

Edgar Filing: DURECT CORP - Form 8-K

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.02. Termination of a Material Definitive Agreement

On January 2, 2019, DURECT Corporation (“DURECT”) received written notice from Sandoz AG that effective January 27, 2019, Sandoz AG is terminating the Development and Commercialization Agreement, dated May 5, 2017, as amended (the “Sandoz Agreement”). As a result of this termination, Sandoz AG will be returning its exclusive commercialization rights to develop and market POSIMIR® (bupivacaine extended release solution) in the United States. POSIMIR is DURECT’s investigational post-operative pain relief depot that utilizes DURECT’s patented SABER® technology and is designed to deliver bupivacaine to provide up to three days of pain relief after surgery.

The parties are in dispute with regard to Sandoz AG’s obligation to pay a termination fee to DURECT. DURECT has initiated a formal dispute resolution process related to the termination fee.

A summary of the material terms of the Sandoz Agreement was included in DURECT’s Annual Report on Form 10-K filed on March 8, 2018, which is qualified in its entirety by reference to the full text of the Sandoz Agreement and amendments (filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 000-31615) filed on August 9, 2017, and Exhibit 10.2 to our Quarterly Report on Form 10-Q (File No. 000-31615) filed with the SEC on August 2, 2018, respectively, and incorporated by reference).

Item 8.01 Other Events

On January 7, 2019, DURECT issued a press release announcing changes to its strategy for DUR-928 to prioritize indications with the potential to generate near-term data that demonstrates the potential of DUR-928 and creates commercial and partnering value by focusing on patients with non-alcoholic steatohepatitis (NASH) and patients with mild to moderate plaque psoriasis. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release of DURECT Corporation dated January 7, 2019

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: January 7, 2019 By: /s/ James E. Brown
James E. Brown
President and Chief Executive Officer