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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## Form 8-K

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**Current Report**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

**October 25, 2018**

**Date of Report**

**(Date of earliest event reported)**

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### **DURECT CORPORATION**

**(Exact name of Registrant as specified in its charter)**

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**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)**

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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.

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**Item 8.01 Other Events**

On October 25, 2018, DURECT Corporation issued a press release announcing that two posters on DUR-928 will be presented at the ASN Kidney Week Meeting on Saturday, October 27 and one poster will be presented at the American College of Toxicology's Annual Meeting, November 4-7. 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 25, 2018](#)

**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: October 25, 2018

**DURECT Corporation**

By: /s/ James E. Brown

James E. Brown  
President and Chief Executive Officer

**DURECT Announces Abstracts on DUR-928 to be Presented at Upcoming Scientific Meetings**

***ASN Kidney Week Meeting and American College of Toxicology's Annual Meeting***

CUPERTINO, CA, October 25, 2018 /PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) announced today that two posters on DUR-928 will be presented at the ASN Kidney Week Meeting on Saturday, October 27 and one poster will be presented at the American College of Toxicology's Annual Meeting, November 4-7. DUR-928, a new chemical entity in Phase 2 development, is the lead candidate in DURECT's Epigenetic Regulator Program. An endogenous small molecule, DUR-928 has been shown in preclinical studies to play an important regulatory role in lipid homeostasis, inflammation, and cell survival.

**Kidney Week Poster Abstract Presentation Details:**

Title: Safety and Single Ascending Dose Pharmacokinetic Study of DUR-928 in Patients with Chronic Kidney Disease versus Matched Control Subjects

Date: Saturday, October 27, 2018

Time: 10:00 a.m.-12:00 noon Pacific Time

Poster Board: SA-PO634

Location: San Diego Convention Center, CA

Title: Attenuation of Renal Ischemic Reperfusion Injury in Rats with DUR-928, a Novel, First-in-Class Therapeutic in Development for Renal Disease

Date: Saturday, October 27, 2018

Time: 10:00 a.m.-12:00 noon Pacific Time

Poster Board: SA-PO650

Location: San Diego Convention Center, CA

**American College of Toxicology's Annual Meeting Abstract Presentation Details:**

Title: A 14-Day Intravenous Infusion Toxicity and Toxicokinetic Study of DUR-928, a Novel, First in Class, Investigational Therapeutic in Sprague-Dawley Rats

Date: Monday, November 5, 2018

Time: 5:00-6:30 p.m. Eastern Time

Location: Palm Beach County Convention Center, West Palm Beach, FL

After the presentation, these posters can be viewed at <http://www.durect.com/science-technologies/publications/>.

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## **Other Recent Poster Presentations**

DURECT also presented two posters at scientific meetings earlier this year that can be viewed at <http://www.durect.com/science-technologies/publications/>.

Meeting: American College of Clinical Pharmacology, September 23-25, 2018  
Title: A Clinical Drug-Drug Interaction Study with Midazolam to Assess the Effect of DUR-928 on CYP3A4

The objective of this open-label, single sequence study in healthy human subjects (n=17) was to assess the potential effect of DUR-928, by either oral or intravenous infusion, on CYP3A4, using concomitant administration of midazolam. This study demonstrated that DUR-928, when administered by either route, had no effect on the safety and PK of midazolam, a drug for detecting potential drug-drug interactions via the enzyme CYP3A4. This enzyme is commonly involved in clinically relevant drug-drug interactions.

Meeting: Society of Toxicology Annual Meeting, March 11-15, 2018  
Title: In Vivo Tissue Distribution and Elimination of DUR-928, a First In Class Therapeutic for Treatment of Hepatic and Renal Disease

In this study, the absorption, distribution, metabolism, and excretion (ADME) of intravenously administered DUR-928 was studied in rats. Biliary excretion in feces was observed to be the primary means of excretion. This ADME study highlighted the preferential uptake of DUR-928 in selected target organs (the liver and small intestine wall had the highest concentrations of DUR-928 relative to plasma, with notable exposure also measured in the kidney).

## **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, hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and Primary Sclerosing Cholangitis (PSC), 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. One late stage product candidate in this category is POSIMIR® (SABER®-Bupivacaine), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery. In addition, for the assignment of certain patent rights, DURECT will receive single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™

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(risperidone) drug for schizophrenia, which was approved by the FDA in July 2018. For more information, please visit [www.durect.com](http://www.durect.com).

NOTE: POSIMIR® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928 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.

### **DURECT Forward-Looking Statement**

The statements in this press release regarding the potential benefits and uses of DURECT's drug candidates, including the potential use of DUR-928 to treat Alcoholic Hepatitis, hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and Primary Sclerosing Cholangitis (PSC), and inflammatory skin conditions such as psoriasis and atopic dermatitis, the potential use of POSIMIR to treat post-surgical pain, and the potential for sales-based earn-out payments from the sale of Indivior's PERSERIS to treat schizophrenia 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 possibility that studies of DUR-928 will not replicate results from earlier preclinical or clinical trials, the risks that Indivior will not launch PERSERIS commercially or that it will not obtain market acceptance and meaningful sales, as well as possible adverse events associated with the use of PERSERIS, POSIMIR and DUR-928, and delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of POSIMIR and DUR-928. Further information regarding risks related to DUR-928 and POSIMIR and other risks related to DURECT is included in DURECT's Form 10-Q filed on August 2, 2018 under the heading "Risk Factors."

SOURCE: DURECT Corporation

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