

**UNITED STATES**  
**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**

**December 22, 2021 (December 21, 2021)**

**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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock \$0.0001 par value per share		The NASDAQ Stock Market LLC

**DRRX**

**(The Nasdaq Capital Market)**

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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 1.01. Entry into a Material Definitive Agreement.**

On December 21, 2021, DURECT Corporation (the “Company”) entered into a License Agreement (the “License Agreement”) with Innocoll Pharmaceuticals Limited (“Innocoll”), pursuant to which the Company granted to Innocoll an exclusive, royalty-bearing, sublicensable right and license to develop, manufacture and commercialize in the United States, POSIMIR®, the Company’s FDA-approved post-surgical pain product, with respect to all uses and applications in humans (the “Licensed Products”). The License Agreement provides for the assignment of the Company’s supply agreement with its contract manufacturing organization to Innocoll and also provides Innocoll with the right, within the United States, to expand the approved indications of POSIMIR®. The Company retains, outside the United States, all of the global rights to POSIMIR®.

Upon execution of the License Agreement, Innocoll shall pay the Company an initial non-refundable, upfront fee of \$4.0 million. The Company will also receive \$2.0 million upon the first commercial sale of a Licensed Product in the United States. The Company is eligible to receive additional milestone payments of up to \$130.0 million in the aggregate, depending on the achievement of certain regulatory, commercial, and intellectual property milestones with respect to the Licensed Products. In addition, upon commercialization, the Company will receive tiered double digit royalty payments of net sales of the Licensed Products in the United States.

Pursuant to the terms of the License Agreement, except as otherwise expressly provided in the License Agreement, Innocoll is generally responsible for expenses relating to the manufacturing, development and commercialization of the Licensed Products in the United States.

The License Agreement will remain in effect until the expiration of the last royalty term under the License Agreement, unless terminated earlier. Innocoll may generally terminate the License Agreement for convenience upon six (6) months’ written notice, or upon thirty (30) days’ written notice if it reasonably believes that there are potential safety or efficacy concerns affecting the Licensed Products. Either party may terminate the License Agreement upon written notice of a material uncured breach or upon the other party’s bankruptcy. The Company may also terminate the License Agreement upon thirty (30) days’ written notice if Innocoll, its affiliates, or a sublicensee of Innocoll challenges the enforceability, validity or scope of any patent rights belonging to the Company, subject to the exceptions set forth in the License Agreement. Upon termination, any license granted by the Company to Innocoll will terminate.

The License Agreement includes customary representations and warranties on behalf of the Company and Innocoll, including representations as to the licensed intellectual property, regulatory matters and compliance with applicable laws. The License Agreement also provides for certain mutual indemnities for breaches of representations, warranties and covenants.

The foregoing description of the License Agreement is qualified in its entirety by reference to the full text of the License Agreement, a copy of which will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the year ending December 31, 2021, to be filed with the Securities and Exchange Commission (the “SEC”).

## **Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements relating to, among other things, the Company’s relationship with Innocoll; milestone and royalty payments that may be potentially paid to the Company under the License Agreement, Innocoll’s ability to achieve regulatory and commercial milestones under the License Agreement; DURECT’s ability to achieve intellectual property milestones under the License Agreement; and statements about the use of POSIMIR® to treat post-operative pain. Any statements contained in this Current Report that are not statements of historical fact may be deemed to be forward-looking statements. Words such as “planned,” “will,” “may,” “expect,” “anticipate,” and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on the Company’s current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties that Innocoll may not commercialize the Licensed Products

successfully, if at all; Innocoll's ability to manufacture and commercialize the Licensed Products; marketplace acceptance of the commercialized Licensed Products; the risk that

Innocoll may terminate the license agreement under conditions specified in the License Agreement, and other risks described in the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2021, filed with the SEC on November 3, 2021, and in other filings filed from time to time with the SEC. The Company does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein, except as required by law.

### **Item 7.01. Regulation FD Disclosure**

On December 22, 2021, the Company issued a press release announcing the License Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report and Exhibit 99.1 hereto are being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor shall such information or that Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

### **Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

99.1 [Press Release of DURECT Corporation dated December 22, 2021](#)

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: December 22, 2021

By: /s/ James E. Brown

James E. Brown

President and Chief Executive Officer