OSCIENT PHARMACEUTICALS CORP
Form 8-K
July 08, 2008

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): July 7, 2008

OSCIENT PHARMACEUTICALS CORPORATION

(Exact name of registrant as specified in its charter)

Massachusetts	**0-10824**	**04-2297484**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

1000 Winter Street, Suite 2200

Waltham, Massachusetts 02451

(Address of principal executive offices, including zip code)

(781) 398-2300

(Registrant s telephone number, including area code)

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 8.01. OTHER EVENTS.

On July 7, 2008, Oscient Pharmaceuticals Corporation (the Company) received notice from the U.S. Food and Drug Administration (the FDA) directing that the prescribing information for all fluoroquinolone products, including FACTIVE® (gemifloxacin mesylate) tablets, be revised to include new safety information.

Currently, warnings regarding the risk of tendon related adverse events are included in the prescribing information, as part of a class labeling, for all fluoroquinolones. The FDA has conducted a new analysis of reports and available literature which it states reconfirms that fluoroquinolones are associated with an increased risk of tendon rupture and that a Boxed Warning related to the risk of tendonitis and tendon rupture associated with fluoroquinolone products should be added to the current labeling of all fluoroquinolones, including FACTIVE. The FDA has cautioned that such risk is increased in patients over the age of 60 and in those on concomitant corticosteroid therapy, as well as kidney, heart and lung transplant recipients.

In addition, the FDA has informed the Company that it, along with the other sponsors of all marketed fluoroquinolone products, should submit a proposed Medication Guide and implement a Risk Evaluation and Mitigation Strategy to ensure patients safe and effective use of all fluoroquinolones, including FACTIVE.

The Company plans to review this request from, and work closely with the FDA to implement any and all changes that may be required to ensure patient safety and improve physician understanding of the risk-benefit profile for fluoroquinolone products, including FACTIVE.

According to the FDA Adverse Event Reporting System (data available through December 31, 2007), three cases of tendon-related side effects associated with FACTIVE have been reported, including: one case of tendon disorder, one case of tendonitis and one case of tendon rupture. The Company estimates, based on prescription and sampling data through the end of March 2008, that 1.6 million patients in the United States had received a FACTIVE course of therapy. These reported adverse events may or may not reflect the actual prevalence of tendon-related side effects associated with FACTIVE. To date, FDA has required equivalent labeling for all the fluoroquinolones, with respect to the risk of tendon-related side effects, and has not distinguished among the benefit-risk profiles of the different fluoroquinolone products.

SIGNATURE

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.

OSCIENT PHARMACEUTICALS CORPORATION

By: /s/ Philippe M. Maitre
Name: Philippe M. Maitre

Title: Executive Vice President and Chief Financial Officer

Date: July 8, 2008