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): January 9, 2023

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

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

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 \Box

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.

Item 7.01 Regulation FD Disclosure

On January 9, 2023, Merus N.V. (the "Company") posted an updated corporate slide presentation in the "Investors and Media" portion of its website at www.merus.nl providing updates including, among other things, that: (i) as of September 30, 2022, the Company had \$372.9 million in cash and cash equivalents, which after undergoing the Company's 2023 budgeting process and based on the Company's current operating plan, the Company is existing cash, eash equivalents and marketable securities are expected to fund the Company's operations into the second half of 2025; (ii) the Company reports updated planned milestones including a clinical update planned for the phase 1/2 eNRGy trial of Zeno in NRG1 fusion ("NRG1+") cancer in 2023, an update on the potential registrational path and timeline of Zeno in NRG1+ cancer planned for the first half of 2023, a planned route to RPC planned for the second half of 2023, a planned regulatory path and program update for petosemtamab in the first half of 2023, and gastric esophageal cancer in the first half of 2023, a planned regulatory path and program update for petosemtamab in the first half of 2023, and a planned initial clinical data update as of January 8, 2023, which indicated this update was expected to occur in the second half of 2023, and a planned initial clinical data ta data ta base for the expansion cohorts of MCLA-129 and development strategy update for MCLA-129 in the second half of 2023. A copy of the slide presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K ("Current Report").

The information in this Item 7.01 of this Current Report, 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.

Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Current Report are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements regarding our plans to develop and commercialize our product candidates, the timing of our ongoing or planned clinical trials or updates concerning such trials, the timing of and our ability to obtain and maintain regulatory approvals, the clinical utility and commercial potential of our product candidates, our commercialization, marketing and manufacturing capabilities and strategy, our expectations surrounding our cluaborations, our expectations about the willingness of healthcare professionals to use our product candidates, the sufficiency of our cash, cash equivalents to fund our operations, and the plans and objectives of management for future operations and capital expenditures are forward-looking statements.

The forward-looking statements in this Current Report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date

of this Current Report and are subject to a number of known and unknown risks, uncertainties, assumptions and other important factors, including those discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the period ended September 30, 2022, filed with the Securities and Exchange Commission, or SEC, on November 3, 2022, and our other reports filed with the SEC, which could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in such forward-looking statements may on be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. 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 Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following Exhibit 99.1 relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit	
NO.	Description
99.1	Merus N

99.1 Merus N.V. Corporate Slide Presentation as of January 9, 2023

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: January 9, 2023

 By:
 /s/ Sven A. Lundberg

 Name:
 Sven (Bill) Ante Lundberg

 Title:
 President, Chief Executive Officer and Principal Financial Officer

Merus closing in on cancer

Corporate Presentation

January 2023



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® and Triclonics* platforms 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 readouts, updates or results from our clinical trials and our collaborations, and anticipated cash runway. 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 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 therapies; 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 perform clinical development 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.

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, 2022 filed on November 3, 2022 with the Securities and Exchange Commission, or SEC, 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.



* Based on 2023 budgeting process and the current operating plan, the existing cash, cash equivalents and marketable securities are expected to fund Merus' operations into second half 2025.



Merus Clinical Pipeline

PROGRAM	BISPECIFIC TARGETS	INDICATION(S)	PRECLINICAL	PHASE 1	PHASE 1/2	STATUS
		NRG1+ cancer				 Phase 1/2 registration- directed trial ongoing in
Zenocutuzumab		with afatinib in NRG1+ NSCLC				NRG1+ cancer
(Zeno) HER2 x HER3 (MCLA-128)	Castration resistant prostate cancer				 Clinical update in NRG1+ cancer planned 2023 	
		Other cancers				 Initial clinical data update on Zeno in CPRC planned 2H23
Petosemtamab (MCLA-158) LGR5 x EGFR	Solid tumors				Phase 1 trial ongoing	
	Solid turnors				Clinical update planned 1H23	
MCI A-145		Solid tumors				Phase 1 trial ongoing
MCCA-145	CD137 X PD-L1	with a PD1 inhibitor in solid tumors				
MCI A 129		Solid tumors	(China)			Phase 1/2 trial ongoing
WCLA-129 EGFR X C-WEI	with a 3rd gen EGFR TKI in NSCLC				Clinical update planned 2H23	
ONO-4685*		Relapsed/Refractory T Cell				Phase 1 trial ongoing
		Lymphoma; Psoriasis				i nove z thei ongoing
INCA32459*	LAG3 x PD-1	Not disclosed	Incore			 Clinical program expected to begin in 2022**

