# 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 16, 2025**

# OMEROS CORPORATION
**(Exact name of Registrant as Specified in Its Charter)**

| **Washington** | **001-34475** | **91-1663741** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |
| **201 Elliott Avenue West Seattle, WA** | | **98119** |
| **(Address of Principal Executive Offices)** | | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (206) 676-5000**

**(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 (see General Instruction A.2. below):

☐ 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 stock, $0.01 par value per share | OMER | The Nasdaq Stock Market LLC |

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 January 16, 2025, Omeros Corporation issued a press release announcing the results of statistical sensitivity analyses related to the previously reported primary endpoint analysis for narsoplimab, Omeros' first-in-class monoclonal antibody inhibiting the lectin pathway of complement, in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated January 16, 2025 |
| 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.

**OMEROS CORPORATION**

Date: January 16, 2025

By: /s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
President, Chief Executive Officer and
Chairman of the Board of Directors

**Omeros Announces Update on Statistical Analysis of Narsoplimab Pivotal Trial Primary Endpoint**
**– Newly Completed Sensitivity Analyses Demonstrate Robustness of Previously Announced Survival Superiority Over External Control in Patients with TA-TMA –**

- ***Sensitivity analyses support the results of the primary endpoint analysis, with representative sensitivity analyses demonstrating:***
  - ***Narsoplimab-treated patients had an over 2-fold reduction (hazard ratio = 0.42 [95% confidence interval: 0.21, 0.83]) to an over 4-fold reduction (hazard ratio = 0.24 [95% confidence interval: 0.13, 0.47] in risk of mortality***
  - ***P-values ranging from 0.0124 to < 0.00001***
- ***The primary endpoint analysis, previously reported on December 19, 2024, showed an over 3-fold reduction in risk of mortality (hazard ratio = 0.32 [95% confidence interval: 0.23, 0.44]; p < 0.00001) in TA-TMA patients treated with narsoplimab compared to the external control registry TA-TMA patients not treated with narsoplimab***
- ***Omeros plans to resubmit to FDA later this quarter the BLA for narsoplimab to become the first approved therapeutic for TA-TMA, a life-threatening complication of hematopoietic stem cell transplantation; MAA submission to European regulators targeted by mid-year***

**SEATTLE, WA – January 16, 2025** – Omeros Corporation (Nasdaq: OMER) today announced statistical sensitivity analysis results related to the primary endpoint analysis for narsoplimab, Omeros' first-in-class monoclonal antibody inhibiting the lectin pathway of complement, in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA), a life-threatening complication in both adult and pediatric hematopoietic stem cell transplantation. The sensitivity analyses, conducted by an independent statistical group, demonstrate the robustness of the results of the previously reported primary endpoint analysis, with representative hazard ratios ranging from 0.24 (95 percent confidence interval: 0.13, 0.47) to 0.42 (95 percent confidence interval: 0.21, 0.83) and p-values ranging from less than 0.00001 to 0.0124.

The following are representative sensitivity analyses conducted by the independent statistical group:

1. Overall survival with only treatment as a factor using Inverse Probability of Treatment Weighting (IPTW):
   Hazard ratio = 0.40 (95 percent confidence interval: 0.29, 0.54)
   P-value < 0.00001

2. Testing proportional hazards assumptions in a sequence of four models in which patient follow-up is truncated at 100 days, 6 months, 1 year, and 2 years using IPTW:
   100 days: Hazard ratio = 0.37 (95 percent confidence interval: 0.25, 0.54)
   P-value < 0.00001
   6 months: Hazard ratio = 0.32 (95 percent confidence interval: 0.22, 0.45)
   P-value < 0.00001
   1 year: Hazard ratio = 0.30 (95 percent confidence interval: 0.22, 0.42)
   P-value < 0.00001
   2 years: Hazard ratio = 0.29 (95 percent confidence interval: 0.21, 0.41)
   P-value < 0.00001

