UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): May 19, 2020

MERUS N.V.

(Exact name of registrant as specified in its charter)

The Netherlands (State or other jurisdiction of incorporation or organization)

001-37773 (Commission File Number) Not Applicable (I.R.S. Employer Identification No.)

Yalelaan 62 3584 CM Utrecht The Netherlands

(Address of principal executive offices) (Zip Code)

+31 85 016 2500

(Registrant's telephone number, including area code)

N/A (Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

Name of each exchange on which **Title of each class**Common Shares, €0.09 nominal value per share registered
The Nasdaq Global Market Trading Symbol(s)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \boxtimes

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \boxtimes

Item 7.01 Regulation FD Disclosure.

On May 19, 2020, Merus N.V. (the "Company") posted an updated corporate slide presentation in the "Investors and Media" portion of its website at www.merus.nl including updates to its clinical programs for MCLA-128 also referred to as zenocutuzumab, MCLA-117, MCLA-158 and MCLA-145. A copy of the slide presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relates to Item 7.01, which shall be deemed to be furnished, and not filed:

Exhibit

No. Description

99.1 <u>Merus N.V. Corporate Slide Presentation as of May 19, 2020</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

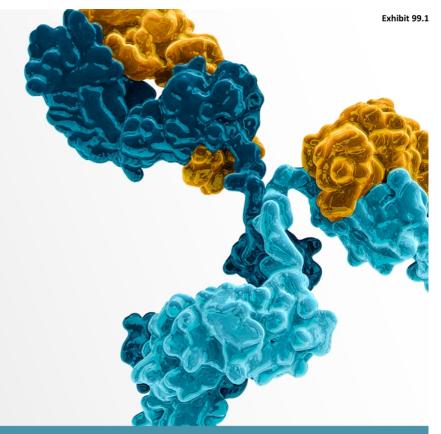
MERUS N.V.

Date: May 19, 2020

By: /S ven A. Lundberg
Name: Sven (Bill) Ante Lundberg
Title: President, Chief Executive Officer and Principal Financial Officer



May 2020



Disclaimer

This presentation (including any oral commentary that accompanies this presentation) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the impact our Biclonics® platform can have on cancer, our product candidates potential to treat certain types of tumors, the timing of regulatory filings and the timing and anticipated data read outs or results from our clinical trials and our collaborations. 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: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding, which may not be available and which may require us to restrict out operations or require us to relinquish rights to our technologies or bispecific antibody candidates; potential delays in regulatory approval and impacts of the COVID-19 pandemic, which would impact our ability to commercialize our product candidates and affect our ability to generate revenue; the unproven approach to therapeutic intervention of our Biclonics®, and Triclonics™ technology; our limited operating history; economic, political, regulatory and other risks involved with international operations; 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 adverse public reaction to the use of cancer immunotherapies; potential delays in enrollment of patients, which could affect the receipt of necessary regulatory approvals; failure to obtain marketing approval internationally; failure to compete successfully against other drug companies; potential competition from other drug companies if we fail to obtain orphan drug designation or maintain orphan drug exclusivity for our products; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; 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 being found invalid or unenforceable; potential lawsuits for infringement of third-party intellectual property; our ability to attract and retain key personnel; managing our growth could result in difficulties; and we may lose our foreign private issuer status and incur significant expenses as a result.

These and other important factors discussed under the caption "Risk Factors" in our in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 filed with the Securities and Exchange Commission, or SEC, on May 11, 2020, 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 presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. 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.

Merus Merus

Merus Overview



Multispecific Antibody Therapies for Oncology

Bispecific and trispecific cancer therapies based on the human IgG format



Established Clinical Pipeline and Preclinical Programs

Clinical proof-of-concept with zenocutuzumab in NRG1+ cancers



Multiclonics® Platforms

Common light chain format enables broad high throughput Biclonics® and Triclonics™ discovery and engineering



Strategic Collaborations to Unlock Platform Value

 $\label{eq:multiple strategic collaborations and license agreements: Incyte, Betta, Simcere and Ono$



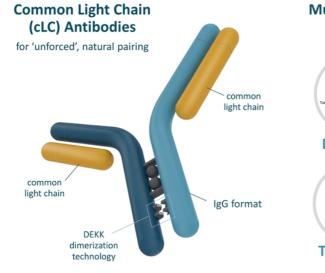
2020-2021 Data Readouts and Program Updates

Zeno NRG-1 phase 1/2 clinical data by end of 2020



Our Science — Multiclonics® Technology

Optimizing the next generation of multispecific antibody therapies



Multiclonics® Format



Biclonics®



Extensive capacity for discovery and engineering

- Common light chains allow for "natural" pairing with heavy chains
- Proprietary DEKK technology allows for efficient multi-specific production
- Fully human IgG format
 - Manufacturability
 - Low immunogenicity
 - Predictable in vivo behavior
- Robust IP portfolio
 - Patents covering our common light chain antibody generation, dimerization and more

