OMEROS CORP
Form 8-K
September 03, 2015

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): September 2, 2015

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

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 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:

¨ Written communication 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 8.01 Other Events

On September 2, 2015, Omeros Corporation (Omeros) filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey and on September 3, 2015, filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, collectively referred to as Par. The lawsuits were filed under the Hatch-Waxman Act for Par s infringement of three Omeros patents, U.S. Patent Nos. 8,173,707, 8,586,633 and 9,066,856, which relate to Omeros drug Omidria® (phenylephrine and ketorolac injection) 1%/0.3% and which are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the *Orange Book*, published by the U.S. Food and Drug Administration (FDA). The lawsuits were filed in response to a Paragraph IV certification notice Omeros received from Par, dated July 23, 2015, regarding Par s filing with the FDA of an Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of Omidria prior to the expiration of the three *Orange Book*-listed patents for Omidria. These patents were granted following review by the U.S. Patent and Trademark Office, are presumed to be valid under governing law, and can only be invalidated in federal court with clear and convincing evidence.

Under the Hatch-Waxman Act, Omeros was permitted to file suit within 45 days from its receipt of Par s notice and thereby trigger a 30-month stay of the FDA s approval of Par s ANDA. The stay is expected to remain in effect until March 2018. Omeros has reviewed Par s Paragraph IV assertions and believes they do not have merit. Omeros has sought access to Par s ANDA, which Par is legally required to provide under reasonable terms, but to date Par has not provided this access. Omeros will obtain access to Par s ANDA and will vigorously prosecute its infringement claims against Par.

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: September 3, 2015