
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

December 19, 2018

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
incorporation or organization)

000-31615
(Commission
File Number)

94-3297098
(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 8.01 Other Events

On December 19, 2018, DURECT Corporation announced that 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. 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 December 19, 2018](#)

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.

Date: December 19, 2018

DURECT Corporation

By: /s/ James E. Brown

James E. Brown
President and Chief Executive Officer

Commercial Launch Plans Announced for PERSERIS™ (risperidone) Extended-Release Injectable Suspension for the Treatment of Schizophrenia in Adults

Indivior PLC Announces Plan for Commercial Launch in February 2019 with 50 Sales Representatives

CUPERTINO, Calif., December 19, 2018 -- DURECT Corporation (Nasdaq: DRRX) today announced that Indivior PLC (LON: INDV) 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 reiterated its confidence in its peak net revenue goal for PERSERIS™ of \$200 to \$300 million.

"We are pleased to see that Indivior is engaged in pre-launch activities, and we look forward to the commercialization of PERSERIS and the associated quarterly earn-out payments that we will receive in the coming years," said James E. Brown, President and CEO of DURECT.

On September 26, 2017, DURECT entered into a patent purchase agreement whereby DURECT assigned to Indivior UK Limited, an affiliate of Indivior PLC, certain patents that may provide further intellectual property protection for PERSERIS. In consideration for such assignment, Indivior made an upfront non-refundable payment to DURECT of \$12.5 million. Indivior made an additional \$5 million payment to DURECT in August 2018 following NDA approval of PERSERIS in July 2018. DURECT is also entitled to quarterly earn-out payments that are based on a single digit percentage of U.S. net sales for certain products covered by the assigned patent rights, including PERSERIS. The patent rights include granted patents extending through at least 2026.

For additional information related to PERSERIS, please see the disclosures made by Indivior or visit www.perserishcp.com.

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 acute organ injury such as Alcoholic Hepatitis (AH), hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and Primary Sclerosing Cholangitis (PSC), 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 Methydrur 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 related to its drug delivery technology, DURECT will receive single digit sales-based earn-out payments from U.S. net sales of PERSERIS™ (risperidone), which was approved by FDA in July 2018 for the treatment of schizophrenia in adults and is owned and marketed by Indivior PLC. For more information, please visit www.durect.com.

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.

DURECT Forward-Looking Statement

The statements in this press release regarding the potential commercial sale of Indivior's PERSERIS to treat schizophrenia, including the timing of U.S. launch, size of U.S. sales force, potential peak net revenue and earn-out payments receivable from Indivior, as well as the potential use of POSIMIR to treat post-surgical pain, and the potential use of DUR-928 to treat Alcoholic Hepatitis, hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and Primary Sclerosing Cholangitis (PSC), and inflammatory skin conditions such as psoriasis and atopic dermatitis 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 risks that Indivior will not launch PERSERIS commercially or that it will not obtain market acceptance and meaningful sales, as well as possible adverse events associated with the use of PERSERIS, POSIMIR and DUR-928, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of POSIMIR and DUR-928, and the possibility that studies of DUR-928 will not replicate results from earlier preclinical or clinical trials. Further information regarding risks related to DUR-928 and POSIMIR and other risks related to DURECT is included in DURECT's Form 10-Q filed on November 8, 2018 under the heading "Risk Factors."

SOURCE: DURECT Corporation

CONTACT: Michael Arenberg, Chief Financial Officer, DURECT Corporation, 408-346-1052