Merus

4

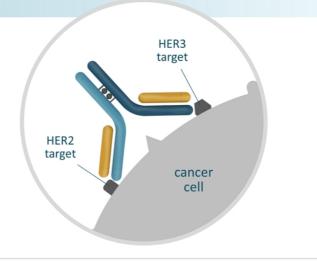
PROGRAM	BISPECIFIC TARGETS	INDICATION(S)	PRECLINICAL	PHASE 1	PHASE 1/2	STATUS
Zenocutuzumab (MCLA-128)	HER3 x HER2	NRG-1 fusion Pancreatic NRG-1 fusion Lung NRG-1 fusion Other solid tumors				Phase 1/2 trial ongoing Update expected by the end of 2020
MCLA-158	Lgr5 x EGFR	Solid tumors				Phase 1 Trial Ongoing
MCLA-145	CD137 x PD-L1	Solid tumors	Incyte (ex- U.S.)			Phase 1 Trial Ongoing
MCLA-129	EGFR x c-MET	Solid tumors	(China)			IND Enabling Studies Ongoing
ONO-4685*	PD-1 x CD3	Autoimmune disease	ono			Phase 1 Trial Ongoing
*	Undisclosed	Autoimmune disease	ono			

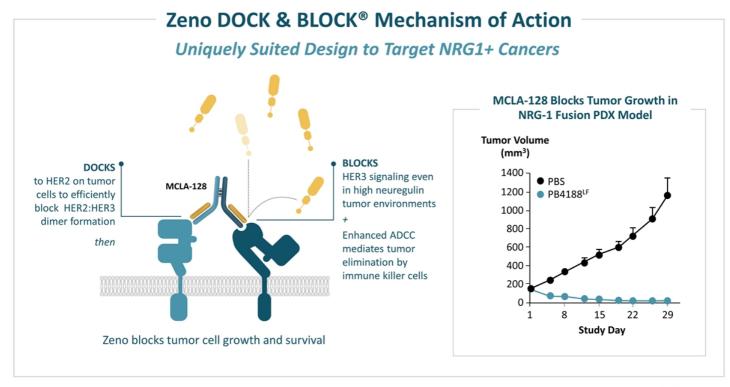
Promising early clinical activity in patients with NRG1+ cancers

Zenocutuzumab

MCLA-128 or "Zeno" HER2 x HER3 bispecific

- NRG-1 fusions (NRG1+) are rare genetic events occurring in lung, pancreatic and other solid tumors
- Unique DOCK & BLOCK® mechanism of Zeno potently inhibits NRG1-driven tumor growth
- Enhanced ADCC mediates tumor elimination by immune effector cells
- eNRGy Trial enrolling and Early Access Program ongoing
- Next program update expected around end of 2020





Zeno Safety Profile for Single Agent Use

Safety Data in Over 100 Patients in Phase 1/2 Trials



Safety and Tolerability in Phase 1/2 Trial

117 PATIENTS EVALUATED*

MCLA-128 Dosing: 750 mg ranging from q1w-q3w

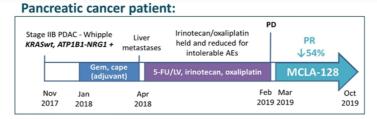
- Single agent well tolerated
- Low risk for immunogenicity
- Most AEs were grade 1-2
- No severe related gastrointestinal or skin toxicity

Data cut off: Jan-2019. Refer to https://merus.nl/publications/ for full data presented. Refer to ASCO poster 2018 and AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2019 https://merus.nl/app/uploads/2019/10/AACR-NCI-EORTC Poster-LB-812 NRG1-MCLA-128 10252019 FINAL.pdf



Zeno Clinical Responses in NRG1+ Cancers

Patient Data Presented at 2019 AACR-NCI-EORTC International Conference





Source: AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2019 https://merus.nl/app/uploads/2019/10/AACR-NCI-EORTC_Poster-LB-B12_NRG1-MCLA-128_10252019_FINAL.pdf,

Zeno Clinical Responses in NRG1+ Cancers

Clinical Activity Reported by MSKCC at 2019 AACR-NCI-EORTC International Conference

	PANCREATIC CANCER		LUNG CANCER	
Tumor size reduction	54% (PR)	25% (SD)	41% (PR)	
PET scan	Neg	Neg	nd	
Decline in tumor marker	~75%	~90%	N/A	
Duration of treatment (mo)	>7*	>7*	~ 5*	

