

DURECT CORP
Form 8-K
May 09, 2018

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 9, 2018

Date of Report

May 4, 2018

(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 (Commission (I.R.S. Employer
incorporation or organization) File Number) Identification No.)

10260 Bubb Road

Cupertino, CA 95014

(Address of principal executive offices) (Zip code)

(408) 777-1417

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(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 1.01 Entry into a Material Definitive Agreement.

Effective May 4, 2018, DURECT Corporation (“DURECT” or the “Company”) and Sandoz AG (“Sandoz”) entered into an amendment (the “Amendment”) to the license agreement dated May 5, 2017, regarding POSIMIR® (SABER®-bupivacaine) in the United States. Pursuant to the original license agreement, DURECT received an upfront payment of \$20 million and was initially eligible for up to an additional \$43 million in milestone payments based on successful development and regulatory milestones (of which \$30 million is feasible following the results of the PERSIST Phase 3 clinical trial), and up to an additional \$230 million in sales-based milestones. Sandoz received exclusive commercialization rights for POSIMIR in the U.S. upon regulatory approval with sole funding responsibility for commercialization activities. Sandoz will pay the Company a tiered double-digit royalty on product sales for a defined period, after which the license granted to Sandoz shall convert to a non-exclusive, fully paid, royalty-free, irrevocable and perpetual license.

Pursuant to the Amendment, DURECT is eligible for up to \$30 million in milestone payments based on NDA approval, and remains eligible for up to an additional \$230 million in sales-based milestones. Pursuant to the Amendment, each party is also permitted to develop or commercialize competing products. The Amendment also includes modifications to DURECT’s development obligations and to both parties’ termination provisions, including a right for DURECT to terminate for convenience prior to NDA approval, and a new termination fee payable to DURECT in the event that Sandoz terminates the agreement for convenience. Except as expressly set forth in the Amendment, the license agreement remains in full force and effect.

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 9, 2018 By: /s/ James E. Brown
James E. Brown
President and Chief Executive Officer