* If commercialized, Merus to receive royalties ** Incyte presentation dated August 2, 2022

Potential first in class and best in class for NRG1 fusion (NRG1+) cancer

• NRG1 fusions

- Translocations of the Neuregulin-1 (NRG1) gene, also called Heregulin, the ligand for the HER3 receptor. Rare events in solid tumors reported to typically occur in the absence of other cancer driver mutations¹
- Reported as associated with poor prognosis¹, lower response rates to standard therapy², and shorter overall survival in lung cancer^{1,3}

Zeno

- Biclonics[®] antibody binds to HER2 and blocks HER3; 100-fold more potent *in vitro* than anti-HER3 mAbs tested
- Granted orphan and fast track designation by FDA for pancreatic cancer, and NRG1+ cancer post standard of care, respectively
- Enrollment in eNRGy trial continues to support potential BLA⁴ filings in NRG1+ NSCLC⁴ and/or PDAC⁴, with potential subsequent tissue agnostic filing
- Additional clinical study ongoing in CRPC, and planned for NRG1+ NSCLC (Zeno with afatinib)⁴

¹ Chang et al., Clin Cancer Research 2021, ² Drilon et al., J Clin Oncol 2021, ³ Shin et al., Oncotarget 2016, 4 BLA, Biologics License Application; NSCLC, non-small cell lung cancer; PDAC, pancreatic ductal adenocarcinoma; and CRPC, castration-resistant prostate cancer

Zenocutuzumab MCLA-128 or "Zeno"

HER2 x HER3 bispecific



Zeno DOCK & BLOCK[®] Mechanism Potently Blocks NRG1 fusions



0.001

0.01

0.1

IgG concentration (nM)

Growth of N87 cells with 12.5 nM HRG and a titration of the indicated antib

Unique-Targeting of NRG1+ Cancer

Shown to Potently Inhibit Growth and NRG1:HER3 Signalling Preclinically

10

1

Geuijen et al. Cancer Cell. 2018;33:922-36; Odintsov et al. AACR. 2021; abstract 956; Schram et al., ASCO 2022,

AKT

Merus



Zeno in NRG1+ Cancer: Global Phase 1/2 Clinical Trial





Robust Clinical Efficacy in NRG1+ Cancer

Overall response rate 34%; Median DOR > 9 months





Note: The waterfall plot shows data for 75 of 79 patients. Change in tumor size could not be measured for 4 patients, 3 due to absence of post baseline assessment (early progression) and one due to incomplete assessment. NSCLC, Non-Small Cell Lung Cancer, PDAC, Pancreatic Ductal Adenocarcinoma

Arrows indicate treatment was ongoing at the cutoff date

Zeno: Continued Progress in NRG1+ Cancer and Beyond

Potential First & Best in Class for NRG1+ Cancer

- Meaningful, durable response rate
 - ORR 34% (95% CI: 24-46%; n=79)
 - Median DOR 9.1 months (95% CI: 7.4-NR)
 - Antitumor activity observed across multiple tumor types

Well tolerated safety profile

- Most adverse events were low grade
- Very low rate of discontinuations due to toxicity

Broad Zeno Clinical Development Program

Registration-directed clinical program

- Enrollment continues; as of year-end 2022 more than 150 patients treated in the eNRGy trial and EAP;
- Initial tumor-specific approach planned in NRG1+ NSCLC and/ or PDAC with potential agnostic BLA to follow
- In NRG1+ NSCLC, combination therapy with a fatinib currently recruiting
- Beyond NRG1+ cancer
 - Castration-resistant prostate cancer cohort initiated, enrolling
- Additional indications being considered



~ 47% includes NRG1 fusion testing (n=12)

