DURECT CORP
Form 8-K
June 28, 2011

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: June 28, 2011 (June 27, 2011)

(Date of earliest event reported)

DURECT CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**000-31615**	**94-3297098**

(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2 Results Way

Cupertino, CA 95014

(Address of principal executive offices) (Zip code)

(408) 777-1417

(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 June 27, 2011, Pain Therapeutics, Inc., issued a press release providing further information about the Complete Response Letter received by Pfizer, Inc. on June 23, 2011 from the U.S. Food and Drug Administration (FDA) on the resubmission to the new drug application (NDA) for REMOXY® (oxycodone) Extended-Release Capsules CII.

According to Pain Therapeutics: The FDA s Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Certain drug lots showed inconsistent release performance during *in vitro* testing. It is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency. Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA s Complete Response Letter. In the opinion of Pain Therapeutics, potential regulatory approval of REMOXY in the U.S. is unlikely to occur in less than one year, and could be delayed significantly longer than a year.

Corporate Relationships:

In December 2002, DURECT licensed to Pain Therapeutics, Inc. the right to develop and commercialize on a worldwide basis REMOXY and other oral sustained release drug candidates using the ORADUR® technology which incorporate four specified opioid compounds. Pain Therapeutics sublicensed the commercialization rights of REMOXY and other licensed drug candidates to King Pharmaceuticals in November 2005. Pfizer completed its acquisition of King Pharmaceuticals in February 2011 and as a result has assumed the development and commercialization rights and obligations to REMOXY.

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.

DURECT Corporation

Date: June 28, 2011

By: /s/ Matt Hogan
Matt Hogan
Chief Financial Officer