
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

October 5, 2020

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))

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

Title of Each Class

Trading Symbol

Name of Each Exchange on Which Registered

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 October 5, 2020, DURECT Corporation issued a press release announcing that it will present a poster at The AASLD Liver Meeting Digital Experience™ (TLMdX) 2020, to be held virtually on November 13-16, 2020. 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 October 5, 2020](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 5, 2020

By: /s/ Michael H. Arenberg
Michael H. Arenberg
Chief Financial Officer

DURECT Corporation to Present Additional Safety and Efficacy Signals from Phase 1b Clinical Trial of DUR-928 in NASH Patients at The Liver Meeting Digital Experience™ 2020

CUERTINO, Calif., October 5, 2020/PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced it will present a poster at The AASLD Liver Meeting Digital Experience™ (TLMdX) 2020, to be held virtually on November 13-16, 2020.

Topline results from the 4-week Phase 1b clinical study of orally administered DUR-928 in nonalcoholic steatohepatitis (NASH) patients were released previously, showing an overall improvement from baseline in liver enzymes, liver stiffness, and serum lipid profiles. At day 28, 43% of patients showed $\geq 10\%$ liver fat reduction from baseline as measured by magnetic resonance imaging - proton density fat fraction (MRI-PDFF). Daily oral dosing of DUR-928 was well tolerated at all three doses evaluated, 50mg QD, 150mg QD, and 300mg BID (600mg/day). Additional safety and efficacy data will be presented in the poster.

Poster Presentation Details:

Title: Safety and Efficacy Signals of 4-Week Oral DUR-928 in NASH Subjects
 Session: *NAFLD and NASH: Therapeutics - Pharmacologic and Other*
 Presenter: Eric Lawitz, M.D., Vice President, Scientific and Research Development, Texas Liver Institute
 Date/Time: The poster will be available for viewing by attendees of the Liver Meeting throughout the entire meeting and will transition to LiverLearning® after the meeting concludes

About DUR-928

DURECT's lead drug candidate, DUR-928, is an endogenous sulfated oxysterol and an epigenetic regulator. It represents a new class of therapeutics with a unique mechanism of action. DUR-928 epigenetically modulates the expression of multiple clusters of master genes that are involved in many important cell signaling pathways, through which it stabilizes mitochondria, reduces lipotoxicity, regulates inflammatory or stress responses, and promotes cell survival.

About DURECT Corporation

DURECT is a biopharmaceutical company committed to transforming the treatment of acute organ injury and chronic liver diseases by advancing novel and potentially lifesaving therapies based on its endogenous epigenetic regulator program. DUR-928, the company's lead drug candidate is in clinical development for the potential treatment of alcoholic hepatitis (AH), COVID-19 patients with acute liver or kidney injury, and nonalcoholic steatohepatitis (NASH). DURECT's proprietary drug delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. One late-stage product candidate in this category is POSIMIR® (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to three days of continuous pain relief after surgery. For more information about DURECT, please visit www.durect.com and follow us on Twitter <https://twitter.com/DURECTCorp>.

DURECT Forward-Looking Statement

The statements in this press release regarding clinical development plans for DUR-928, including the potential use of DUR-928 to treat COVID-19 patients with liver or kidney injury, the potential use of DUR-928 to treat acute organ injuries, such as AH, and chronic liver diseases, such as NASH, and the potential use of POSIMIR to provide pain relief after surgery 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 clinical trial of DUR-928 in COVID-19 patients is delayed or stopped because of changes to the standard of care, the availability of alternative therapies, required protocol changes or lack of available patients, the risk that future clinical trials of DUR-928 are not started when anticipated, take longer to conduct than anticipated, do not confirm the results from earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, the risk that the FDA will not approve POSIMIR or approve POSIMIR with a limited label, the risk that additional time and resources may be required for development, testing and regulatory approval of DUR-928 or the Company's other product candidates, potential adverse effects arising from the testing or use of our drug candidates, our potential failure to maintain our collaborative agreements with third parties and risks related to our ability to obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on August 4, 2020 under the heading "Risk Factors."

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

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