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): October 16, 2023

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 October 16, 2023, Omeros Corporation issued a press release announcing results from the Phase 3 ARTEMIS-IGAN trial evaluating narsoplimab for the treatment of immunoglobulin A (IgA) nephropathy. A copy of such 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 October 16, 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.

OMEROS CORPORATION

Date: October 16, 2023

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

Exhibit 99.1

Omeros Corporation Provides Update on Interim Analysis of ARTEMIS-IGAN Phase 3 Trial of Narsoplimab in IgA Nephropathy

- *The ARTEMIS-IGAN trial did not reach statistical significance on the primary endpoint of reduction in proteinuria from baseline compared to placebo*
- *Proteinuria reduction in the placebo group was substantially greater than reported in other IgA nephropathy clinical trials*
- *Webcast conference call planned for 8:30 a.m. ET today*

SEATTLE, WA – October 16, 2023 – Omeros Corporation (Nasdaq: OMER), a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and addictive and compulsive disorders, today provided an update regarding the interim analysis outcome in ARTEMIS-IGAN, the Company's Phase 3 trial evaluating narsoplimab for the treatment of immunoglobulin A (IgA) nephropathy.

The primary endpoint is reduction in proteinuria assessed by 24-hour urine protein excretion (UPE) at 36 weeks compared to placebo in the intent-to-treat population of 180 IgA nephropathy patients with high baseline proteinuria (24-hour UPE > 2 g/day). Topline results show that narsoplimab did not achieve statistically significant improvement over placebo. The UPE reduction in the placebo group was markedly greater than that reported in trials of other agents in IgA nephropathy. Based on the absence of statistical significance and as previously agreed with FDA, Omeros will not submit an application for approval of narsoplimab in this indication and will discontinue the ARTEMIS-IGAN clinical trial.

"We want to thank all the patients and investigators who participated in the trial," said Gregory A. Demopulos, M.D, chairman and chief executive officer of Omeros. "We will conduct more detailed analyses of the data to understand better the outsized placebo effect and the overall trial results and to try to identify useful biomarkers. The funds earmarked for commercialization in IgAN and continuation of the ARTEMIS-IGAN trial will be redirected to our other later-stage programs, including our ongoing Phase 2 and upcoming Phase 3 programs for our alternative pathway inhibitor OMS906. In addition, our near-term focus remains the planned resubmission of our biologics license application for narsoplimab in hematopoietic stem-cell transplant-associated thrombotic microangiopathy."

Consistent with the safety profile observed in other narsoplimab studies, results from the interim analysis in ARTEMIS-IGAN indicate that narsoplimab has been generally well tolerated without any safety signal of concern.

Conference Call Details

Omeros' management will host a conference call and webcast to discuss the results. The call will be held today at 5:30 a.m. Pacific Time; 8:30 a.m. Eastern Time.

For online access to the live webcast of the conference call, go to Omeros' website at https://investor.omeros.com/upcoming-events.

To access the live conference call via phone, participants must register at this link to receive a unique PIN. Once registered, you will have two options: (1) Dial in to the conference line provided at the registration site using the PIN provided to you, or (2) choose the "Call Me" option, which will instantly dial the phone number you provide. Should you lose your PIN or registration confirmation email, simply re-register to receive a new PIN.

A replay of the call will be made accessible online at https://investor.omeros.com/archived-events.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and 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 (TA-TMA). Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including COVID-19. Omeros' long-acting MASP-2 inhibitor OMS1029 is currently in a Phase 1 clinical trial. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing across multiple clinical programs for alternative pathway-related diseases, including paroxysmal nocturnal hemoglobinuria (PNH) and complement 3 (C3) glomerulopathy. For more information about Omeros and its programs, visit www.omeros.com.

Forward-Looking Statements

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Without limiting the foregoing, these statements are often identified by the words "may", "might", "believes", "thinks", "anticipates", "plans", "expects", "intends" or similar expressions. In addition, expressions of our strategies, intentions or plans are also forward-looking statements. Such forward-looking statements include, but are not limited to, references to the Company's current and anticipated strategies in relation to its clinical development programs. Such forward-looking statements are based on current information available to the Company and involve inherent risks and uncertainties, including factors that could delay, divert or change any such forward-looking statements, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with the regulatory review and approval process. In addition, such risks and uncertainties may include those described in the Company's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the SEC, which are available at the Company's website (www.omeros.com) under "Investors & News". You are cautioned not to place undue reliance on any forward-looking statements as there are important factors that could cause actual results to differ materially from those in any

forward-looking statements, many of which are beyond our control. Except to the extent required by law, the Company undertakes no obligation to publicly update any forward-looking statement.

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