

OMEROS CORP
Form 8-K
October 05, 2017

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 4, 2017

OMEROS CORPORATION

(Exact name of Registrant as Specified in Its Charter)

Washington
(State or Other Jurisdiction

of Incorporation)

201 Elliott Avenue West

001-34475
(Commission

File Number)

91-1663741
(IRS Employer

Identification No.)

98119

Seattle, WA
(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))
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 1.01 Entry Into a Material Definitive Agreement.

On October 4, 2017, Omeros Corporation (the Company) entered into a Settlement Agreement (the Settlement Agreement) and consent judgment with Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC (collectively, Par), resolving the Company's patent litigation against Par, which arose from Par's filing of an Abbreviated New Drug Application seeking approval from the U.S. Food and Drug Administration to market a generic version of the Company's drug OMIDRIA® (phenylephrine and ketorolac injection) 1% / 0.3%. Pursuant to the Settlement Agreement, Par, which had previously stipulated to infringement, acknowledged and confirmed the validity of each of the patents listed in the Orange Book for OMIDRIA, which are U.S. Patent No. 8,173,707, U.S. Patent No. 8,586,633, U.S. Patent No. 9,066,856, U.S. Patent No. 9,278,101, U.S. Patent No. 9,399,040, and U.S. Patent No. 9,486,406.

Under the terms of the Settlement Agreement, the parties executed a consent judgment that was filed with the U.S. District Court for the District of Delaware on October 5, 2017. Pursuant to the Settlement Agreement and consent judgment, Par and its affiliates will be prohibited by court order from launching a generic version of OMIDRIA until the earlier of April 1, 2032 or a date on which the Company or a third party, through licensing or any future final legal judgment, should one ever exist, with respect to the Company's Orange Book listed patents, is able to launch a generic version of OMIDRIA, as further detailed in the Settlement Agreement (such date, the Entry Date). Under the Settlement Agreement, the Company granted Par a non-exclusive, non-sublicensable license to make, sell and distribute a generic version of OMIDRIA between the Entry Date and the latest expiration of the Company's U.S. patents related to OMIDRIA (i.e., October 23, 2033). During this period, Par will pay to the Company a royalty equal to 15% of Par's net sales of its generic version of OMIDRIA.

The foregoing is a brief description of the material terms of the Settlement Agreement, does not purport to be a complete description of the rights and obligations of the parties thereunder, and is qualified in its entirety by reference to the Settlement Agreement which is filed as Exhibit 10.1 to this Current Report on Form 8-K. The Settlement Agreement contains representations, warranties and covenants that were made only for purposes of such agreement and, as of specific dates, were solely for the benefit of the parties to such agreement and may be subject to limitations agreed on by the contracting parties. The Settlement Agreement is not intended to provide any other factual information about the Company.

Item 8.01 Other Events.

On October 5, 2017, Omeros Corporation issued a press release announcing its entry into the Settlement Agreement. 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) Exhibit Index.

| Exhibit | No. | Description |
|---------|-----|---|
| 10.1 | | <u>Settlement Agreement, dated October 4, 2017, by and among Omeros Corporation, Par Sterile Products, LLC and Par Pharmaceutical, Inc.</u> |
| 99.1 | | <u>Press Release dated October 5, 2017.</u> |

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 5, 2017

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