# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): March 18, 2013

# **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)

| 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)) |  |  |  |  |  |
|  |  |  |  |  |  |  |

#### Item 2.02 Results of Operation and Financial Condition.

On March 18, 2013, Omeros Corporation issued a press release announcing financial results for the three months and year ended December 31, 2012. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the United States Securities and Exchange Commission made by Omeros Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number Description

99.1 Press release dated March 18, 2013 relating to Omeros' financial results for the three months and year ended December 31, 2012.

### **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. Demopulos

Gregory A. Demopulos, M.D.

President, Chief Executive Officer, and Chairman of the

**Board of Directors** 

Date: March 18, 2013

# EXHIBIT INDEX

Exhibit Number

Description

99.1

Press release dated March 18, 2013 relating to Omeros' financial results for the three months and year ended December 31, 2012.



#### Omeros Corporation Reports Fourth Quarter and Year-End 2012 Financial Results

**Seattle, WA – March 18, 2013** – Omeros Corporation (NASDAQ: OMER), a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system, today announced financial results for the fourth quarter and year ended December 31, 2012.

#### **Financial Results**

Total operating expenses for the three months ended December 31, 2012 were \$9.1 million, compared to \$11.0 million for the same period in 2011. Omeros received a \$3.95 million payment from its insurer during the 2012 period as reimbursement for an expense recognized by Omeros in the third quarter of 2012. Excluding this reimbursement, Omeros' operating expenses increased during the 2012 period related to advancing its MASP-2 program toward the clinic, marketing expenses in connection with the planned 2014 commercial launch of OMS302, and increased legal costs and employee compensation, including non-cash stock-based compensation. These increases were partially offset by lower expenses related to Omeros' OMS302 and OMS103HP Phase 3 clinical programs and its PDE10, PDE7 and Plasmin programs.

Total operating expenses for the year ended December 31, 2012 were \$42.9 million, compared to \$31.9 million in 2011. The increase was primarily due to higher expenses related to Omeros' OMS302 Phase 3 clinical program and marketing costs tied to the drug's planned 2014 commercial launch, advancing its PDE10 and MASP-2 programs into and toward the clinic, respectively, the Company's GPCR program, and increased legal costs and employee compensation, including non-cash stock-based compensation. These increases were partially offset by lower expenses in Omeros' OMS103HP program and in several of its preclinical programs, including its PDE7 and Plasmin programs.

For the quarter ended December 31, 2012, Omeros reported a net loss of \$7.7 million, or \$0.30 per share, compared to a net loss of \$10.2 million, or \$0.46 per share, for the same period in 2011. For the year ended December 31, 2012, Omeros reported a net loss of \$38.4 million, or \$1.59 per share, compared to a net loss of \$28.5 million, or \$1.29 per share, in 2011.

At December 31, 2012, Omeros had cash and cash equivalents and short-term investments of \$22.4 million. Omeros expects that, taking into account its at-the-market equity facility with MLV & Co. LLC and its committed equity line financing facility with Azimuth Opportunity Ltd., it has sufficient resources to fund anticipated operating expenses, capital expenditures and note payments for at least the next 12 months.

"In 2012, our lead program, OMS302 for lens replacement surgery, completed two successful Phase 3 clinical trials – we are preparing to submit the NDA and MAA in the coming months and are planning the drug's commercial launch in 2014," said Gregory A. Demopulos, M.D., chairman and chief executive officer of Omeros. "OMS103HP, our product for arthroscopic surgery, delivered statistically significant

and clinically important pain reduction in a Phase 3 clinical trial and will enter its next pivotal Phase 3 trial later this year. In addition, we are planning to report data soon from our PDE10 Phase 1 program for schizophrenia and cognitive disorders, and our MASP-2 and PDE7 programs are on track to enter the clinic this year. All of these programs, together with our GPCR program and the rest of our pipeline, provide us multiple opportunities for success in 2013."

