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): April 14, 2023

MERUS N.V.
(Exact name of registrant as specified in its charter)

The Netherlands	001-37773	Not Applicable
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

Uppsalalaan 17
3584 CT Utrecht
The Netherlands
(Address of principal executive offices) (Zip Code)

+31 30 253 8800
(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 ☐

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 8.01 Other Events

Merus, N.V. (the "Company") is providing the following updates.

Clinical Development

On April 14, 2023, the Company announced initiation of a cohort in the petosemtamab phase 1/2 trial investigating petosemtamab in combination with Keytruda in patients with untreated head and neck squamous cell carcinoma, or HNSCC, designed to evaluate safety and clinical activity in this population.

On April 17, 2023, the Company announced interim clinical data as of a February 1, 2023 data cutoff, from the ongoing phase 1/2 trial of petosemtamab in previously treated HNSCC during a plenary session presentation at the American Association of Cancer Research Annual Meeting, or the AACR Annual Meeting.

As of the February 1, 2023 data cutoff date, 49 previously treated HNSCC patients were treated with petosemtamab at the recommended phase 2 dose of 1500 mg intravenous (IV) every two weeks, 6 patients excluded per protocol (5 withdrew due to infusion-related reactions, or IRRs, on day 1 and 1 patient with exclusion criterion).

- Patient population:
    - Median age was 63 (range of 31-77); 78% were male
    - Median prior lines of systemic therapy was 2 (range 1-4); including PD-(L)1 inhibitor in 96% of patients, chemotherapy in 94% and platinum-based chemotherapy in 92% of patients; 2 patients received prior cetuximab
    - Most frequent primary tumor locations were oropharynx (35%), oral cavity (31%), and larynx (16%)
- 43 patients were evaluable for efficacy, receiving ≥2 treatment cycles (≥8 weeks) with ≥1 post-baseline tumor assessment or experiencing early progressive disease:
    - Antitumor activity among 43 patients:
        - Overall response rate was 37.2% (16/43; 95% CI 23%-53.3%) by RECIST 1.1. per investigator assessment, including 15 confirmed partial responses, or PRs, and 1 confirmed complete response, or CR (ongoing after 20 months)
        - Disease control rate (CR + PR + stable disease) was 72.1% (31/43; 95% CI 56.3%-84.7%)
        - Median time to response was 1.8 months (range 0.8-3.5)
        - Median duration of response was 6.0 months (95% CI 3.7-NC), with 10 of 16 (62.5%) responders ongoing, and 12 of 43 (27.9%) patients overall ongoing at the time of the data cutoff
        - Median progression free survival was 5.3 months (95% CI 3.7-6.8); with 29 of 43 patients progressing and 14 of 43 patients censored
        - Median overall survival was 11.5 months (95% CI 7.2-20.6); with 29 of 49 patients still alive at the data cutoff date

Petosemtamab continued to demonstrate manageable safety results:

- 80 patients were treated with 1500 mg petosemtamab every two weeks across dose escalation and expansion cohorts of the study
- Gastrointestinal and skin toxicities were mostly mild to moderate
- No treatment-related Grade 5 adverse events, or AEs:
    - Most frequent related AEs were signs and symptoms of IRRs
    - 74% Grade 1-4, 21% Grade 3-4 (as grouped term)

- Mainly occurred during first infusion
- 6 of 80 patients discontinued on Day 1 due to a Grade 3-4 IRR
- For all patients rechallenged after an IRR, rechallenge was successful
- IRRs were manageable with prophylaxis/prolonged infusion (necessary on day 1 only)

Further, on April 14, 2023, the Company announced the publication of an abstract for a poster presentation of early clinical data on petosemtamab in advanced gastric/esophageal adenocarcinoma, or GEA, at the AACR Annual Meeting.

Although petosemtamab has demonstrated encouraging clinical activity among GEA patients having EGFR gene amplification and/or overexpression, the Company announced that it decided to pause further clinical exploration of the GEA cancer cohort at this time, with plans to prioritize investigating petosemtamab in HNSCC.

As of an October 24, 2022 data cutoff date, 14 previously treated GEA patients were treated with petosemtamab 1500 mg IV every two weeks.

- Patient Population:
  - Median age was 63 (range of 40-80); 79% were male
  - Median prior lines of systemic therapy was 3 (range 1-4); including platinum-based chemotherapy (36% of patients) and checkpoint inhibitors (14%)
- 14 patients were evaluable for efficacy, receiving ≥2 treatment cycles (≥8 weeks) with ≥1 post-baseline tumor assessment or experiencing early progressive disease
  - Antitumor activity among the 14 patients:
    - 1 patient with tumor EGFR protein overexpression and gene copy number amplification, or CNA, showed a confirmed sustained PR (67% tumor reduction; response ongoing after 24 cycles);
    - 3 patients had stable disease (1 with EGFR overexpression and gene CNA; 2 not evaluable for IHC), with tumor reductions of 2%, 17%, and 40%.
- Petosemtamab continued to demonstrate manageable safety results:
  - Of 78 patients treated at the recommended phase 2 dose of 1500 mg every two weeks (escalation and all expansion cohorts), the most frequent AEs regardless of causality (all grades/grades 3-4) were rash (33%/0%), hypotension (26%/6%), dyspnea (26%/4%), nausea (26%/1%), dermatitis acneiform (24%/1%), blood magnesium decreased (19%/5%), erythema (19%/0%), diarrhea (19%/0%); IRRs (composite term) were reported in 74%/21% of patients, mostly at the first infusion, and all resolved. 5 patients (6%) discontinued treatment due to IRRs on day 1.

Petosemtamab Regulatory Update

The Company met with the U.S. Food and Drug Administration, or the FDA, in an end-of-phase meeting to discuss interim results from the previously treated HNSCC cohort of the petosemtamab phase 1/2 trial. The FDA recognized recurrent or metastatic HNSCC represents an area of unmet medical need, and provided clear recommendations for the path to potential registration.

Based on the strong clinical data and discussions with the FDA, the Company believes a randomized clinical trial in previously treated (2L/3L) or untreated (front-line) HNSCC may support a possible registration. Additionally, the Company 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. The Company plans to continue to acquire data to confirm a suitable dose for future randomized clinical trials.

Forward-Looking Statements

This Current Report on Form 8-K (the "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, including without limitation, statements regarding the clinical development of petosemtamab, current and future clinical trial progress, enrollment, results, clinical activity and safety profile of petosemtamab in the ongoing phase 1/2 trial, expected impact of petosemtamab and expected timing of regulatory approvals. 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 contain these words. All statements other than statements of historical fact contained in this Current Report, including without limitation 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 collaborations, our expectations about the willingness of healthcare professionals to use our product candidates, the sufficiency of our cash, cash equivalents and investments 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 Annual Report on Form 10-K for the period ended December 31, 2022, filed with the Securities and Exchange Commission, or SEC, on February 28, 2023, 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 not 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.

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: April 17, 2023

By: /s/ Sven (Bill) Ante Lundberg, M.D.
Name: Sven (Bill) Ante Lundberg, M.D.
Title: President, Chief Executive Officer and Principal Financial Officer