 Drilon A et al. Cancer Discov. 2018;8(6):666-695. 2. Jonna 5 et al. Clin Cancer Res. 2019;25(16):4664-49723. Laskin J et al. Am Oncol. 2020;31(12):1693-1703. 4. Knepper TC et al. J Glin Oncol. 2022;40(16 suppl);4155. 5. Jones MR et al. Clin Cancer Res. 2019;25(15):4674-46816. Data from Discovics Data Repository: 10;2022. Testing rate das/board (Jug. 2022 assessment) & 20202 Data: Testing coverage from Discovics Data Repository: 10;2022 Discovics PC or its difficience. All rights reserved. Potential first in class LGR5xEGFR Biclonics[®] designed to potently block dysregulated signaling and growth in solid tumors

MCLA-158

Petosemtamab LGR5 x EGFR bispecific

- Binds to EGFR and LGR5, a cancer-stem cell antigen
- Blocks growth in WNT-dysregulated tumor models including Ras^{mut}
- Modifications to enhance ADCC
- Phase 1 trial ongoing; clinical update planned for 1H23
- Early evidence of clinical activity in advanced Head & Neck Squamous Cell Carcinoma (HNSCC) reported at AACR-NCI-EORTC 2021*



* Source: Hollebecque https://merus.nl/wp-content/uploads/2021/10/P185_MCLA-158-HNSCC_virtual-poster_10Sep21_2.pdf

Petosemtamab — Novel Target and Innovative MoA

Superior Growth Inhibition and Selectivity of Tumor Versus Healthy Tissue*



Activity observed in xenograft models resistant to treatment with Cetuximab
Petosemtamab discriminated between organoids from tumor and healthy tissue

T= 15 min T= 24 hr

Induces EGFR internalization and degradation**

P18T colorectal cancer organoids

•

After 24h exposure, MCLA-158 (red) is localized intracellularly and overall EGFR expression (green) is strongly reduced

*Source: Rob C. Roovers (ASCO 2017 Poster Presentation) <u>https://merus.nl/app/uploads/2019/02/MCLA-158-poster-AACR2017.pdf</u> ** Source: Guillem Argilés (ASCO GI 2021 Poster Presentation) <u>https://merus.nl/wp-content/uploads/2021/01/MCLA-158 ASCO GI final.pdf</u>

Phase 1 Cohort Expansion in Head and Neck Squamous Cell Carcinoma



12 Investigator review, efficacy data cutoff Aug. 9, 2021, refer to Hollebecque https://merus.nl/wp-content/uploads/2021/10/P185_MCLA-158-HNSCC_virtual-poster_10Sep21_2.pdf

Designed to target lung cancer and other solid tumors expressing EGFR and c-MET

MCLA-129

EGFR x c-MET Bispecific

- Targets both EGFR and c-MET on cancer cells
- Modifications to enhance ADCC
- Significant opportunity in lung cancer and other solid tumors
- Phase 1/2 trial ongoing; 2H22 clinical update provided at the EORTC/NCI/AACR 2022
- Expansion cohorts ongoing, including in combination with a third generation EGFR TKI
- Clinical update planned for 2H23

13





Dose Escalation Phase of MCLA-129 in NSCLC and Other Solid Tumors*

Study Design



Expansion Cohorts Ongoing

Cohort A: NSCLC with EGFR exon20 insertion
Cohort B: NSCLC with c-MET exon14 skipping
Cohort C: HNSCC
Cohort D + 3rd gen EGFR TKI: NSCLC 1L (EGFR sensitizing mutations)
Cohort E + 3rd gen EGRF TKI: NSCLC post-Osimertinib

	Irrespective of causality		Suspected related	
Preferred term	All grades n(%)	Grade 3-4 n(%)	All grades n(%)	Grade 3-4 n(%)
Any event	19 (95%)	9 (45%)	19 (95%)	4 (20%)
Infusion related reaction**	18 (90%)	1 (5%)	18 (90%)	1 (5%)
Dyspnea	11 (55%)	1 (5%)	9 (45%)	1 (5%)
Flushing	9 (45%)		9 (45%)	-
Nausea	9 (45%)		8 (40%)	-
Fatigue	6 (30%)	1 (5%)	3 (15%)	-
Back pain	5 (25%)		2 (10%)	-
Chills	5 (25%)		5 (25%)	-
Myalgia	5 (25%)		4 (20%)	
Vomiting	5 (25%)		5 (25%)	-
Cough	4 (20%)		3 (15%)	-
Abdominal pain	3 (15%)		1 (5%)	-
Arthralgia	3 (15%)		2 (10%)	-
Dermatitis acneiform	3 (15%)	-	3 (15%)	-
Lipase increased	(15%)		2 (10%)	-
Oedema peripheral	3 (15%)	-	-	-
Pruritus	3 (15%)	1 (5%)	3 (15%)	1 (5%)

