

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

**OMEROS CORP**

CIK: **1285819** | IRS No.: **911663741** | State of Incorp.: **WA** | Fiscal Year End: **1231**  
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SIC: **2834** Pharmaceutical preparations

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549**

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**FORM 8-K**

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**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 22, 2013**

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**OMEROS CORPORATION**

(Exact name of registrant as specified in its charter)

**Washington**  
(State or other jurisdiction  
of incorporation)

**001-34475**  
(Commission  
File Number)

**91-1663741**  
(IRS Employer  
Identification No.)

**201 Elliott Avenue West  
Seattle, Washington 98119**

(Address of principal executive offices, including zip code)

**(206) 676-5000**

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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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))
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**Item 8.01 Other Events.**

On January 22, 2013, we issued a press release announcing the safety data from our second Phase 3 clinical trial evaluating OMS302 in patients undergoing intraocular lens replacement surgery. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated January 22, 2013

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## 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

By: /s/ Gregory A. Demopoulos  
Gregory A. Demopoulos, M.D.

President, Chief Executive Officer, and Chairman  
of the Board of Directors

Date: January 23, 2013

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**EXHIBIT INDEX**

**Exhibit  
Number**

**Description**

99.1 Press release dated January 22, 2013



## Omeros Announces Positive OMS302 Safety Data in Phase 3 Clinical Trial

– Market Launch Expected First Half of 2014–

**Seattle, WA - January 22, 2013** - Omeros Corporation (NASDAQ: OMER) today announced the successful completion of the 90-day safety database lock in the second of the Company's two pivotal Phase 3 clinical trials evaluating OMS302 in patients undergoing intraocular lens replacement surgery. OMS302, added to standard irrigation solution used during ophthalmological procedures, is Omeros' proprietary PharmacoSurgery™ product designed to maintain intraoperative mydriasis and reduce postoperative pain and irritation resulting from cataract and other lens replacement surgery. In November 2012, Omeros announced that OMS302 met the co-primary efficacy endpoints in this second pivotal Phase 3 clinical trial by demonstrating statistically significant ( $p < 0.00001$ ) maintenance of intraoperative mydriasis (pupil dilation) and statistically significant ( $p = 0.0002$ ) reduction of pain in the early postoperative period.

This multicenter, double-blind, Phase 3 clinical trial enrolled 416 patients randomized 1:1 to receive either OMS302 or placebo. Safety data were collected through postoperative day 90. In this Phase 3 clinical trial, OMS302 was well tolerated. The incidence of adverse events was similar between the two treatment groups, and the adverse event profile was similar to that seen in prior OMS302 clinical trials. No safety concerns have been identified in the OMS302 clinical development program. Results from this study are expected to be presented at an upcoming major ophthalmology meeting. Omeros also plans to publish the results in a leading peer-reviewed ophthalmology journal.

“While these data were expected, they underscore the safety benefits of intraoperative and local delivery of OMS302 - administration of efficacious and low concentrations of the active ingredients directly to the surgical site reduces systemic uptake and the probability of adverse side effects,” stated Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. “Together with the strong and consistent efficacy data observed throughout its clinical development program, we believe that OMS302 represents a significant advance in lens replacement surgery, and our NDA and MAA are progressing well. We also expect to read out data from our OMS824 multiple-dose pharmacokinetic clinical trial later this quarter and to begin our second OMS103HP meniscectomy Phase 3 trial next quarter.”

### About Omeros' OMS302 Program

OMS302 is Omeros' product being developed for use during intraocular lens replacement (ILR) surgery, including cataract surgery and refractive lens exchange. OMS302 is a proprietary combination of ketorolac, an anti-inflammatory agent, and phenylephrine, a mydriatic (pupil dilating) agent. FDA-approved drugs containing each of these agents have been used in ophthalmological clinical practice for more than 15 years, and both are contained in generic, FDA-approved drugs.

ILR surgery involves replacement of the original lens of the eye with an artificial intraocular lens. These procedures are typically performed to replace a lens opacified by a cataract or to correct a refractive error of the lens (i.e., refractive lens exchange). OMS302 is added to standard irrigation solution used in ILR surgery and delivered intracamerally to maintain intraoperative mydriasis (pupil dilation), to prevent

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surgically induced miosis (pupil constriction), and to reduce postoperative pain and irritation. Maintenance of mydriasis is critical to the safety and surgical ease of the procedure. Intraoperative pupil constriction increases the risk of injury to intraocular structures and can substantially prolong surgical time.

### **About Ophthalmological Procedures (Cataract and Other Lens Replacement Surgery)**

There are 3.6 million intraocular lens replacement procedures expected in the U.S. this year and 15 million in developed countries, with a projected annual growth rate of three to four percent. There are multiple commercial opportunities within the lens replacement market, including both standard and premium lenses. The premium market includes toric, multifocal and accommodating lenses. Refractive lens exchange is also a growing segment of the lens replacement market.

### **About Omeros Corporation**

Omeros is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. The Company's most clinically advanced product candidates, OMS302 for lens replacement surgery and OMS103HP for arthroscopy, are derived from its proprietary PharmacoSurgery™ platform designed to improve clinical outcomes of patients undergoing a wide range of surgical and medical procedures. Omeros has five clinical development programs. Omeros may also have the near-term capability, through its GPCR program, to add a large number of new drug targets and their corresponding compounds to the market. Behind its clinical candidates and GPCR platform, Omeros is building a diverse pipeline of protein and small-molecule preclinical programs targeting inflammation, coagulopathies and central nervous system disorders.

### **Forward-Looking Statements**

This press release contains forward-looking statements as defined within the Private Securities Litigation Reform Act of 1995, which are subject to the "safe harbor" created by those sections. These statements include, but are not limited to, Omeros' expectations regarding the date of the expected market launch of OMS302, when it will read out data from its OMS824 program and begin enrolling its second OMS103HP Phase 3 trial, the growth rate of the number of intraocular lens replacement procedures performed annually and that Omeros may have capability, through its GPCR program, to add a large number of new drug targets and their corresponding compounds to the market. Forward-looking statements 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, the risks, uncertainties and other factors described under the heading "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2012. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and the Company assumes no obligation to update these forward-looking statements publicly, even if new information becomes available in the future.

### **Contact:**

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