
**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

June 25, 2020

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
Preferred Share Purchase Rights

Trading Symbol
DRRX

Name of Each Exchange
The NASDAQ Stock
(The Nasdaq Cap

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 1.02 Termination of a Material Definitive Agreement.

On June 26, 2020, DURECT Corporation (the “Company”) announced that Gilead Sciences, Inc., (“Gilead”) had exercised its right to terminate (i) the Research and Development Master Services Agreement dated June 7, 2017, amended April 26, 2019 (the “R&D Agreement”) and (ii) the License Agreement dated July 19, 2019 (the “License Agreement” and, together with the R&D Agreement, the “Agreements”), between Gilead and the Company. Pursuant to Gilead’s termination notice, the Agreements will terminate effective as of December 22, 2020.

A summary of the material terms of the License Agreement was included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 5, 2020 with the Securities and Exchange Commission (the “SEC”). The summary is qualified in its entirety by reference to the full text of the License Agreement filed as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 filed on November 5, 2019 with the SEC and incorporated by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 [Press Release of DURECT Corporation dated June 26, 2020](#)

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: June 26, 2020

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

Gilead Terminates License Agreement for Long-Acting Injectable HIV Investigational Product

CUPERTINO, Calif., June 26, 2020/PRNewswire / -- DURECT Corporation (Nasdaq: DRRX) today announced that Gilead Sciences, Inc., (Gilead) has provided notice that, effective as of December 22, 2020, it is terminating the License Agreement dated July 19, 2019 and a related R&D agreement between Gilead and DURECT related to the development and commercialization of a long-acting injectable HIV investigational product utilizing DURECT's SABER® technology.

As a result of this termination, DURECT anticipates recognizing remaining deferred revenue of approximately \$23.1 million in the second quarter of 2020, associated with the receipt of the upfront license and development milestone payment received in 2019 from Gilead. Therefore DURECT expects to recognize net income for the second quarter of 2020. Recognition of this deferred revenue is a non-cash financial item.

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, has demonstrated the ability to regulate the expression of genes involved in lipid metabolism, inflammatory responses and cell survival. This drug candidate is under development for the treatment of alcoholic hepatitis (AH), COVID-19 patients with acute liver or kidney injury as well as 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.

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 replicate 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, 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 May 11, 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.

Corporate Contact

Mike Arenberg
DURECT
Chief Financial Officer
+1-408-346-1052
mike.arenberg@durect.com

Media Contact

Alison Chen
LifeSci Communications
+1-646-876-4932
achen@lifescicomms.com