Safety

Efficacy



Merus

No dose limiting toxicities (DLTs) reported

•

• The majority of IRR events occurred during the first infusion

* Ou et al., EORTC-NCI-AACR 2022, data cutoff August 15, 2022; Safety: most frequent (>)10% adverse events among n=20 pts as of Aug 15, 2022 data cutoff date; ** Grouped term covering all AEs occurring within 24 hours of the infusion considered by the investigator as an IRR; **PB: platinum based chemotherapy; O: osimertinib; N: nivolumab; P: pembrolizumab; Cr: crizotinib; Cap: capmatinib; Cet: cetuximab; Tep: tepotinib; (+) patient ongoing; PR partial response; uPR unconfirmed partial response; SD stable disease; PD progression disease

14

Designed to recruit and activate tumor infiltrating T-cells

MCLA-145

PD-L1 x CD137 bispecific

- Binds to PD-L1 on tumor cells and CD137 (4-1BB), a potent activator of tumor infiltrating T-cells, on activated T-cells
- Targets PD-L1 positive cells in the tumor and blocks the PD-1/PD-L1 inhibitory signal
- Potential in a variety of solid tumors

15

- Global phase 1 trial ongoing, including in combination with a PD1 inhibitor
- Clinical update presented at ESMO Immuno-Oncology Congress 2021



MCLA-145 — Targets PD-L1 Positive Tumor Cells



Source: Geuijen <u>https://merus.nl/app/uploads/2019/04/IC171-19E-AACR19-Mayes-MCLA-145-MoA-Poster_MT06_for-approval-032019.pdf</u> Source: Prenen <u>https://merus.nl/wp-content/uploads/2021/12/MCLA-145-Poster-ESMO-IO_12.3.21_Final.pdf</u> 16

Data from ESMO-IO 2021



17 https://merus.nl/wp-content/uploads/2021/12/MCLA-145-Poster-ESMO-IO_12.3.21_Final.pdf

Our Platform – Unique Capabilities in Multispecific Antibodies



Merus Collaborations

Strategic relationships expand pipeline potential and clinical reach



¹ Combination of upfront license payment, and share purchase at a premium (Incyte, Merus collaboration agreement of 120m USD upfront and 80m USD equity investment; Lilly, Merus collaboration agreement of 40m upfront and 20m USD equity investment

19

Merus Multiclonics®

Bispecific and Trispecific therapeutic candidates for cancer with broad application for human disease



20

Large-scale screening of Biclonics® and Triclonics®

• To select the best molecules from up to 1,000s of candidates

Fully human IgG structure

- Ease of manufacturing
- Low immunogenicity risk
- Predictable in vivo behavior
- Durable, consistent half life
- Potential for ADCC enhancement and Fc silencing

Novel, innovative trispecific Triclonics® format

- · Stable format with predictable behavior; production similar to monoclonal antibody
- Allows for 3 specificities without the need to engineer each individual Fab
- Leverages Merus' extensive library of established antibody panels against ~50 established cancer targets

Robust IP portfolio of patents covering the platform technology, including

- Common light chain antibody generation and screening
- Dimerization by charge engineering

Upcoming Milestones 2023

Zenocutuzumab (Zeno, MCLA-128)	Petosemtamab (MCLA-158)	MCLA-129
 Update potential registrational path and timeline in NRG1+ cancer (planned 1H23) Update clinical data in NRG1+ cancer (planned 2023) 	 Update clinical data in previously treated HNSCC (planned 1H23) Initial clinical data in previously treated gastric esophageal cancer (planned 1H23) 	 Initial clinical data from expansion cohorts (planned 2H23) Provide further clinical development strategy (planned 2H23)
 Initial clinical data on Zeno in castration-resistant prostate cancer (CPRC) (planned 2H23) 	 Provide regulatory path and program next steps (planned 1H23) 	

Based on 2023 budgeting process and the current operating plan, the existing cash, cash equivalents and marketable securities are expected to fund Merus' operations into second half 2025.

Merus closing in on cancer