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

January 7, 2019

(January 2, 2019)

Date of Report

(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))

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

Exhibit 99.1

DURECT Corporation Provides Corporate Update

Live Webcast Today at 8:00 a.m. Eastern Time

CUPERTINO, Calif., January 7, 2019 -- DURECT Corporation (Nasdaq: DRRX) has refined and focused its clinical development strategy for DUR-928, the lead product candidate in its Epigenetic Regulator Program, to prioritize indications with unmet medical needs where we expect to be able to generate near-term data with the potential to create significant commercial and partnering value. The new DUR-928 clinical development strategy is:

1. Accelerate DUR-928 clinical trial in non-alcoholic steatohepatitis (NASH) patients.
    - DURECT previously announced that it would be initiating a new clinical trial of orally-administered DUR-928 in NASH patients in the first half of 2019, and is now updating that guidance to indicate that the Company expects to begin enrolling patients in Q1 2019.
    - This will be an open-label, Phase 1b study conducted in the U.S. to evaluate safety, pharmacokinetics and signals of biological activity of DUR-928 in patients with NASH. Patients will be administered DUR-928 orally for 28 consecutive days. Further details on the trial design will be provided later in Q1 2019.
    - DURECT expects to announce initial data in the second half of 2019.
2. Complete the Phase 2a proof-of-concept trial with topical DUR-928 in patients with mild to moderate plaque psoriasis as planned. The Company reiterates its prior guidance that the psoriasis trial is on track to begin dosing this quarter with top line data expected in the second half of 2019.
3. Continue and then transition the ongoing DUR-928 alcoholic hepatitis (AH) Phase 2a trial to Dr. Craig McClain at the University of Louisville.
    - Since the Company's announcement of the initiation of dosing in Part B (severe AH patients) in November 2018, two severe AH patients have been treated at the 30 mg I.V. dose of DUR-928.
    - Upon completing the 30 mg dose group in Part B, we plan to transition the study to Dr. McClain, who was recently awarded an NIH grant to study DUR-928 in AH patients. After the transition, the trial will be funded via grants and conducted by Dr. McClain.
4. Discontinue the primary sclerosing colangitis (PSC) trial. Given that the Company's efforts have not resulted in an increase in the inherently slow enrollment rates commonly seen for this indication, the Company has decided to discontinue its PSC study in order to focus more of its resources on NASH and psoriasis.

"Our revised development strategy for DUR-928 will allow our team to focus on the indications that could provide value-creating, near-term clinical data and help us formulate a plan to advance DUR-928 into late stage clinical development," stated James E. Brown, D.V.M., President and CEO of DURECT. "Showing positive signals of biological activity after 28 days in NASH

patients could be particularly valuable in demonstrating the potential of DUR-928 in this important disease, while obtaining positive proof-of-concept data in psoriasis could lead to a partnership for DUR-928 in the dermatology space."

Update on Selected Other Programs:

POSIMIR® (bupivacaine extended-release solution)

Sandoz AG provided notice that it is returning to DURECT all of its U.S. development and commercialization rights to POSIMIR® (bupivacaine extended release solution) post-operative pain relief depot. The parties are in dispute with regard to Sandoz's obligation to pay a termination fee to DURECT. DURECT has initiated a formal dispute resolution process related to the termination fee.

"We understand their decision to focus resources on other programs as their new US leadership continues to implement its strategy," stated James Brown, President and CEO of DURECT. "We maintain our belief that there is a need for additional non-opioid products in the post-operative pain setting and will continue to evaluate and consider potential next steps for POSIMIR."

POSIMIR is the Company's investigational post-operative pain relief depot that utilizes the Company's patented SABER technology and is designed to deliver bupivacaine to provide up to 3 days of pain relief after surgery.

Indivior (LON: INDV) Agreement and PERSERIS™

Indivior PLC stated on December 18, 2018 that it is moving ahead with the launch of PERSERIS in the U.S. with a sales force consisting of approximately 50 representatives. While PERSERIS has been available in the U.S. since November 19, 2018, Indivior stated that the commercial launch is scheduled to take place in February 2019. Indivior stated that its PERSERIS team is currently engaged in creating payor access, growing prescriber awareness and interest, as well as establishing its INSUPPORT patient hub. Indivior also affirmed that it remained confident in its peak net revenue goal for PERSERIS of $200 to $300 million. Under the terms of the agreement with Indivior, DURECT will receive quarterly earn-out payments that are based on a single digit percentage of U.S. net sales of PERSERIS into 2026.

"We look forward to the expected PERSERIS launch in February by Indivior, and other potential catalysts in 2019 from our drug delivery programs," stated James Brown, President and CEO of DURECT.

Conference Call Information
A live audio webcast of a conference call to discuss this corporate update will be broadcast live over the internet at 8:00 a.m. Eastern Time on January 7 and will be available by accessing DURECT's homepage at www.durect.com and clicking "Investor Relations." If you are unable to participate in the live webcast, the call will be archived on DURECT's website under Audio Archive in the "Investor Relations" section.

About DURECT Corporation

DURECT is a biopharmaceutical company actively developing therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DUR-928, a new chemical entity in Phase 2 development, is the lead candidate in DURECT's Epigenetic Regulator Program. An endogenous, orally bioavailable small molecule, DUR-928 has been shown in preclinical studies to play an important regulatory role in lipid homeostasis, inflammation, and cell survival. Human applications may include chronic liver diseases such as nonalcoholic steatohepatitis (NASH), acute organ injury such as Alcoholic Hepatitis (AH) and acute kidney injury (AKI), and inflammatory skin conditions such as psoriasis and atopic dermatitis. DURECT's advanced oral and injectable delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. Late stage product candidates in this category include POSIMIR® (bupivacaine extended release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery, and ORADUR®-Methylphenidate ER Capsules, approved in Taiwan as Methydur Sustained Release Capsules, where it is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). In addition, for the assignment of certain patent rights, DURECT will receive single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was approved in July 2018. For more information, please visit *www.durect.com*.

DURECT Forward-Looking Statement

The statements in this press release regarding clinical trial plans for DUR-928, including plans to begin patient enrollment of a new clinical trial of orally-administered DUR-928 in NASH patients in Q1 2019 and the potential to show positive signals of biological activity in such trial, plans to obtain and announce positive top-line proof of concept data for the planned clinical trial of DUR-928 in psoriasis in the second half of 2019, the potential to receive a termination fee from Sandoz related to POSIMIR and the potential commercial sales of Indivior's PERSERIS to treat schizophrenia, including the timing of U.S. launch and amount of potential sales amounts 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 of delays in the commencement and enrollment of planned clinical trials, potential adverse effects arising from the testing or use of DUR-928, potential adverse outcomes in the dispute resolution process with Sandoz, our ability to avoid infringing patents held by other parties and secure and defend patents of our own patents, and our ability to manage and obtain capital to fund our operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on November 8, 2018 under the heading "Risk Factors."

NOTE: ORADUR®, POSIMIR® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928 and POSIMIR are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

SOURCE DURECT Corporation

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