OMEROS CORP
Form 8-K
May 24, 2018

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): May 22, 2018

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		**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 May 22, 2018, Omeros Corporation (the Company) entered into a Settlement Agreement (the Settlement Agreement) and consent judgment with Lupin Ltd. and its subsidiary Lupin Pharmaceuticals, Inc. (collectively, Lupin), resolving the Company s patent litigation against Lupin. The litigation arose from Lupin s filing of an Abbreviated New Drug Application (ANDA) seeking approval from the U.S. Food and Drug Administration to market a generic version of the Company s commercial drug OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% in May 2017. Pursuant to the Settlement Agreement, Lupin 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, U.S. Patent No. 9,486,406 and U.S. Patent No. 9,855,246.

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 May 23, 2018. The Company previously entered into a settlement agreement with ANDA-filer Par Sterile Products, LLC and Par Pharmaceutical, Inc. (collectively Par) under which Par is precluded from launching a generic version of OMIDRIA until April 1, 2032 unless subsequently authorized pursuant to terms in that settlement agreement. In accordance with the Settlement Agreement and consent judgment with Lupin, Lupin will be prohibited by the judgment from launching a generic version of OMIDRIA until the earlier of (i) April 1, 2032 if Par has forfeited its six month first-ANDA filer exclusivity, (ii) October 1, 2032 if Par has not forfeited its six month first-ANDA filer exclusivity, or (iii) a date on which the Company or a third party, through licensing of, any future final legal judgment regarding, or the delisting, abandonment or expiration of the Company s U.S. OMIDRIA patents, is able to launch a generic version of OMIDRIA.

Under the Settlement Agreement, Lupin is granted a non-exclusive, non-sublicensable license to make, sell and distribute a generic version of OMIDRIA between the permitted launch date and the latest expiration of the Company s U.S. patents related to OMIDRIA (*i.e.*, at least October 23, 2033) and a non-exclusive, non-sublicensable waiver of the Company s pediatric exclusivity for OMIDRIA until at least April 23, 2034. During these license and exclusivity waiver periods, unless Par has not forfeited its six month first-ANDA filer exclusivity and until the Company or a third party launches a generic version of OMIDRIA, Lupin will be required to pay the Company a royalty equal to 15% of Lupin s net sales of its generic version of OMIDRIA until the Company s U.S. patents related to OMIDRIA expire, and thereafter an exclusivity waiver fee of 15% of Lupin s net sales of its generic version of OMIDRIA until the Company s pediatric exclusivity for OMIDRIA expires.

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 hereto. 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 May 24, 2018, the Company 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	Settlement Agreement, dated as of May 22, 2018, by and among Omeros Corporation and Lupin Ltd. and Lupin Pharmaceuticals, Inc.
99.1	Press Release dated May 24, 2018.

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: May 24, 2018

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