DURECT CORP
Form 8-K
March 21, 2017

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 21, 2017

Date of Report

(March 20, 2017 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.)

10260 Bubb Road

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 8.01 Other Events

On March 20, 2017, Pain Therapeutics, Inc., DURECT's licensee for REMOXY® ER, announced that it plans to resubmit the REMOXY ER NDA after completing two additional studies regarding REMOXY ER based on guidance following a recent meeting with the U.S. Food and Drug Administration (FDA). The two studies are a clinical abuse potential study via the intranasal route of abuse and a non-clinical abuse potential study using household solvents. Pain Therapeutics expects to complete these studies by year end 2017, after which they intend to have a pre-NDA meeting with the FDA followed by resubmission of the REMOXY NDA, with anticipated Priority Review, under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. REMOXY ER is an oral, long-acting oxycodone gelatin capsule under development with Pain Therapeutics to which we have licensed exclusive, worldwide, development and commercialization rights under a development and license agreement entered into in December 2002.

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 21, 2017 By: /s/ James E. Brown
James E. Brown
President and Chief Executive Officer