#### **Fourth Quarter Highlights**

- Announced the identification of compounds that interact selectively with four additional orphan G protein-coupled receptors (GPCRs), bringing the total number of orphans GPCRs unlocked by Omeros to 46, representing approximately 60 percent of the Class A orphan GPCRs. These four orphans GPR65/TDAG8, GPR82, MRGE and MRGF are linked to a series of important indications, including several types of cancer and inflammatory disorders, such as asthma (GPR65/TDAG8), appetite and body weight (GPR82) and pain (MRGE and MRGF). Omeros also recently announced its ability to unlock Class B orphan GPCRs.
- Reported positive data from its second pivotal Phase 3 clinical trial evaluating OMS302 in patients undergoing intraocular lens replacement surgery. OMS302 met its co-primary endpoints 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. Now with positive data from both trials in the OMS302 Phase 3 clinical program, Omeros plans to submit a New Drug Application with the U.S. Food and Drug Administration in the first half of 2013 and a Marketing Authorization Application with the European Medicines Agency in mid-2013. Omeros is building its marketing and sales capabilities in expectation of OMS302's planned commercial launch in 2014.
- Announced promising data from the single-ascending-dose (SAD) study portion of its Phase 1 clinical trial evaluating OMS824, the lead compound in Omeros' phosphodiesterase 10 (PDE10) program for schizophrenia and cognitive disorders. In this SAD study, OMS824 was well tolerated and demonstrated linear pharmacokinetics, a long half-life consistent with once daily dosing and good systemic exposure that resulted in the expected pharmacological effects in healthy subjects. With these encouraging data, Omeros advanced OMS824 to the next stage of the Phase 1 clinical program the evaluation of multiple-ascending dosing (MAD) of the compound. Omeros expects to report data from this MAD trial in the near future
- Completed the first Phase 3 clinical trial comparing OMS103HP to vehicle control in 344 patients undergoing arthroscopic partial meniscectomy surgery. The pre-specified primary endpoint was the Symptoms Subscale of the KOOS a patient-reported measure that is comprised of questions about knee swelling, clicking, catching and stiffness. In addition, pain measured in the early postoperative period was a pre-specified secondary endpoint. Although the Symptoms Subscale of the KOOS did not reach statistical significance, OMS103HP achieved statistically significant (p=0.0003) reduction of postoperative pain. The pain reduction data were similar in magnitude to those in the Phase 2 clinical trial. Omeros expects to conduct two concurrent Phase 3 clinical trials with reduction of early postoperative pain as the pre-specified primary endpoint and to begin enrolling patients in the first of these two planned trials in the first half of 2013. Each of these two additional Phase 3 clinical trials will enroll substantially fewer subjects than were required for the first Phase 3 trial assessing KOOS as the primary endpoint given the increased statistical power associated with reduction in early postoperative pain shown in the Phase 2 and first Phase 3 meniscectomy clinical trials.

#### **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 that it has sufficient resources to fund operations for at least the next 12 months; that it will submit a New Drug Application and Marketing Authorization Application for OMS302 in 2013; that it will be able to market and sell OMS302 in 2014; when it will be able to announce data from its PDE10 Phase 1 program; that it will advance its MASP-2 and PDE7 programs into this clinic this year; that it will conduct two additional Phase 3 clinical trials evaluating OMS103HP, with enrollment in the first trial beginning in the first half of 2013; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 18, 2013. 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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# OMEROS CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)

|   |          | Three Months Ended<br>December 31, |         |          |    | Twelve Months Ended<br>December 31, |    |           |  |
|---|----------|------------------------------------|---------|----------|----|-------------------------------------|----|-----------|--|
|   | <u> </u> | 2012                               |         | 2011     |    | 2012                                |    | 2011      |  |
|   |          | (unaudited)                        |         |          |    |                                     |    |           |  |
| Revenue                                 | \$       | 1,583                              | \$      | 1,143    | \$ | 6,022                               | \$ | 4,524     |  |
| Operating expenses:                     |          |                                    |         |          |    |                                     |    |           |  |
| Research and development                |          | 9,354                              |         | 8,895    |    | 31,922                              |    | 23,718    |  |
| General and administrative              |          | 3,715                              |         | 2,095    |    | 10,985                              |    | 8,216     |  |
| Litigation settlement                   |          | _                                  |         | _        |    | 3,953                               |    | _         |  |
| Litigation recovery                     |          | (3,953)                            |         | _        |    | (3,953)                             |    | _         |  |
| Total operating expenses                |          | 9,116                              |         | 10,990   |    | 42,907                              |    | 31,934    |  |
| Loss from operations                    |          | (7,533)                            | <u></u> | (9,847)  |    | (36,885)                            |    | (27,410)  |  |
| Investment income                       |          | 8                                  |         | 11       |    | 40                                  |    | 51        |  |
| Interest expense                        |          | (369)                              |         | (536)    |    | (1,729)                             |    | (1,884)   |  |
| Other income, net                       |          | 160                                |         | 171      |    | 130                                 |    | 697       |  |
| Net loss                                | \$       | (7,734)                            | \$      | (10,201) | \$ | (38,444)                            | \$ | (28,546)  |  |
| Basic and diluted net loss per share    | \$       | (0.30)                             | \$      | (0.46)   | \$ | (1.59)                              | \$ | (1.29)    |  |
| Weighted-average shares used to compute |          |                                    |         |          |    | <del></del> -                       |    |           |  |
| basic and diluted net loss per share    | 25       | ,886,586                           | 22,3    | 378,753  | 24 | 1,155,690                           | 22 | 2,212,351 |  |

# OMEROS CORPORATION CONSOLIDATED BALANCE SHEET DATA (In thousands)

|  | December 31,<br>2012 | December 31,<br>2011 |  |
|--|----------------------|----------------------|--|
| Cash and cash equivalents and short-term investments | \$ 22,350            | \$ 24,570            |  |
| Total assets   | 26,575               | 26,982               |  |
| Total notes payable                                  | 20,103               | 19,446               |  |
| Total current liabilities                            | 9,318                | 18,985               |  |
| Accumulated deficit                                  | (214,577)            | (176,133)            |  |
| Total shareholders' (deficit) equity                 | (6,531)              | (5,554)              |  |