## 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 13, 2014

# **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))

Dere-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 13, 2014, Omeros Corporation issued a press release announcing financial results for the three months and year ended December 31, 2013. 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 13, 2014 relating to Omeros' financial results for the three months and year ended December 31, 2013.

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 13, 2014

#### EXHIBIT INDEX

#### Exhibit <u>Number</u>

99.1

Press release dated March 13, 2014 relating to Omeros' financial results for the three months and year ended December 31, 2013.

Description



#### Omeros Corporation Reports Fourth Quarter and Year-End 2013 Financial Results

#### - 4Q 2013 net loss of \$1.8 million, or \$0.05 per share -

**SEATTLE, WA – March 13, 2014** – Omeros Corporation (NASDAQ: OMER), a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics targeting inflammation, coagulopathies and disorders of the central nervous system, today announced recent highlights and financial results for the fourth quarter and year ended December 31, 2013, which include:

- 4Q 2013 net loss of \$1.8 million, or \$0.05 per share, and for the full year of 2013 a net loss of \$39.8 million, or \$1.39 per share
- Operating expenses in 4Q 2013 were \$14.1 million including \$2.4 million of non-cash expenses, and for the full year of 2013 were \$52.1 million including non-cash expenses of \$9.7 million
- U.S. and European regulators accepted Omidria<sup>™</sup> (OMS302) marketing applications for review
- Omeros' OMS721 received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for complement-mediated thrombotic microangiopathies (TMAs)
- Closed senior loan facility with Oxford Finance and MidCap Financial in March 2014, receiving \$12.6 million in net proceeds
- Received \$12.5 million in settlement of insurance coverage lawsuit with former insurer

"Omeros achieved a number of significant milestones in 2013," said Gregory A. Demopulos, M.D., chairman and chief executive officer of Omeros. "In addition to submitting the NDA and MAA for Omidria, we completed successful clinical trials for OMS824 and OMS721, advancing both into Phase 2 clinical programs. In connection with the latter two programs, OMS824 received Orphan Drug and Fast Track Designations for Huntington's disease and OMS721 received Orphan Drug Designation for complement-mediated thrombotic microangiopathies. 2014 promises to be an exciting year — we look forward to the planned commercial launch of Omidria, Phase 2 data in Huntington's disease and TMAs, and continued success across our pipeline."

#### Fourth Quarter and Recent Highlights

- U.S. and European regulators accepted Omidria marketing applications for review. Omeros is preparing for a planned commercial launch of Omidria in the second half of 2014.
- Received Orphan Drug designation for OMS721, the company's lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), for the treatment of complement-mediated TMAs.

- Closed a senior credit facility with Oxford Finance and MidCap Financial in March 2014, consisting of a \$32.0 million term loan. The new loan requires interest-only payments through March 2015, and thereafter calls for monthly principal and interest payments through March 2018. Omeros used a portion of the loan proceeds to repay its obligations under its prior loan and security agreement with Oxford Finance and affiliates, and the remaining net proceeds of approximately \$12.6 million will be used for general corporate purposes and working capital.
- Began enrollment in the first quarter of 2014 in a Phase 2 clinical trial evaluating OMS824, the company's phosphodiesterase 10 (PDE10) inhibitor, in patients with Huntington's disease. OMS824 also received Fast Track Designation from the FDA for the treatment of cognitive impairment in patients with Huntington's disease.
- Announced positive results from its OMS824 Phase 2a clinical trial, in which OMS824 was well tolerated and demonstrated comparable systemic
  pharmacokinetics when administered alone and concomitantly with approved antipsychotic agents in patients with stable schizophrenia, opening
  the potential for OMS824 to be delivered as monotherapy or as an adjunct to commercially available antipsychotics.
- Reported positive data following completion of dosing in a Phase 1 clinical trial of OMS721, the company's lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2). Omeros expects to initiate a Phase 2 clinical trial to evaluate OMS721 in the treatment of TMAs in the second quarter of 2014.
- Received positive data using OMS721 in *ex vivo* studies of endothelial activation relevant to the pathophysiology of human atypical hemolytic uremic syndrome (aHUS), a form of TMA. The data reported showed that OMS721 significantly inhibited complement deposition in the system using serum samples from aHUS patients obtained during the acute phase of disease (p<0.01) and during remission (p<0.001) compared to untreated controls.</li>
- Announced that it had identified compounds that functionally interact with each of six additional orphan G protein-coupled receptors (GPCRs), bringing the number of Class A orphan GPCRs reported "unlocked" by Omeros to 52. Omeros also reported that it had identified small molecules that interact with two non-orphan Class B GPCRs, the glucagon-like peptide 1 receptor (GLP-1R) and the parathyroid hormone 1 receptor (PTH-1R).
- Entered into a settlement agreement with Carolina Casualty Insurance Company, or, CCIC, in October 2013, related to CCIC's defense of, and coverage obligations owed to, Omeros and its chief executive officer and chairman, Dr. Demopulos, in previously settled litigation. The settlement included a release of each party's respective claims in the insurance coverage lawsuit and payment by CCIC of \$12.5 million to Omeros.

