8-K 1 d8k.htm FORM 8-K

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

February 22, 2010
Date of Report
(February 18, 2010)
(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 or organization)	**(Commission File Number)**	**(I.R.S. 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)

(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:

¨ 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 1.01Entry into or Amendment of Material Definitive Agreement

Effective February 18, 2010, DURECT Corporation (the Company) and Nycomed Danmark ApS (Nycomed) entered into an amendment (Amendment) to the Development and License Agreement entered into between the parties effective November 29, 2006 (Agreement) covering the development and commercialization of POSIDUR™ (also known as SABER™-Bupivacaine or OPTESIA™ in the European Union (E.U.)), an investigational drug for the treatment of post-surgical pain.

Prior to the Amendment, the Agreement provided for the two parties to jointly direct and equally fund a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. Under the Amendment, the Company will now have final decision-making authority over clinical trials intended for the U.S. registration of POSIDUR. Subject to the Company's right to initiate dispute resolution procedures in specified circumstances, Nycomed will now have final decision-making authority over clinical trials for the E. U. and other countries licensed to it.

The Amendment provides that the Company will have sole funding responsibility for all current and future clinical trials intended for U.S. registration of POSIDUR and, commencing April 1, 2010, Nycomed will have sole funding responsibility for all clinical trials intended for E.U. registration of POSIDUR. The Amendment does not alter the final decision making authority and financial responsibility for the remainder of the development activities, such as the non-clinical and CMC activities, which will continue to be jointly managed and funded by the Company and Nycomed.

The Amendment expands the territories licensed to Nycomed to include China, Hong Kong, Malaysia, Philippines, Singapore, Taiwan, Vietnam, Thailand, Indonesia, India and Venezuela. The Company retains full ownership of POSIDUR in the U.S., Canada, Japan and other territories not licensed to Nycomed.

The Amendment provides Nycomed with additional pre-specified opportunities for Nycomed to terminate the Agreement within specified periods after certain clinical trials of POSIDUR. In addition, Nycomed has granted to the Company a royalty-free, exclusive license (with the right to sublicense) to the trademark OPTESIA™ for use outside the territory licensed to Nycomed in connection with the commercialization of POSIDUR.

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: February 22, 2010

By: /s/ JAMES E. BROWN

James E. Brown
President and Chief Executive Officer