3. Overall survival with day zero for the external control registry patients set at the median time between the date of TA-TMA diagnosis and the date of narsoplimab treatment initiation for the patients in the OMS721-TMA-001 pivotal trial using IPTW:
   Hazard ratio = 0.32 (95 percent confidence interval: 0.23, 0.44)
   P-value < 0.00001

4. Overall survival with and without all specified risk factors (RFs) using 1:1 and 1:2 patient propensity score matching (OMS721-TMA-001 trial patients versus external control registry patients):
   1:1 with RFs: Hazard ratio = 0.29 (95 percent confidence interval: 0.14, 0.61)
   P-value = 0.0012
   1:1 w/out RFs: Hazard ratio = 0.42 (95 percent confidence interval: 0.21, 0.83)
   P-value = 0.0124
   1:2 with RFs: Hazard ratio = 0.24 (95 percent confidence interval: 0.13, 0.47)
   P-value < 0.0001
   1:2 w/out RFs: Hazard ratio = 0.40 (95 percent confidence interval: 0.22, 0.72)
   P-value = 0.0024

As reported on December 19, 2024, narsoplimab met its primary endpoint, with TA-TMA patients in its OMS721-TMA-001 pivotal trial demonstrating clinically meaningful and statistically significant superiority in overall survival – a hazard ratio of 0.32 (95 percent confidence interval: 0.23 to 0.44) with p-value less than 0.00001 – compared to the TA-TMA registry patients. The hazard ratio of 0.32 indicates that the narsoplimab-treated TA-TMA patients had an over 3-fold reduction in risk of mortality. Across all its clinical trials in various indications to date, narsoplimab has been well tolerated and has shown no safety signal of concern.

"While we have long been confident in the benefits of narsoplimab in TA-TMA patients, it is gratifying to see the consistency and strength of the sensitivity analyses, which collectively demonstrate the robustness of our previously reported primary analysis results," said Gregory A. Demopulos, M.D., Omeros' Chairman and Chief Executive Officer. "We now await the final set of analyses comparing survival of high-risk TA-TMA patients in our narsoplimab global expanded access program – and, importantly, combined with the 28 high-risk TA-TMA patients in OMS721-TMA-001 – to survival of similarly at-risk control TA-TMA registry patients. We expect those soon from the independent statistical group and, again, analyses will be shared publicly

when available. Given the strength of the data already in hand, we are moving ahead with narsoplimab as quickly as possible, targeting BLA resubmission for later this quarter and European MAA submission before mid-year."

Prior to the independent statistical group conducting any narsoplimab analyses, Omeros had received and incorporated FDA's recommendations on the statistical analysis plan for the primary analysis and sensitivity analyses comparing overall survival from time of first dosing in the 28 narsoplimab-treated TA-TMA patients in OMS721-TMA-001 to overall survival, adjusted for immortal time bias, of the more than 100 TA-TMA patients in the external control registry, none of whom received narsoplimab. The two cohorts had similar demographics, diagnostic criteria, baseline characteristics, underlying diseases, conditioning regimens, and transplant procedures. All patients in both cohorts met the published criteria for high risk of death as defined by an international expert panel tasked with reaching consensus on diagnostic and prognostic criteria and representing the American Society for Transplantation and Cellular Therapy, the Center for International Bone Marrow Transplant Research, the Asia-Pacific Blood and Marrow Transplantation Group, and the European Society for Blood and Marrow Transplantation.

While awaiting the results from the expanded access program (EAP)-related analyses, international groups of transplant experts have begun preparing two manuscripts – one directed to primary endpoint analyses and the other to EAP-related analyses – for submission to peer-reviewed journals.

