

DURECT CORP
Form 8-K
May 13, 2015

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

May 13, 2015

(May 11, 2015)

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

000-31615
(Commission

94-3297098
(I.R.S. Employer

incorporation or organization)

File Number)
10260 Bubb Road

Identification No.)

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 May 11 and 12, 2015, DURECT Corporation's licensee for REMOXY[®], Pain Therapeutics, Inc. (Pain Therapeutics), announced information about clinical trials and its plans for REMOXY, a novel long-acting oral formulation of the opioid oxycodone targeted to decrease the potential for oxycodone abuse. DURECT licensed development and commercialization rights to REMOXY to Pain Therapeutics, and Pain Therapeutics subsequently licensed these rights to King Pharmaceuticals, Inc. (King). King was later acquired by Pfizer Inc. (Pfizer), and in October 2014, Pfizer informed Pain Therapeutics that it was returning its development and commercialization rights for REMOXY to Pain Therapeutics. Under the terms of DURECT's agreement with Pain Therapeutics, if REMOXY is commercialized, DURECT will receive royalties of between 6.0% to 11.5% of net sales depending on sales volumes.

Pain Therapeutics disclosed that it has substantially completed the transition of REMOXY from Pfizer. Pain Therapeutics also disclosed that it plans to refile the REMOXY NDA with the FDA in the first quarter of 2016, and that it believes that, if accepted, the NDA will have a six-month review cycle. Pain Therapeutics does not believe that new clinical trials are required to refile the REMOXY NDA. Pain Therapeutics also disclosed that it plans to conduct certain non-clinical activities prior to refiling the REMOXY NDA, including in vitro work that was initiated but never completed by REMOXY's previous sponsor due to the timing of their decision to return REMOXY. Pain Therapeutics has indicated that it may take up to six months to conduct such work, depending on the workflow and availability of its consultants and vendors. Pain Therapeutics also announced that it intends to continue to retain Mallinckrodt for contract manufacturing and supply chain support for REMOXY.

According to Pain Therapeutics, its former partner for REMOXY had sole responsibility for an FDA Category 3 Human Abuse Potential Study with REMOXY, which was conducted in accordance with draft FDA Guidance to Industry on Abuse Deterrent Opioids and interactions between the study sponsor and FDA. The study was randomized, double-blind, placebo and active controlled, using a 4-way crossover design in healthy, non-dependent recreational opioid users. Nearly 60 subjects completed this study, with an average age of 27 years. The study's primary objective was to measure the abuse potential of chewed and intact 40mg REMOXY compared to 40mg immediate-release (IR) oxycodone when taken orally. Study subjects were instructed to chew REMOXY capsules vigorously for up to 5 minutes, but none were able to do so in light of REMOXY's high viscosity, texture or taste. Pharmacodynamic measures of the primary endpoints, Drug Liking and Drug High, included use of a standard 0-100 point Visual Analogue Scale (VAS) in the initial two hours post-dose (AUC02h), as recommended by FDA to assess a formulation's abuse potential. The sponsor generated study tables for this Abuse Potential Study in December 2014. DURECT has not been provided the study tables or any other study reports, and Pain Therapeutics stated that it has not performed an independent analysis of the study results.

According to Pain Therapeutics, clinical and statistical highlights of this study include:

On the co-primary endpoint of Drug Liking, scores were significantly lower for intact REMOXY ($p < 0.0001$) and for chewed REMOXY ($p < 0.0001$) compared to IR oxycodone.

On the co-primary endpoint of Drug High, scores were significantly lower for intact REMOXY ($p < 0.0001$) and for chewed REMOXY ($p < 0.0001$) compared to IR oxycodone.

On the secondary endpoint of Good Drug Effects, scores were significantly lower for intact REMOXY ($p < 0.0001$) and for chewed REMOXY ($p < 0.0001$) compared to IR oxycodone.

On the secondary endpoint of Bad Drug Effects, scores were significantly higher for intact REMOXY ($p < 0.0001$) and for chewed REMOXY ($p < 0.0079$) compared to IR oxycodone.

On the secondary endpoint of Pupil Constriction, scores were significantly lower for intact REMOXY ($p < 0.0001$) and for chewed REMOXY ($p < 0.0001$) compared to IR oxycodone.

On the secondary endpoint of Nausea, scores were significantly lower for intact REMOXY ($p < 0.0001$) and for chewed REMOXY ($p < 0.0143$) compared to IR oxycodone.

On the secondary endpoint of Feel Sick, scores were significantly lower for intact REMOXY ($p < 0.0002$) and for chewed REMOXY ($p < 0.039$) compared to IR oxycodone.

Forward-looking Statements

The statements in this press release regarding REMOXY and Pain Therapeutics' beliefs, plans and expectations regarding REMOXY, the abuse deterrent qualities of REMOXY, the continued development of REMOXY by Pain Therapeutics, potential resubmission of an NDA for REMOXY with the FDA, and the timing of such resubmission, proposed non-clinical activities with respect to REMOXY, the sufficiency of data and other information to support the resubmission and approval of an NDA for REMOXY and the intended source of commercial supply for REMOXY, are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, the risk that Pain Therapeutics will discontinue development of REMOXY, the risk of difficulties or delays in development, testing, regulatory approval, production and marketing of REMOXY, the risk that additional non-clinical work will not have satisfactory outcomes, the risk of unexpected delays in the submission and regulatory review of, or adverse decisions by, regulatory agencies, including non-acceptance of the REMOXY NDA, the requirement to conduct additional clinical trials, product non-approval, further delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of REMOXY or inadequate therapeutic efficacy of REMOXY, the potential that data submitted to the FDA will not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of REMOXY (including the risk that current and past results of clinical trials and studies may be found to be insufficient for marketing approval), and the risk of obtaining marketplace acceptance of REMOXY, developments of products or technologies by current or future competitors, avoiding infringing patents held by other parties and securing and defending patents related to REMOXY. Further information regarding these and other risks is included in DURECT's Form 10-Q for the quarter ending March 31, 2015 under the heading "Risk Factors."

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: May 13, 2015

By: /s/ James E. Brown
James E. Brown

President and Chief Executive Officer