

DURECT CORP
Form 8-K
March 14, 2005

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

March 10, 2005

Date of Report

(Date of earliest event reported)

DURECT CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-31615
(Commission File Number)

94-3297098
(I.R.S. Employer
Identification No.)

10240 Bubb Road
Cupertino, CA 95014

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(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))
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Item 1.01 Entry Into a Definitive Material Agreement.

On March 10, 2005, DURECT Corporation entered into a license agreement with Endo Pharmaceuticals Inc. (Endo) under which DURECT granted to Endo the exclusive right to develop and commercialize DURECT's proprietary sufentanil transdermal patch product candidate (TRANSDUR-Sufentanil) in the U.S. and Canada. Under the terms of the agreement, Endo will assume all remaining development and regulatory filing responsibility in the U.S. and Canada, including the funding thereof. DURECT will perform all formulation development for Endo unless DURECT defaults on such obligations, and DURECT will be reimbursed for fully allocated cost in performance of such work. Endo will also be responsible and pay for the manufacture, marketing, sales and distribution of TRANSDUR-Sufentanil in the U.S. and Canada. Endo will pay DURECT an upfront fee of \$10 million, with additional payments of up to approximately \$35 million in the aggregate based upon achievement of predetermined regulatory and commercial milestones. Endo will also pay DURECT product royalties based on the net sales of TRANSDUR-Sufentanil under the agreement. DURECT has the right to co-promote TRANSDUR-Sufentanil under terms specified in the agreement. The agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties and indemnities. The agreement shall continue in effect until terminated. The agreement provides each party with specified termination rights, including the right of each party to terminate the agreement upon material breach of the agreement by the other party. In addition, Endo shall have the right to terminate the agreement at any time without cause subject to a specified notice period and due to adverse product events, legal impediment or the issuance of a final, non-appealable court order enjoining Endo from selling TRANSDUR-Sufentanil in the U.S. and Canada as a result of an action for patent infringement by a third party, provided that in the latter instance, DURECT will be required to pay Endo a termination fee ranging from \$5 million to \$10 million, depending on the date of termination. DURECT has the right to terminate the agreement in the event that Endo pursues directly or indirectly any proceeding seeking to have any of DURECT's TRANSDUR-Sufentanil related patents revoked or declared invalid, unpatentable or unenforceable.

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: March 14, 2005

By: /s/ James E. Brown

James E. Brown
President and Chief Executive Officer