**About Narsoplimab**

Narsoplimab, also known as "OMS721," is an investigational fully human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), a novel pro-inflammatory protein target and the effector enzyme of the lectin pathway of complement. Importantly, inhibition of MASP-2 has been demonstrated to leave intact the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection. A biologics license application (BLA) is pending before the FDA for use of narsoplimab in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA). Omeros will resubmit the BLA for narsoplimab in TA-TMA followed by our planned submission of the corresponding European marketing authorisation application (MAA) in 2025. FDA has granted narsoplimab breakthrough therapy and orphan drug designations for TA-TMA and orphan drug status for the prevention (inhibition) of complement-mediated thrombotic microangiopathies. The European Medicines Agency (EMA) has granted orphan drug designation to narsoplimab for treatment in hematopoietic stem-cell transplant.

**About Hematopoietic stem cell transplant-associated thrombotic microangiopathy**

Hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) is a significant and often lethal complication of stem cell transplantation. This condition is a systemic, multifactorial disorder caused by endothelial cell damage induced by conditioning regimens, immunosuppressant therapies, infection, graft-versus-host disease, and other factors associated with stem cell transplantation. Endothelial damage, which activates the lectin pathway of complement, plays a central role in the development of TA-TMA. The condition occurs in both autologous and allogeneic transplants but is more common in the allogeneic population. In the United States and Europe, approximately 30,000 allogeneic transplants are performed annually. Recent reports in both adult and pediatric allogeneic stem cell transplant populations have found an approximately 40-percent incidence of TA-TMA, and high-risk features may be present in up to 80 percent of these patients. In severe cases of TA-TMA, mortality can exceed 90 percent and, even in those who survive, long-term renal sequalae (e.g., dialysis) are common. There is no approved therapy or standard of care for TA-TMA.

**About Omeros Corporation**

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing first-in-class small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders, including complement-mediated diseases and cancers, as well as addictive and compulsive disorders. Omeros' lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application pending before FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Omeros' long-acting MASP-2 inhibitor OMS1029 has successfully completed Phase 1 single- and multiple-ascending dose clinical studies. Zaltenibart, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing toward Phase 3 clinical trials for paroxysmal nocturnal hemoglobinuria and complement 3 glomerulopathy. Funded by the National Institute on Drug Abuse, Omeros' lead phosphodiesterase 7 inhibitor OMS527 is in clinical development for the treatment of cocaine use disorder. Omeros also is advancing a broad portfolio of five novel cellular and molecular immuno-oncology programs. For more information about Omeros and its programs, visit www.omeros.com.

**Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the "safe harbor" created by those sections for such statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "aim," "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "look forward to," "may," "objective," "plan," "potential," "predict," "project," "should," "slate," "target," "will," "would" and similar expressions and variations thereof. Forward-looking statements, including statements regarding the anticipated resubmission of the BLA for narsoplimab in the United States and the submission of a marketing authorization application with the EMA, the timing and outcomes of regulatory events, the availability and outcomes of additional analyses, the prospects for obtaining FDA or EMA approval of narsoplimab in any indication, expectations regarding future cash expenditures, and expectations regarding the sufficiency and availability of our capital resources to fund current and planned operations, including the potential commercialization of narsoplimab if it is approved by FDA or the EMA, are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. Omeros' actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, unfavorable, unexpected or inconclusive results of our statistical analyses relating to an external registry of TA-TMA patients, potential differences between the diagnostic criteria used in our pivotal trial and in the external registry, and whether FDA and the EMA determine the registry used in our statistical analysis is sufficiently representative of TA-TMA patients, unanticipated or unexpected outcomes of regulatory processes in relevant jurisdictions, unproven preclinical and clinical development activities, our financial condition and results of operations, regulatory processes and oversight, challenges associated with manufacture or supply of our products to support clinical trials, regulatory inspections and/or commercial sale following any marketing approval, changes in reimbursement and payment policies by government and commercial payers or the application of such policies, intellectual property claims, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 1, 2024, an in our subsequently filed Quarterly Reports on Form 10-Q. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

**Contact**
Jennifer Cook Williams

Cook Williams Communications, Inc.
Investor and Media Relations
IR@omeros.com