Source: AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2019 https://merus.nl/app/uploads/2019/10/AACR-NCI-EORTC_Poster-LB-B12_NRG1-MCLA-128_10252019_FINAL.pdf

Overall Experience with Zeno in NRG1+ Tumors as of October 2019

	N	PANCREATIC CANCER	LUNG CANCER
Evaluable	6	PR 7 mo*; SD 7 mo	PR 5 mo*; SD 7 mo; PD; PD
Non-evaluable	3 Died of p prior to		2 Pts not yet at first evaluation

⁵ patients enrolled on the eNRGy trial; 4 patients treated under Early Access Program



Source: Merus Press Release Oct 27, 2019 https://ir.merus.nl/news-releases/news-release-details/*Indicates treatment was ongoing at the time of the conference; nd, no data; N/A, not applicable

Zeno Clinical Programs in NRG1+ Cancers

eNRGy Clinical Trial and Early Access Program ongoing



- Phase 1/2 global single arm trial of Zeno in NRG1+ cancers
- · Cohorts include Pancreatic, Lung, and other solid tumors
- Majority of clinical trial sites open and enrolling
- Ongoing Phase 1/2 trial update expected by the end of 2020







Early Access Program

- For eligible patients who do not enroll on the eNRGy trial
- Allows patients with NRG1+ cancers to receive treatment with Zeno
- Evaluations and patient follow up may be similar to eNRGy protocol
- May provide additional clinical data in support of Zeno NRG1+ program

Identifying and Recruiting NRG-1+ Patients

NRG1 Fusions are Found Across **Multiple Solid Tumor Types**

TUMOR TYPE		ESTIMATED Incidence (%)	
新春	Lung	0.3 – 3.0	
T	Pancreas	0.5 – 1.5	
	Other	< 1.0	

Comprehensive Effort to Identify and Recruit NRG1+ Patients







IDENTIFICATION

Patient testing and physician engagement campaigns

COLLABORATION

Physician, trial site engagement & support 1-833-NRG-1234 www.nrg1.com

PLACEMENT

Patient logistics / support for eNRGy trial or EAP



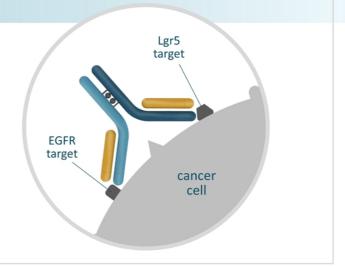
Early Access Program

Designed to potently block signaling and growth in Wnt-dysregulated solid tumors

MCLA-158

Lgr5 x EGFR bispecific

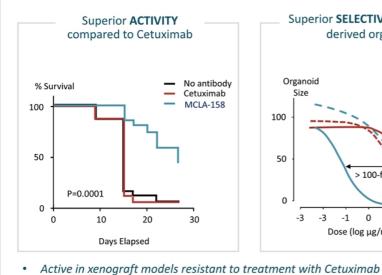
- Lgr5 is an intestinal cancer initiating cell antigen
- Blocks growth in Wnt-dysregulated tumor models including ${\sf Ras}^{\it mut}$
- Modifications to enhance ADCC
- Global phase 1 clinical trial enrolling

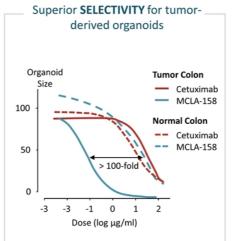


Merus Merus

MCLA-158 Novel Target and Innovative MoA

Superior growth inhibition and selectivity of tumor versus healthy tissue





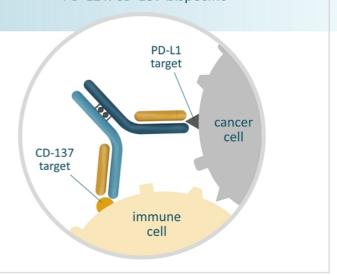
- Ongoing Phase 1 Trial
- Binds to Lgr5 and EGFR
- Global open-label Phase 1 dose escalation trial
- Protocol includes dose expansion phase at RP2D
- MCLA-158 discriminates between organoids derived from tumor and healthy tissue



Designed to recruit and activate tumor infiltrating T-cells

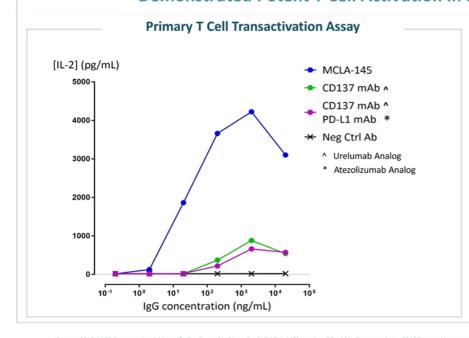
MCLA-145 PD-L1 x CD-137 bispecific

- CD137 is a potent activator of tumor infiltrating T-cells
- Targeting to PD-L1 positive cells in the tumor and blocking the PD-1/PD-L1 inhibitory signal
- Global phase 1 trial ongoing in partnership with Incyte



