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

September 23, 2020

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))

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)**

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 September 23, 2020, DURECT Corporation issued a press release announcing that it has dosed the first patient in its randomized, double-blind, placebo-controlled, multi-center Phase 2 study to evaluate the safety and efficacy of DUR-928 in hospitalized COVID-19 patients with acute liver or kidney injury. 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 September 23, 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: September 23, 2020

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

DURECT Corporation Announces First Patient Dosed in Phase 2 Safety and Efficacy Study of DUR-928 in COVID-19 Patients with Acute Liver or Kidney Injury

CUPERTINO, Calif., September 23, 2020/PRNewswire / -- DURECT Corporation (Nasdaq: DRRX) today announced it has dosed the first patient in its randomized, double-blind, placebo-controlled, multi-center Phase 2 study to evaluate the safety and efficacy of DUR-928 in hospitalized COVID-19 patients with acute liver or kidney injury. The primary efficacy endpoint is a composite of survival and being free of acute organ failure at Day 28. The company plans to enroll approximately 80 patients in multiple study sites across the U.S.

"We are excited to have begun dosing DUR-928 in this population of hospitalized COVID-19 patients with the additional complications of acute liver or kidney injury. These patients are at risk of multi-organ failure and death, similar to hospitalized patients with AH," stated James E. Brown, D.V.M., President and CEO of DURECT. "Based on the positive clinical results of DUR-928 in hospitalized AH patients from our Phase 2a trial and our preclinical data in multi-organ failure models, we believe that DUR-928, in combination with standard of care, has the potential to help these COVID-19 patients."

About the Phase 2 Trial

This Phase 2, randomized, double-blind, placebo-controlled, multi-center study is designed to evaluate safety and efficacy of DUR-928 in COVID-19 patients with acute liver or kidney injury. A total of approximately 80 patients are planned to be enrolled into two study treatment groups in a 3:1 (DUR-928: placebo) ratio. Patients will receive a dose of 150 mg of DUR-928 or placebo by intravenous infusion on day 1 and day 4 in combination with standard of care therapy, which will be determined by the principal investigator (PI) at each clinical trial site. The primary efficacy endpoint is a composite of survival and being free of acute organ failure (free of mechanical ventilation, free of liver failure events and free of renal replacement therapy) at day 28. Patients will be followed for 60 days. Should any drug product be determined by the FDA to be safe and effective for the treatment of COVID-19 while the trial is ongoing, such treatments may be offered, at each PI's discretion, to any remaining and future patients in this trial. For more information, refer to ClinicalTrials.gov Identifier: NCT04447404

About COVID-19

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus (SARS-COV-2). The rapid spread of the disease has resulted in a pandemic with millions of confirmed cases and hundreds of thousands of deaths worldwide. While most cases result in mild symptoms, including fever, cough and shortness of breath, some rapidly progress into acute respiratory distress syndrome (ARDS), multi-organ failure, and death. Many of these patients experience a rapid elevation of inflammation-inducing signaling molecules (cytokine storm) that trigger acute injuries in multiple organs including the liver and the kidney. Organ injury may also occur in hospitalized COVID-19 patients as the result of other complications of the viral infection. In a study of 1,059 adult cases of confirmed hospitalized COVID-19, 62% of patients presented with at least one elevated liver enzyme. In another study, 36.6% of 5,449 patients admitted with COVID-19 had or developed acute kidney injury (AKI).

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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