Merus appointed Ms. Campbell as Executive Vice President and Chief Commercial Officer to lead the commercial strategy for the most advanced clinical candidate, Zeno, as well as Merus' robust pipeline of multispecific product candidates in development. Ms. Campbell brings over 25 years of pharmaceutical commercialization experience and joins Merus from Novartis Pharmaceuticals Corporation, where she led Novartis's U.S. Oncology Solid Tumor Franchise and was responsible for a broad portfolio of therapies in oncology and rare diseases. Prior to Novartis, Ms. Campbell was with Bayer HealthCare Pharmaceuticals, where she was instrumental in helping to build, launch and lead Bayer's U.S. Oncology business.

##### Cash Runway, Merus expects to be funded beyond 2024

Based on the Company's current operating plan, Merus expects our existing cash, cash equivalents and marketable securities will fund Merus' operations beyond 2024.

##### Annual General Meeting and Board of Directors

The Company's annual general meeting of shareholders (AGM) is planned to be held on May 31, 2022.

##### First Quarter 2022 Financial Results

We ended the first quarter with cash, cash equivalents and marketable securities of \$384.3 million compared to \$430.8 million at December 31, 2021. The decrease was primarily the result of cash used to fund the operations.

Collaboration revenue for the three months ended March 31, 2022 increased by \$3.4 million as compared to the three months ended March 31, 2021, primarily as a result of an increase from a Lilly upfront payment amortization and reimbursement revenues of \$3.6 million. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended March 31, 2022 increased by \$6.2 million as compared to the three months ended March 31, 2021, primarily as a result of an increase in clinical and manufacturing costs related to our programs and stock-based compensation.

General and administrative expense for the three months ended March 31, 2022 increased by \$2.4 million as compared to the three months ended March 31, 2021, primarily as a result of an increase in stock-based compensation 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 per share data)**

	<b>March 31, 2022</b>	<b>December 31, 2021</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 194,575	\$ 241,435
Marketable securities	164,239	168,990
Accounts receivable	2,671	1,697
Accounts receivable (related party)	—	4,609
Prepaid expenses and other current assets	18,248	7,448
Total current assets	379,733	424,179
Marketable securities	25,466	20,297
Property and equipment, net	3,509	3,549
Operating lease right-of-use assets	3,334	3,733
Intangible assets, net	2,233	2,347
Deferred tax assets	80	417
Other assets	3,145	2,078
Total assets	\$ 417,500	\$ 456,600
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,388	\$ 13,237
Accrued expenses and other liabilities	20,948	22,506
Income taxes payable	—	—
Current portion of lease obligation	1,491	1,494
Current portion of deferred revenue	33,696	16,613
Current portion of deferred revenue (related party)	—	18,048
Total current liabilities	61,523	71,898
Lease obligation	1,874	2,257

Deferred revenue, net of current portion	56,630	10,962
Deferred revenue, net of current portion (related party)	—	55,282
Total liabilities	120,027	140,399
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 shares authorized; 43,549,325 and 43,467,052 shares issued and outstanding as at March 31, 2022 and December 31, 2021, respectively	\$ 4,489	\$ 4,481
9,22Additional paid-in capital	794,074	787,869
Accumulated other comprehensive income	(15,269)	(9,221)
Accumulated deficit	(485,821)	(466,928)
Total stockholders' equity	297,473	316,201
Total liabilities and stockholders' equity	\$ 417,500	\$ 456,600

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

	Three Months Ended March 31,	
	2022	2021
Collaboration revenue	\$ 11,655	\$ 1,599
Collaboration revenue (related party)	—	6,751
Total revenue	11,655	8,350
Operating expenses:		
Research and development	26,975	20,806
General and administrative	11,753	9,333
Total operating expenses	38,728	30,139
Operating loss	(27,073)	(21,789)
Other income, net:		
Interest (expense) income, net	106	(82)
Foreign exchange gains	7,730	12,203
Other losses	458	(437)
Total other income, net	8,294	11,684
Net loss before income taxes	(18,779)	(10,105)
Income tax expense	114	49
Net loss	\$ (18,893)	\$ (10,154)
Other comprehensive loss:		
Currency translation adjustment	(6,048)	(9,391)
Comprehensive loss	\$ (24,941)	\$ (19,545)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.43)	\$ (0.52)
Weighted-average common shares outstanding:		
Basic and diluted	43,490	36,210

**About Merus N.V.**

Merus is a clinical-stage oncology company developing innovative full-length human bispecific and trispecific antibody therapeutics, referred to as Multiclomics®. Multiclomics® 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, <http://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 planned clinical updates for our product candidates, including with respect to enrollment and timing of data in our eNRGy trial, and the treatment potential of Zeno; statements regarding the sufficiency of our cash, cash equivalents and marketable securities; the advancement of the phase 1/2 eNRGy trial and planned interim clinical data update at ASCO from that trial and EAP; the advancement of the Phase 1 trial of MCLA-145, as monotherapy and planned combination with a PD-1 blocking antibody; the advancement of the phase 1 trial for Peto and the content and timing of a planned update in second half of 2022; the advancement of the phase 1/2 trial for MCLA-129 and the content and timing of a planned update in second half of 2022; the design and treatment potential of our bispecific antibody candidates and impact of their preclinical data; our global collaboration and license agreement with Incyte; our collaboration and license agreement with Betta, which permits Betta to exclusively develop MCLA-129 in China, while Merus retains full ex-China rights, and any developments that may arise from these agreements; and Merus' appointment of Ms. Campbell as Senior Vice President & Chief Commercial Officer to lead the commercial strategy. 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 development of our product candidates, and the potential for those third parties to not perform satisfactorily; impacts of the COVID-19 pandemic; we may not identify

suitable Biclomics® 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 Quarterly Report on Form 10-Q for the period ended March 31, 2022, filed with the Securities and Exchange Commission, or SEC, on May 9, 2022, 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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The Merus logo consists of the word "Merus" in a bold, blue, sans-serif font. The letter 'M' is significantly larger than the other letters, and the 'e' and 's' are also larger than the 'r' and 'u'. The logo is positioned in the lower-left quadrant of the page.