

**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): December 4, 2024**

**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.)

**Uppsalaalaan 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<br>Symbol(s) | Name of each exchange<br>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**

On December 4, 2024, Merus N.V. announced that the United States Food and Drug Administration has approved BIZENGRI® (zenocutuzumab-zbco) for treatment indicated for adults with pancreatic adenocarcinoma or non–small cell lung cancer (NSCLC) that are advanced unresectable or metastatic and harbor a neuregulin 1 (NRG1) gene fusion who have disease progression on or after prior systemic therapy. These indications are approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). BIZENGRI® has a Boxed WARNING for Embryo-Fetal Toxicity and warnings for infusion-related reactions (IRRs), hypersensitivity and anaphylactic reactions, interstitial lung disease (ILD)/pneumonitis, and left ventricular dysfunction.

The approval of BIZENGRI® is based on data from the eNRGy trial, a multicenter, open-label clinical trial that enrolled patients with NRG1+ pancreatic adenocarcinoma or NRG1+ NSCLC that is advanced unresectable or metastatic and had disease progression on or after prior systemic therapy. In patients with NRG1+ pancreatic adenocarcinoma (n=30), BIZENGRI® demonstrated an ORR of 40% (95% confidence interval (CI), 23%-59%). DOR in NRG1+ pancreatic adenocarcinoma ranged from 3.7 months to 16.6 months. In the same trial, patients with NRG1+ NSCLC (n=64) who were treated with BIZENGRI® demonstrated an ORR of 33% (95% CI, 22%-46%). The median DOR in NRG1+ NSCLC was 7.4 months (95% CI, 4.0-16.6). Response rates were measured using the Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by blinded independent central review (BICR). In the pooled safety population (N=175), the most common ( $\geq 10\%$ ) adverse reactions were diarrhea, musculoskeletal pain, fatigue, nausea, IRR, dyspnea, rash, constipation, vomiting, abdominal pain, and edema. The most common Grade 3 or 4 laboratory abnormalities ( $\geq 2\%$ ) were increased gamma-glutamyltransferase, decreased hemoglobin, decreased sodium, decreased platelets, increased aspartate aminotransferase, increased alanine aminotransferase, increased alkaline phosphatase, decreased magnesium, decreased phosphate, increased activated partial thromboplastin time, and increased bilirubin.

Please see full Prescribing Information, including Boxed WARNING, at [www.BIZENGRI.com/pi](http://www.BIZENGRI.com/pi).

## Forward-Looking Statements

This Current Report on Form 8-K (the “Form 8-K”) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding product development, the potential benefits and treatment impact of BIZENGRI® (zenocutuzumab-zbco) and potential contingencies on the continued approval of BIZENGRI®. These 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; our reliance on the success of BIZENGRI®, our only approved product; the efficacy of BIZENGRI® compared to competing drugs; our ability to successfully commercialize BIZENGRI®; serious adverse, undesirable or unacceptable side effects associated with BIZENGRI® which could adversely affect our ability to commercialize BIZENGRI®; potential issues associated with 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; our reliance on third parties to conduct our clinical trials, and the potential for those third parties to not perform satisfactorily; impacts of the volatility in the global economy, including global instability, including the ongoing conflicts in Europe and the Middle East; we may not identify suitable Biclomics® 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 BIZENGRI® or 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 Quarterly Report on Form 10-Q for the period ended September 30, 2024, filed with the Securities and Exchange Commission, or SEC, on October 31, 2024, 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 Form 8-K. 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 Form 8-K.

Multiclomics®, Biclomics®, Triclomics®, and BIZENGRI® are registered trademarks of Merus N.V.

**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: December 5, 2024

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