
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

May 3, 2019

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))

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.

Title of Each Class
Common Stock \$0.0001 par value per share
Preferred Share Purchase Rights

Trading Symbol
DRRX

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

Item 8.01 Other Events

On May 3, 2019, DURECT Corporation issued a press release announcing that it will report preliminary data from the ongoing DUR-928 alcoholic hepatitis (AH) trial and its financial results for the three months ended March 31, 2019 after the market close on Tuesday, May 7. The following morning, Wednesday, May 8th at 8:30 a.m. Eastern Time, DURECT will host a Key Opinion Leader (KOL) and earnings conference call and webcast with slides. 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 May 3, 2019](#)

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: May 3, 2019

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

DURECT Corporation to Present Preliminary Data from the Ongoing DUR-928 Alcoholic Hepatitis Phase 2a Trial and Report First Quarter 2019 Financial Results

Call will feature discussions by KOLs Steven Flamm, M.D., Tarek I. Hassanein, M.D., and Paul Kwo, M.D.

Conference call and live webcast with slides on Wednesday, May 8th at 8:30 a.m. ET

CUPERTINO, Calif., May 3, 2019 /PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced that it will report preliminary data from the ongoing DUR-928 alcoholic hepatitis (AH) trial and its financial results for the three months ended March 31, 2019 after the market close on Tuesday, May 7. The following morning, Wednesday, May 8th at 8:30 a.m. Eastern Time, DURECT will host a Key Opinion Leader (KOL) and earnings conference call and webcast with slides.

During the webcast and conference call, DURECT management will provide a corporate business update, including a presentation of preliminary data from the ongoing Phase 2a open label, dose escalation, multi-center U.S. clinical trial investigating DUR-928 administered intravenously in patients with moderate and severe AH. The objectives of this study include assessment of safety, PK and pharmacodynamic signals, including liver biochemistry and biomarkers.

KOL Discussion on Alcoholic Hepatitis

Also participating in the call will be three Key Opinion Leaders on alcoholic hepatitis: Drs. Steven Flamm, Tarek Hassanein, and Paul Kwo. Dr. Kwo will present an overview of AH including details on the disease and its progression, current treatment options and new treatments in development. Drs. Hassanein and Flamm will discuss their experience treating patients in the ongoing DUR-928 AH clinical trial.

Steven L. Flamm, M.D. is a Professor of Medicine and Surgery with the Division of Hepatology at Northwestern University Feinberg School of Medicine. He also serves as the Chief of Transplant Hepatology. Dr. Flamm has published widely in the field of hepatic diseases and has spoken both nationally and internationally on many other liver-related topics including viral hepatitis, autoimmune hepatitis, hepatic encephalopathy, and liver transplantation. He has an active clinical research program in chronic viral hepatitis (HBV and HCV) and autoimmune hepatitis. Dr. Flamm is a member of the American Gastroenterological Association (AGA) and the American Association for the Study of Liver Diseases (AASLD), where he recently served as the Chair of the AASLD Development and Publication and Practice Guidelines Committee, as well as the AASLD Foundation. He has also served as the Region 7 Representative to the UNOS Liver and Intestine Committee. Dr. Flamm received his MD degree from the University of

Pennsylvania School of Medicine. He completed both a clinical fellowship in gastroenterology and a research fellowship in gastroenterology and hepatology at Beth Israel Hospital, Harvard Medical School. He also completed a clinical fellowship in hepatology and liver transplantation at The Deaconess Hospital, Harvard Medical School before joining Northwestern University.

Tarek I. Hassanein, M.D. is currently a Professor of Medicine at the School of Medicine and Director of Outreach Services for Liver Transplantation at the University of California San Diego, Director of the Southern California Research Center, Medical Director of the Southern California GI and Liver Centers, and Medical Director, Gastroenterology Services and Comprehensive Liver Care Services at Sharp Coronado Hospital in Coronado, California. Dr. Hassanein has been recognized for his work in gastroenterology and has been the recipient of many awards and honors. He has been the principal investigator on multiple international trials and has been extensively published. He is a regular university, television, and radio lecturer on gastroenterology and digestive diseases. He is currently on the Editorial Board of Hepatology and Gastroenterology, Digestive Diseases & Sciences, Arab Journal of Gastroenterology, Egyptian Liver Cancer Association, and a Reviewer for Hepatology, Journal of Hepatology, Gastroenterology, American Journal of Gastroenterology, Digestive Diseases and Sciences, Mayo Clinic Proceedings, Journal of Medical Virology, Medical Principles and Practice, Cancer Investigation, Oncology, International Neuropsychological Society, and Alimentary Pharmacology & Therapeutics.

Paul Kwo, M.D. is currently Professor of Medicine and Director of Hepatology at the Stanford University where he joined the faculty in November 2016. Prior to joining the faculty at Stanford, he was at Indiana University for 21 years where he served as the Medical Director of Liver Transplantation. He received his MD from Wayne State University School of Medicine, his Internal Medicine training at University of Maryland, and his Gastroenterology/Hepatology training at Mayo Clinic Rochester. He has served on numerous committees for national and international societies. He has distinguished himself in the field of chronic Hepatitis C and has served as the PI for multiple seminal trials in the treatment of hepatitis C. He is the author of the recent ACG Practice Guideline Evaluation of Abnormal Liver Chemistries. He has won multiple awards, both at the university, local, and national level.

Conference Call and Webcast with Slides

Wednesday, May 8th at 8:30 a.m. Eastern Time/5:30 a.m. Pacific Time

Toll Free: 888-882-4478

International: 323-794-2590

Conference ID: 7156796

Webcast: <http://public.viavid.com/index.php?id=134476>

A live audio webcast and data slide presentation will be available by accessing DURECT's homepage at www.durect.com and clicking "Investors." If you are unable to participate during the live webcast, the call and slide presentation will be archived on DURECT's website under "Event Calendar – Past Events" in the "Investors" section.

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 such as Alcoholic Hepatitis (AH) and acute kidney injury (AKI), chronic hepatic diseases such as nonalcoholic steatohepatitis (NASH), 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. Late stage product candidates in this category include POSIMIR® (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery, and ORADUR®-Methylphenidate ER Capsules, approved in Taiwan as Methydur Sustained Release Capsules, where it is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). In addition, for the assignment of certain patent rights, DURECT receives single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was commercially launched in February 2019. For more information, please visit www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding DUR-928, including regarding its clinical trial in AH patients and the potential use of DUR-928 to treat AH, AKI, chronic hepatic diseases such as NASH, and inflammatory skin disorders such as psoriasis and atopic dermatitis, as well as statements regarding the use of POSIMIR to treat post-surgical pain, the use of Methydur to treat ADHD, and potential earn-out payments from U.S. sales of PERSERIS, 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 risk of delays in the enrollment of the ongoing clinical trials of DUR-928 in AH, NASH and psoriasis, potential adverse effects arising from the testing or use of DUR-928, the risk that the FDA may not approve the POSIMIR NDA, the risk that PERSERIS and Methydur will not have successful launches, our ability to avoid infringing patents held by other parties and secure and defend patents of our own patents, and our ability to manage and obtain capital to fund our operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-K on March 8, 2019 under the heading "Risk Factors."

NOTE: ORADUR®, 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. Full prescribing information for PERSERIS, including BOXED WARNING, and Medication Guide can be found at www.perseris.com.

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