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

August 27, 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 August 27, 2020, DURECT Corporation issued a press release announcing the presentation of pharmacokinetic (PK) data from a Phase 2a study of DUR-928 in alcoholic hepatitis (AH) at the Digital International Liver Congress™ 2020 (EASL), taking place on August 27-29. 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 August 27, 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: August 27, 2020

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

Exhibit 99.1

DURECT Corporation Announces Presentation of Phase 2a Pharmacokinetic Data of DUR-928 in Alcoholic Hepatitis at Digital International Liver Congress (EASL)

CUPERTINO, Calif., August 27, 2020/PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced the presentation of pharmacokinetic (PK) data from a Phase 2a study of DUR-928 in alcoholic hepatitis (AH) at the Digital International Liver Congress™ 2020 (EASL), taking place on August 27-29. DUR-928 was well tolerated at all doses tested in 19 AH patients, including 12 severe AH patients. These PK data, together with other available information for the drug, have been used to inform dose selection in the Company's upcoming Phase 2b study of DUR-298 in AH, planned to begin in the second half of 2020.

DURECT's Phase 2a AH study was an open-label, multi-center, dose escalation safety, PK and pharmacodynamic (PD) trial which evaluated doses of 30, 90, or 150 mg of DUR-928 administered by intravenous infusion for 2 hours on Day 1 and Day 4 (if still hospitalized), with patients followed for 28 days.

Key results presented include:

- Mean baseline laboratory characteristics and prognostic scores:
  - Bilirubin 14.2 mg/dL, (upper limit of normal is 1.2 mg/dL)
  - MELD (Model for End-Stage Liver Disease) score 22.3, (≥21 is severe)
  - Maddrey's Discriminant Function 53.4 (≥32 is severe AH)
- Drug exposure for DUR-928 (as measured by both AUC and Cmax) was dose proportional and comparable between moderate and severe AH patients.
- Due to the severe liver injury in AH patients, the systemic clearance of DUR-928 was reduced resulting in an approximately 2-fold higher Cmax in these AH patients compared to healthy subjects.

As previously reported, DUR-928 was well tolerated at all doses tested. All patients treated with DUR-928 survived through the 28-day follow-up period. Patients treated with DUR-928 had a statistically significant reduction from baseline in bilirubin at days 7 and 28, and in model of end-stage liver disease (MELD) score at day 28. There was a 100% treatment response rate (as defined by Lille score <0.45) in patients receiving 30 or 90 mg doses; and an 89% response rate in all patients. 74% of all DUR-928 treated patients and 67% of those with severe AH were discharged from the hospital within four days after receiving a single dose of DUR-928. There were no drug-related serious adverse events, discontinuations or early withdrawals, or termination of study drug or study participation due to adverse events.

"We are encouraged by the PK results presented at EASL which demonstrate that DUR-928 was well tolerated at all doses tested in AH patients and contributed to the dose selection in our upcoming Phase 2b AH trial, which we look forward to initiating in the upcoming months," stated James E. Brown, D.V.M., President and CEO of DURECT.

About the DUR-928 Alcoholic Hepatitis Phase 2a Trial

This open-label, dose escalation, multi-center study was designed to determine the safety, pharmacokinetics (PK) and pharmacodynamics (PD) of DUR-928 in AH patients following treatment. This included assessing liver biochemistry, biomarkers, and prognostic scores such as the Lille score. Final enrollment included 19 patients with moderate and severe AH, who were administered DUR-928

intravenously at three different doses. Eight patients (four moderate and four severe) were dosed at 30mg, seven patients (three moderate and four severe) were dosed at 90mg and four patients (all severe) were dosed at 150mg. For more information, refer to ClinicalTrials.gov identifier: NCT03432260.

DUR-928: next steps in alcoholic hepatitis

DURECT is finalizing its preparations to initiate a multi-center, international, randomized, double blind, placebo-controlled Phase 2b clinical trial of DUR-928 in severe AH patients later this year. Based on these results and other information generated during the program, the 30 and 90 mg doses have been selected for this next study. The primary endpoint will be survival rate for patients treated with DUR-928 compared to those treated with placebo. Further details of the trial design, including the size of the trial and other trial parameters will be provided at a future date.

About Alcoholic Hepatitis (AH)

AH is an acute form of alcoholic liver disease (ALD), associated with long-term heavy intake of alcohol, and often occurs after a recent period of increased alcohol consumption. AH is typically characterized by recent onset jaundice and hepatic failure. An analysis of 77 studies published between 1971 and 2016, which included data from a total of 8,184 patients, showed the overall mortality from AH was 26% at 28 days. According to the most recent data provided by the Agency for Healthcare Research and Quality (AHRQ), a part of the US Department of Health and Human Services (HHS), there were over 117,000 hospitalizations for patients with alcoholic hepatitis in 2016. From a recent publication analyzing the mortality and costs associated with alcoholic hepatitis, the cost per patient is estimated at over $50,000 in the first year. Liver transplantation usually involves a long waiting period, a burdensome selection process and a costly procedure over $800,000.

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. DURECT's lead 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. This drug candidate is currently in Phase 2 development for the treatment of alcoholic hepatitis (AH) and the treatment of COVID-19 patients with acute liver or kidney injury as well as Phase 1 development for the treatment of 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 and plans for DUR-928, including initiating a Phase 2b trial of DUR-928 in AH in the second half of 2020, and the potential benefits and uses of our drug candidates, including the potential use of DUR-928 to treat acute organ injuries such as AH and COVID-19 patients with acute liver or kidney injury as well as chronic liver diseases such as NASH, and the use of POSIMIR to treat pain 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 future clinical

trials of DUR-928 are not started or finalized when anticipated, take longer to conduct than anticipated, do not generate similar positive results as generated in 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, the risk of disruptions to our business operations resulting from the COVID-19 pandemic, the risk that additional time and resources may be required for development, testing and regulatory approval of DUR-928 or POSIMIR, potential adverse effects arising from the testing or use of our drug candidates, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations 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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