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 28, 2024

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 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 ☐

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 May 28, 2024, the Company announced interim clinical data as of a March 6, 2024 data cutoff from the ongoing Phase 1/2 trial of the bispecific antibody petosemtamab in combination with pembrolizumab as first-line treatment of recurrent/metastatic head and neck squamous cell carcinoma.

- As of a March 6, 2024 data cutoff date, 45 patients were treated
    - 26 patients were enrolled as of the abstract cutoff date
        - The efficacy population consisted of 24 patients who had the opportunity for 4 or more months follow up, with ≥2 treatment cycles and ≥1 post-baseline tumor assessment; or who discontinued early due to disease progression or death.
        - Two patients were not included: One patient withdrew consent prior to first tumor assessment and the other patient discontinued due to toxicity with less than 2 cycles of treatment.
    - Response rates overall (N=24): 67%, including 1 confirmed complete response, 12 confirmed partial responses ("PRs") and 3 unconfirmed PRs (all of whom confirmed after the data cutoff) by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. per investigator assessment, including
        - 3 of 4 patients with HPV associated cancer responded
        - Responses observed across PD-L1 levels (CPS 1-19: 60% [6/10]; CPS ≥ 20: 71% [10/14])
    - At the time of data cutoff, 32 patients of the 45 enrolled, remained on treatment, including 14 of 16 responders and 18 of the initial 26 patients enrolled
        - Of those that discontinued, 9 for disease progression; 2 withdrawal of consent; 1 death (unrelated to treatment); and 1 related adverse events ("AE") (asthenia, diarrhea, creatinine increase; all Grade ("G") <3)
    - Median follow up of 3.6 months for the 45 patients
- In 45 patients the combination was well tolerated and no significant overlapping toxicities with pembrolizumab were observed
- Treatment-emergent AEs were reported in 45 patients
    - Most were G 1 or 2 in severity (no G4–5 were observed)
    - Infusion-related reactions (composite term) were reported in 38% (all Gs) and 7% (G3) of patients, most occurred during the first infusion and resolved

The Company plans to initiate a phase 3 clinical trial by year end 2024 to evaluate petosemtamab in combination with pembrolizumab, regardless of HPV status, in first line, PD-L1 expressing, head and neck cancer.

The Company also plans to initiate a phase 3 clinical trial in mid-2024 to evaluate petosemtamab monotherapy in 2L+ HNSCC. In the planned trial, patients will be randomized to petosemtamab monotherapy or investigators' choice of single agent methotrexate, docetaxel or cetuximab.

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 ½ 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 on management's 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 March 31, 2024, filed with the Securities and Exchange Commission, or SEC, on May 8, 2024, 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: May 28, 2024

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