DURECT CORP
Form 8-K
February 09, 2011

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 9, 2011

Date of Report

(February 8, 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 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 1.01 Entry into or Amendment of Material Definitive Agreement

Effective February 8, 2011, DURECT Corporation (DURECT) and Nycomed Danmark ApS (Nycomed) entered into an amendment (Amendment) to the Development and License Agreement entered into between the parties dated November 29, 2006 covering the development and commercialization of POSIDUR , an investigational drug for the treatment of post-surgical pain, in the European Union (E.U.) and other selected countries (the Agreement).

Prior to the Amendment, the Agreement provided for the two parties to jointly direct and equally fund the non-clinical and Chemistry Manufacturing and Controls (CMC) activities for POSIDUR for the U.S. and E.U. territories. The Amendment now provides that during the period commencing from January 1, 2011 until a specified period after the results are delivered from DURECT to Nycomed from DURECT s U.S. Phase III clinical trial for POSIDUR referred to as BESST (Bupivacaine Effectiveness and Safety in SABER Trial) (such period the Interim Period), DURECT shall assume full funding responsibility and final decision making authority for these activities. Furthermore, during this Interim Period, Nycomed s development and commercialization responsibility relating to POSIDUR for the territory licensed to Nycomed shall be confined to bringing its E.U. Phase IIb Clinical Trial in shoulder surgery to a full completion. Unless the Agreement is otherwise terminated, at the conclusion of the Interim Period, under the Amendment, Nycomed would resume joint control and shared funding responsibility with DURECT for the non-clinical and Chemistry Manufacturing and Controls (CMC) activities for POSIDUR for the U.S. and E.U. territories.

Prior to the Amendment, Nycomed had the right to terminate the Agreement after specified periods after data was received from certain clinical trials of POSIDUR in the E.U. and the U.S., including BESST. The foregoing right was modified by the Amendment to provide that Nycomed may exercise its right to terminate the Agreement at its sole election if BESST data was not available by December 31, 2011.

Item 8.01 Other Events

On February 9, 2011, DURECT issued a press release announcing results from a European Phase IIb shoulder clinical trial conducted by Nycomed of POSIDUR and the amendment of the DURECT s collaboration agreement with Nycomed. A copy of DURECT s press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release of DURECT Corporation dated February 9, 2011

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 9, 2011

By: /s/ James E. Brown
James E. Brown
President and Chief Executive Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release of DURECT Corporation dated February 9, 2011