UNITED STATES
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

June 27, 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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock $0.0001 par value per share Preferred Share Purchase Rights	DRRX	The NASDAQ Stock Market LLC (The Nasdaq Capital Market)

Item 8.01 Other Events

On June 27, 2019, DURECT Corporation issued a press release announcing that it has submitted a full response to the Complete Response Letter (CRL) it previously received from U.S. Food and Drug Administration (FDA) related to POSIMIR® (bupivacaine extended-release solution).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 June 27, 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: June 27, 2019

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

Exhibit 99.1

DURECT Announces Submission to FDA of a Full Response to the POSIMIR® Complete Response Letter

CUPERTINO, Calif., June 27, 2019 /PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced it has submitted a full response to the Complete Response Letter (CRL) it previously received from U.S. Food and Drug Administration (FDA) related to POSIMIR® (bupivacaine extended-release solution). The submission is intended to address the issues raised in the CRL and seeks FDA approval of POSIMIR based on what the Company and its advisors believe is adequate evidence of both safety and efficacy.

DURECT commissioned the advisory services of Dr. Lee S. Simon to first evaluate the adequacy of the existing POSIMIR package to address the issues raised in FDA correspondence, including the CRL, and then to lead the Company's efforts to submit its response to the CRL. Dr. Simon is a physician and research scientist who served as the FDA's Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products from 2001 to 2003, and is now a Principal at SDG, LLC, an FDA advisory firm. As the submission is intended to be a full response to the CRL, as opposed to a new NDA submission, the Company expects a six-month FDA review period.

"We believe that the submitted response to the CRL includes multiple positive adequate and well controlled trials and addresses the issues raised in the FDA's Complete Response Letter," stated Dr. Simon.

"We greatly appreciate Dr. Simon's leadership and expertise in working with our team to prepare this thorough response to the POSIMIR CRL," said James E. Brown, President and CEO of DURECT. "We continue to believe that POSIMIR, if approved, can play an important role in addressing the need for additional long-acting, non-opioid products in the post-operative pain setting and look forward to the FDA's response to our submission."

About POSIMIR

POSIMIR is the Company's investigational post-operative pain relief depot product that utilizes DURECT's patented SABER® technology. POSIMIR is designed to be administered directly into the surgical site to deliver bupivacaine for up to three days after surgery. POSIMIR has not been approved by the FDA for marketing in the U.S. for any indication.

About the POSIMIR Clinical Development Program

The POSIMIR clinical development program was designed to evaluate the safety and efficacy of a single dose of POSIMIR to treat post-surgical pain for up to three days.

In two completed adequate and well-controlled clinical trials, conducted in patients undergoing inguinal hernia repair and subacromial decompression (shoulder) surgeries respectively, POSIMIR demonstrated a significant decrease in pain and opioids consumed over the 0-72 hour period following surgery as compared to placebo. DURECT believes that these completed trials support the safety and efficacy of POSIMIR in post-operative pain and meet the requirements to be considered pivotal clinical trials.

In all, the Company has completed 16 clinical trials in the POSIMIR program, involving over 1,400 patients, over 850 of whom received POSIMIR, with the remainder in control groups. DURECT believes this is a sufficiently sized safety database. DURECT further believes that, with safety data from the PERSIST trial included, there are now sufficient data to address FDA's issues raised in the CRL.

Market Opportunity

According to data published by the Center for Disease Control and Prevention, there are approximately 72 million ambulatory and inpatient surgical procedures performed annually in the U.S. Insufficient postoperative pain control remains a significant problem, with studies indicating that approximately 65% of patients experience moderate-to-extreme pain after surgery. The current standard of care for post-surgical pain includes a variety of opiate and non-opiate analgesics and muscle relaxants. While systemic opioids can effectively control post-surgical pain, they commonly cause side effects including drowsiness, constipation, nausea and vomiting, and cognitive impairment. Post-surgical pain also can be treated effectively with local anesthetics; however, their usefulness often is limited by their short duration of action.

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) and acute kidney injury (AKI), chronic hepatic diseases such as nonalcoholic steatohepatitis (NASH), 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 receives single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was commercially launched in February 2019. For more information about DURECT, please visit www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding future events and expectations, including without limitation, the time for the FDA to respond to DURECT's response to the FDA's Complete Response Letter, the potential regulatory approval of POSIMIR by the FDA and the potential uses and benefits of POSIMIR, as well as the potential use of DUR-928 to treat chronic hepatic diseases such as NASH, acute organ injuries such as AH and AKI, and inflammatory skin disorders such as psoriasis and atopic dermatitis, the use of POSIMIR to treat post-surgical pain, the use of Indivior's PERSERIS™ to treat schizophrenia, as well as the potential commercial sales of Indivior's PERSERIS 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 the FDA will not accept the submitted response to the CRL for filing, the FDA will treat the Company's submission as a new NDA rather than a full response to the CRL, that the FDA will require additional trials or additional information regarding POSIMIR, the risk that the FDA may not approve the POSIMIR NDA, the risk of delays in the enrollment of the ongoing clinical trials of DUR-928 in NASH, AH and psoriasis, potential adverse effects arising from the testing or use of DUR-928, the risk that PERSERIS and Methydur Sustained Release Capsules will not have successful launches, our ability to avoid infringing patents held by other parties and secure and defend 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 for the three months ended March 31, 2019 filed with the Securities and Exchange Commission on May 7, 2019 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, ORADUR-Methylphenidate ER Capsules 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. Full prescribing information for PERSERIS, including BOXED WARNING, and Medication Guide can be found at www.perseris.com.

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