#### **Financial Results**

Operating expenses for the three months ended December 31, 2013 were \$14.1 million, including \$2.4 million of non-cash expense, compared to \$9.1 million, including \$2.6 million of non-cash expenses, for the same period in 2012. During the fourth quarter of 2012, operating expenses were reduced by \$3.95 million due to a reimbursement Omeros received from its former insurer for expenses Omeros recognized in the third quarter of 2012 in connection with a litigation settlement. Excluding this reimbursement, Omeros' operating expenses for the three months ended December 31, 2013 increased by \$1.0 million from the prior year period. The increase was primarily related to our Phase 1 clinical trials evaluating OMS824 and OMS721, legal costs for patents, employee costs and expenses associated with preparing for our planned commercial launch of Omidria in the U.S. These increased expenses were

partially offset by lower clinical research and development expenses in the three months ended December 31, 2013 as compared to the same period in 2012 due to completion of our Omidria Phase 3 clinical trial in January 2013 and the completion of the first OMS103 Phase 3 clinical trial for meniscectomy in December 2012.

Operating expenses for the year ended December 31, 2013 were \$52.1 million, including \$9.7 million of non-cash expenses, compared to \$42.9 million, including \$4.9 million of non-cash expenses, in 2012. The 2013 increase related primarily to our Phase 1 clinical trials evaluating OMS824 and OMS721, non-cash rent expense associated with the lease of our new facilities, higher expenses related to the preparation and filing of the NDA and MAA and planned commercial launch for Omidria and increased legal and employee costs, including non-cash stock-based compensation. These increased expenses were partially offset by lower clinical research and development expenses related to the completion of our Omidria Phase 3 clinical trial in January 2013 and the first OMS103 Phase 3 clinical trial for meniscectomy in December 2012. These two clinical programs were ongoing during 2012.

Revenue for the year ended December 31, 2013, was \$1.6 million, compared to \$6.0 million in 2012. The decrease was primarily due to lower deferred revenue being recognized from our GPCR funding agreements, which were fully amortized in the first quarter of 2013.

For the quarter ended December 31, 2013, Omeros reported a net loss of \$1.8 million, or \$0.05 per share. The receipt of \$12.5 million in October 2013 from Omeros' settlement with CCIC reduced our net loss by \$0.41 per share. This compares to a net loss of \$7.7 million, or \$0.30 per share, for the same period in 2012, including a \$3.95 million (\$0.15 per share) reduction of our loss related to a payment received upon settlement of litigation. Noncash expenses were \$2.4 million (\$0.08 per share) for the quarter ended December 31, 2013 and \$2.6 million (\$0.10 per share) for the same period in 2012.

For the year ended December 31, 2013, Omeros reported a net loss of \$39.8 million, or \$1.39 per share. The receipt of the \$12.5 million settlement payment from CCIC reduced our net loss by \$0.44 per share. This compares to a net loss of \$38.4 million, or \$1.59 per share, in 2012. Noncash expenses were \$9.7 million (\$0.34 per share) for 2013 and \$4.9 million (\$0.20 per share) for 2012.

At December 31, 2013, Omeros had cash and cash equivalents and short-term investments of \$14.1 million.

#### **About Omeros Corporation**

Omeros is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics targeting inflammation, coagulopathies and disorders of the central nervous system. Derived from its proprietary PharmacoSurgery<sup>®</sup> platform, the company's lead drug product, Omidria (OMS302) for lens replacement surgery, is currently under review for marketing approval by both the US Food and Drug Administration and the European Medicines Agency with U.S. commercial launch planned for the second half of 2014. Omeros' six other clinical programs are focused on schizophrenia, Huntington's disease and cognitive impairment; addictive and compulsive disorders; complement-related diseases; and preventing problems associated with surgical procedures. Omeros also has a proprietary GPCR platform, which is making available an unprecedented number of new GPCR drug targets and corresponding compounds to the pharmaceutical industry for drug development.

#### **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 "anticipate,"

"believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions. 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, risks associated with Omeros' unproven preclinical and clinical development activities, regulatory oversight, product commercialization, intellectual property claims, competitive developments and 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 13, 2014. 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 unless required by law, 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 December 31,				Twelve Months Ended December 31,			
		2013	- 124 - 11	2012		2013	_	2012
Revenue	\$	169	udited) \$	1,583	\$	1,600	\$	6,022
Operating expenses:				,		,		,
Research and development		10,186		9,354		36,297		31,922
General and administrative		3,885		3,715		15,819		10,985
Litigation settlement								3,953
Litigation recovery				(3,953)				(3,953)
Total operating expenses		14,071		9,116		52,116		42,907
Loss from operations		(13,902)		(7,533)		(50,516)		(36,885)
Litigation settlement		12,500				12,500		
Investment income		2		8		12		40
Interest expense		(598)		(369)		(2,366)		(1,729)
Other income (expense), net		153		160		574		130
Net loss	\$	(1,845)	\$	(7,734)	\$	(39,796)	\$	(38,444)
Basic and diluted net loss per share	\$	(0.05)	\$	(0.30)	\$	(1.39)	\$	(1.59)
Weighted-average shares used to compute basic and diluted net loss per share	30	),289,041	25	5,886,586	2	8,560,360		24,155,690

#### OMEROS CORPORATION CONSOLIDATED BALANCE SHEET DATA (In thousands)

	December 31, 2013	December 31, 2012	
Cash and cash equivalents and short-term investments	\$ 14,101	\$ 22,350	
Total assets	16,535	26,575	
Total notes payable	20,498	20,103	
Total current liabilities	11,873	8,359	
Accumulated deficit	(254,373)	(214,577)	
Total shareholders' (deficit) equity	(18,384)	(6,531)	