MCLA-145 Targets PD-L1 Positive Tumor Cells

Demonstrated Potent T Cell Activation in Preclinical Studies



Ongoing Phase 1 Trial

- Binds to PD-L1 on tumor cells and CD137 (4-1BB) on activated T-cells
- Global open-label Phase 1 dose escalation trial ongoing
- Clinical trial co-developed in collaboration with Incyte Corporation

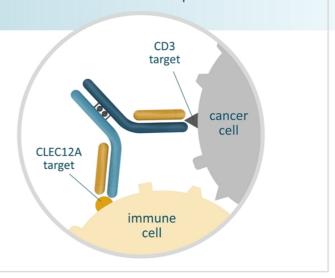
• Source: 2019 AACR Presentation A bispecific Fc-silenced IgG1 antibody (MCLA-145) requires PD-L1 binding to activate CD137 https://merus.nl/app/uploads/2019/04/IC171-19E-AACR19-Mayes-MCLA-145-MoA-Poster MT06 for-approval-032019.pdf



Interim phase 1 trial results of novel T-cell engager at EHA 2020

- · Designed with lower affinity CD3 binding
- Reduced risk of cytokine release syndrome, acceptable safety profile
- Active in acute myeloid leukemia (AML) with Tcell activation, cytokine elevation and AML blast reductions in some patients
- Insufficient clinical activity in escalation to continue to enroll dose expansion cohorts
- Findings from this trial expected to inform further development of our extensive proprietary T-cell engager platform.

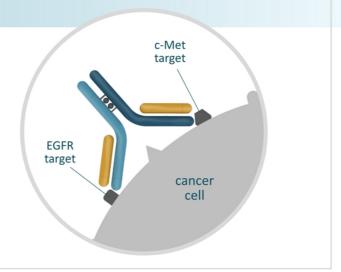
MCLA-117 CLEC12A x CD3 bispecific



Designed to target lung cancer and other solid tumors

MCLA-129 c-MET x EGFR Bispecific

- Targets both c-Met and EGFR on cancer cell models as well as resistance mechanism
- Preclinical program directed at a targetpair combination with clinical validation
- Significant opportunity in lung cancer and other solid tumors



Merus Merus

Merus Collaborations & Licensing Agreements

Expanding Merus pipeline through development of innovative therapeutics

INCYTE CORPORATION

Global Collaboration up to 11 bispecific and monospecific antibodies from the Biclonics® platform

Merus has full U.S. rights to develop, commercialize MCLA-145 BETTA
PHARMACEUTICALS
CO. LTD.

MCLA-129 EGFR x C-MET Collaboration

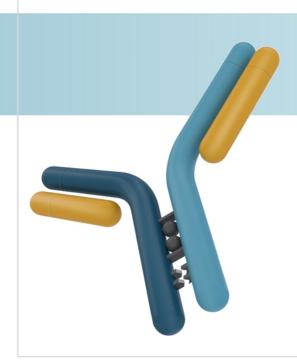
Betta conducting IND-enabling studies; Merus has global rights ex-China SIMCERE PHARMACEUTICAL CORP

> Collaboration with 3 Immuno-oncology Biclonics® programs

Simcere responsible for IND-enabling studies; Merus has global rights ex-China ONO
PHARMACEUTICAL
CO. LTD.

Biclonics® Licensing Agreement for Autoimmune diseases

Phase 1 trial in Japan for ONO-4685, a PD-1 x CD3 bispecific antibody



Merus Multiclonics® Antibody Platforms

- Extensive landscape of cLC antibodies against targets, multi-specific formats, and ways of killing cancer cells
- Transgenic Merus Mouse (MeMo®) for human cLC antibody production
- Sophisticated, automated molecular biology and screening thousands of target combinations of choice
- Novel insights and unique understanding of multispecific approaches to killing cancer cells

Merus Overview



Multispecific Antibody Therapies for Oncology

Bispecific and trispecific cancer therapies based on the human IgG format



Established Clinical Pipeline and Preclinical Programs

Clinical proof-of-concept with zenocutuzumab in NRG1+ cancers



Multiclonics® Platforms

Common light chain format enables broad high throughput Biclonics® and Triclonics™ discovery and engineering



Strategic Collaborations to Unlock Platform Value

 $\label{eq:multiple strategic collaborations and license agreements: Incyte, Betta, Simcere and Ono$



2020-2021 Data Readouts and Program Updates

Zeno NRG-1 phase 1/2 clinical data by end of 2020

