Merus Announces Financial Results for the Second Quarter and Provides Business Update

August 5, 2021

UTRECHT, The Netherlands and CAMBRIDGE, Mass., Aug. 05, 2021 (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 second quarter that ended June 30, 2021 and provided a business update.

"We are encouraged by the interim results on Zeno in patients with NRG1 fusion cancers that we reported in the second quarter and remain focused on successful execution of our Zeno program and our other clinical trials," said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. "We are planning to provide a clinical update on MCLA-145 and MCLA-158 later this year."

Clinical Programs

Zenocutuzumab (Zeno or MCLA-128: HER3 x HER2 Biclonics®)

Phase 2 part of the phase 1/2 trial continues: update planned by the first half of 2022

We shared interim clinical data of our zenocutuzumab (Zeno) program in patients with NRG1 fusion (NRG1+) cancers at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting. The highlights from the presentation included:

- As of the April 13, 2021, efficacy data cutoff, 61 patients with NRG1+ cancer were enrolled, including 45 patients evaluable for response.
- Encouraging early clinical activity was observed, with confirmed partial responses by investigator review (RECIST v1.1) in 42% (5 of 12) patients with pancreatic cancer and in 29% (13 of 45) patients across all NRG1+ tumor types treated.
    - One additional partial response was confirmed after the data cutoff date, which if included in the interim efficacy analysis, would increase the percentage of confirmed partial responses across all NRG1+ tumor types treated to 31% (14 of 45 patients).
- More than three quarters (34 of 45) of evaluable patients showed tumor reduction. In addition, 40% (19 of 47) of all patients remained on therapy as of the data cutoff date.
- Zeno continues to be well tolerated with a favorable safety profile.

As of June 4, 2021, more than 70 patients had been treated in the eNRGy trial and Early Access Program (EAP). We continue to be encouraged by the ongoing trial, rate of enrollment, observed clinical activity and safety profile, and plan to provide a clinical and regulatory program update by the first half of 2022.

In the second quarter of 2021, we entered into collaborations with several companies and medical organizations in Israel, Italy and Spain with the goal of raising awareness of the eNRGy trial and providing access to molecular screening opportunities for eligible patients with cancers that may have NRG1 fusions. Merus is now working with more than ten different industry and academic collaborators across Asia, North America and Europe aimed to enhance testing for NRG1 fusions, to raise awareness of and support enrollment into the eNRGy trial.

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

MCLA-158 (Lgr5 x EGFR Biclonics®): Solid Tumors

Phase 1 trial continues with dose expansion cohorts: update planned for Q4'21

The phase 1, open-label, multicenter clinical trial of MCLA-158 is ongoing in the dose expansion phase. Enrollment of patients with gastro-esophageal and head-and-neck cancers continues, and preliminary evidence of antitumor activity has been observed. We plan to provide an update at a medical conference in the fourth quarter of 2021.

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

Phase 1 trial continues: update planned for Q4'21

The phase 1, open-label, single-agent clinical trial of MCLA-145 is ongoing and consists of a dose escalation phase, to be followed by a planned dose expansion phase. MCLA-145 is the first drug candidate co-developed under Merus' global collaboration and license agreement with Incyte Corporation ("Incyte"), which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from the Biclonics® platform. Merus retains full rights to develop and commercialize MCLA-145, if approved, in the United States; and Incyte holds full rights to develop and commercialize MCLA-145 outside the United States. We plan to provide an update at a medical conference in the fourth quarter of 2021.

We published a report in *Nature Communications* in July titled "A human CD137×PD-L1 bispecific antibody promotes anti-tumor immunity via context dependent T cell costimulation and checkpoint blockade" demonstrating in preclinical models that MCLA-145 potently activates T cells, even in the presence of suppressive conditions, as well as enhances T cell priming and promotes long-term T cell immunity. In addition, the antitumor activity of MCLA-145 in *in vivo* models was superior to those of the current standard immune checkpoint inhibitor comparators and associated with recruitment and intratumoral expansion of CD8+ T cells.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors

The phase 1/2, open-label, single-agent clinical trial of MCLA-129 is ongoing and consists of a dose escalation phase, to be followed by planned expansion cohorts evaluating MCLA-129 for the treatment of patients with advanced non-small cell lung cancer (NSCLC) and other solid tumors. MCLA-129 is a Biclonics®, which binds to EGFR and c-MET and is being investigated for the treatment of solid tumors. EGFR is an important oncogenic driver in many cancers, and upregulation of c-MET signaling has been associated with resistance to EGFR inhibition.

Second Quarter 2021 Financial Results

We ended the second quarter with cash, cash equivalents and marketable securities of $352.8 million compared to $207.8 million at December 31, 2020. The increase was primarily the result of net proceeds from our follow-on offering and proceeds from the collaboration with and equity investment by Eli Lilly and Company ("Lilly"), net of cash used in operations and other items. Based on the Company's current operating plan, we expect that our existing cash and cash equivalents and marketable securities of $352.8 million as of June 30, 2021, will fund the Company's operations into the second half of 2024.

