

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

November 10, 2021

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
Common Stock \$0.0001 par value per share

Trading Symbol
DRRX

Name of Each Exchange on Which Registered
The NASDAQ Stock Market LLC
(The Nasdaq Capital Market)

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 November 10, 2021, DURECT Corporation issued a press release announcing that it dosed the first ex-U.S. patient in Australia as part of its AHFIRM randomized, double-blind, placebo-controlled, multi-center Phase 2b study to evaluate the safety and efficacy of larsucosterol in severe alcohol-associated hepatitis (AH) patients. 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 November 10, 2021](#)

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.

Date: November 10, 2021

DURECT Corporation

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

DURECT Corporation Doses First ex-U.S. Patient in Phase 2b AHFIRM Study of Larsucosterol (DUR-928) in Severe Alcohol-Associated Hepatitis

CUPERTINO, Calif., November 10, 2021/PRNewswire / -- DURECT Corporation (Nasdaq: DRRX) today announced it dosed the first ex-U.S. patient in Australia as part of its AHFIRM randomized, double-blind, placebo-controlled, multi-center Phase 2b study to evaluate the safety and efficacy of larsucosterol in severe alcohol-associated hepatitis (AH) patients.

“AH is a global condition and we are excited to have started dosing severe AH patients in the AHFIRM trial outside of the United States. We recently opened the first ex-U.S. clinical trial sites in Australia and are pleased that the first Australian subject has now been dosed,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We continue working to open 60 or more clinical trial sites across the U.S., Australia, EU, and U.K.”

About the AHFIRM Trial

Enrollment is ongoing in our Phase 2b randomized, double-blind, placebo-controlled, international, multi-center study in subjects with severe acute alcohol-associated hepatitis (AH) to evaluate safety and efficacy of larsucosterol (DUR-928) treatment (AHFIRM). The study is comprised of three arms targeting enrollment of 300 total patients, with approximately 100 patients in each arm: (1) Placebo plus standard of care (SOC) which may include the use of methylprednisolone, a corticosteroid, at the discretion of the treating physician); (2) larsucosterol (30 mg); and (3) larsucosterol (90 mg). All patients in the trial receive supportive care. The primary outcome measure is 90-day survival rate for patients treated with larsucosterol compared to those treated with placebo plus SOC. The Company is targeting more than 60 clinical trial sites across the U.S., EU, U.K., and Australia. Reflecting the life-threatening nature of AH and the lack of therapeutic options, the U.S. Food and Drug Administration (FDA) has granted larsucosterol Fast Track Designation for the treatment of AH. We believe demonstration of a robust survival benefit in the AHFIRM trial would support an NDA filing. For more information, refer to ClinicalTrials.gov Identifier: NCT04563026.

About alcohol-associated hepatitis (AH)

AH is a life-threatening acute alcohol-associated liver disease (ALD) often caused by chronic heavy alcohol and a recent period of increased alcohol consumption (e.g., a binge). It is characterized by severe inflammation and destruction of liver tissue (i.e., necrosis), potentially leading to life-threatening complications, including liver failure, acute renal injury and multi-organ failure. There are no FDA approved therapies for AH and the overall average mortality of AH patients in clinical trials has been reported to be 26% at 28 days, 29% at 90 days and 44% at 180 days. Stopping alcohol consumption is not sufficient for recovery in many moderate and severe patients and the use of treatments to reduce liver inflammation, such as corticosteroids, are limited by contraindications and have been shown to provide no survival benefit at 90 days or 1 year. While liver transplantation is becoming more common for alcoholic liver disease patients, including for AH patients, the procedure involves a long waiting period, a burdensome selection process and costs more than \$875,000 on average.

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. Larsucosterol (also known as DUR-928), the Company's lead drug candidate, binds to and inhibits the activity of DNA methyltransferases (DNMTs), epigenetic enzymes which are elevated and associated with hypermethylation found in AH patients. Larsucosterol is in clinical development for the potential treatment of alcohol-associated hepatitis (AH) for which FDA has granted a Fast Track Designation; non-alcoholic steatohepatitis (NASH) is also being explored. In addition, POSIMIR® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABER® platform technology, is FDA-approved. Full prescribing information about POSIMIR, including the Boxed Warning, can be found at www.posimir.com. 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 the potential for larsucosterol (also known as DUR-928) to treat patients with AH, NASH, multiple acute organ injury, chronic liver diseases and other diseases, ongoing clinical trials of larsucosterol and plans to open 60 or more clinical trial sites, the potential benefits of Fast Track Designation, and the commercial potential of POSIMIR 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 larsucosterol in AH takes longer to conduct than anticipated due to COVID-19 or other factors, the risk that clinical trials of larsucosterol, including AHFIRM, do not confirm the results from earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy or the lifesaving potential of larsucosterol in a statistically significant manner, the risk that Fast Track Designation for larsucosterol in AH may not lead to faster FDA review or an approval, risks that we or a third-party licensee may not commercialize POSIMIR successfully, if at all, 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 November 3, 2021 under the heading "Risk Factors."

NOTE: POSIMIR® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. Larsucosterol (DUR-928) is an investigational drug candidate under development and has not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities for any indication. Full prescribing information for POSIMIR, including its Boxed Warning, can be found at www.posimir.com.

SOURCE: DURECT Corporation

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