Collaboration revenue for the three months ended June 30, 2021 increased by $6.3 million as compared to the three months ended June 30, 2020, primarily as a result of an increase from a Lilly upfront payment amortization and reimbursement revenues of $4.6 million that commenced in the first quarter of 2021, and a $1.4 million increase primarily in reimbursement revenues related to Incyte reflecting activities in the period for MCLA-145. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the three months ended June 30, 2021 increased by $10.9 million as compared to the three months ended June 30, 2020, 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 June 30, 2021 increased by $2.6 million as compared to the three months ended June 30, 2020, primarily as a result of an increase in stock-based compensation and other personnel related expenses as well as facilities and professional fees, partially offset by decreases in legal and IP related costs.

Collaboration revenue for the six months ended June 30, 2021 increased by $8.4 million as compared to the six months ended June 30, 2020, primarily as a result of an increase from a Lilly upfront payment amortization and reimbursement revenues of $6.0 million that commenced in the first quarter of 2021, and a $2.2 million increase primarily in reimbursement revenues related to Incyte reflecting activities in the period for MCLA-145. The change in exchange rates did not significantly impact collaboration revenue.

Research and development expense for the six months ended June 30, 2021 increased by $14.7 million as compared to the six months ended June 30, 2020, 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 six months ended June 30, 2021 increased by $3.0 million as compared to the three months ended June 30, 2020, primarily as a result of an increase in stock-based compensation and other personnel related expenses as well as facilities and professional fees, partially offset by decreases in legal and IP related costs and travel 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)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 311,472	$ 163,082
Marketable securities	41,280	44,673
Accounts receivable	1,471	46
Accounts receivable (related party)	2,212	1,623
Prepaid expenses and other current assets	10,559	8,569
Total current assets	366,994	217,993
Property and equipment, net	3,596	4,115
Operating lease right-of-use assets	4,762	3,907
Intangible assets, net	2,608	2,843
Deferred tax assets	140	410
Other assets	1,483	1,949
Total assets	$ 379,583	$ 231,217
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,160	$ 3,126
Accrued expenses and other liabilities	24,529	21,803
Income taxes payable	—	206
Current portion of lease obligation	1,597	1,432
Current portion of deferred revenue	13,184	625
Current portion of deferred revenue (related party)	18,937	19,554
Total current liabilities	64,407	46,746
Lease obligation	3,198	2,521
Deferred revenue, net of current portion	25,338	237
Deferred revenue, net of current portion (related party)	67,553	79,450
Total liabilities	160,496	128,954

Commitments and contingencies - Note 6		
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 38,444,580 and 31,602,953 shares issued and outstanding as at June 30, 2021 and December 31, 2020, respectively	$ 3,959	$ 3,211
Additional paid-in capital	649,627	490,093
Accumulated other comprehensive income	3,155	9,071
Accumulated deficit	(437,654)	(400,112)
Total stockholders' equity	219,087	102,263
Total liabilities and stockholders' equity	$ 379,583	$ 231,217

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue	$ 5,118	$ 184	$ 6,717	$ 512
Collaboration revenue (related party)	7,261	5,872	14,012	11,845
Total revenue	12,379	6,056	20,729	12,357
Operating expenses:				
Research and development	24,612	13,709	45,418	30,696
General and administrative	10,569	8,043	19,902	16,925
Total operating expenses	35,181	21,752	65,320	47,621
Operating loss	(22,802)	(15,696)	(44,591)	(35,264)
Other (loss) income, net:				
Interest (expense) income, net	(51)	99	(133)	379
Foreign exchange (losses) gains, net	(4,525)	(2,346)	7,678	539
Other (losses) gains, net	52	—	(385)	—
Total other (loss) income, net	(4,524)	(2,247)	7,160	918
Net loss before income taxes	(27,326)	(17,943)	(37,431)	(34,346)
Income tax expense	62	31	111	128
Net loss	$ (27,388)	$ (17,974)	$ (37,542)	$ (34,474)
Other comprehensive income (loss):				
Currency translation adjustment	3,475	2,201	(5,916)	(906)
Comprehensive loss	$ (23,913)	$ (15,773)	$ (43,458)	$ (35,380)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.71)	$ (0.54)	$ (1.01)	$ (1.22)
Weighted-average common shares outstanding:				
Basic and diluted	38,376	29,034	37,299	28,990

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 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, statements regarding the sufficiency of our cash, cash equivalents and marketable securities; the content and timing of potential milestones, updates, guidance, information, clinical trials and data readouts for our product candidates, including with respect to our focus on successful execution of our Zeno program and our other clinical trials; the advancement of the phase 1/2 eNRGy trial and planned update by the first half of 2022, the advancement of the Phase 1 trial of MCLA-145, and planned update in the fourth quarter of 2021, the advancement of the phase 1 trial for MCLA-158 and the planned update in the fourth quarter of 2021, and the advancement of the phase 1/2 trial for MCLA-129; the design and treatment potential of our bispecific antibody candidates, clinical study designs, the preclinical data and further advancement of our internal pipeline; the impact and benefit, if any, from increased agreements and collaborations with companies and medical organizations in North America, Europe and Asia with the goal of raising awareness of the eNRGy trial and providing molecular screening opportunities for eligible patients with cancers that may have NRG1 fusions; the continued enrollment of patients with gastro-esophageal and head-and-neck cancer in the MCLA-158 trial in the dose expansion phase, and preliminary evidence of antitumor activity observed; and our global collaboration and license agreement with Incyte, its progress and potential development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform. 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; 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 10-K for the period ended December 31, 2020 filed with the Securities and Exchange Commission, or SEC, on March 16 2021, 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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