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

December 22, 2021 (December 21, 2021)

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	**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 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

DURECT and Innocoll Announce a $136 Million U.S. Licensing Agreement for POSIMIR® (Bupivacaine Solution)

- ***DURECT to receive near-term upfront cash payments totaling $6 million, potential additional milestone payments of up to $130 million and tiered low to mid double-digit royalties based on U.S. sales***
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- ***Innocoll granted exclusive development and commercialization rights to POSIMIR in the United States***

- ***DURECT to discuss agreement on Conference Call and Webcast Today at 8:30 a.m. ET***

CUPERTINO, Calif., and ATHLONE, Ireland, December 22, 2021/PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced a licensing agreement granting Innocoll Biotherapeutics plc, a specialty pharmaceutical company and portfolio business of Gurnet Point Capital, exclusive development and commercialization rights to POSIMIR® (bupivacaine solution) for infiltration use, DURECT's FDA-approved non-opioid, sustained-release local analgesic for the treatment of post-surgical pain in adults following arthroscopic subacromial decompression surgery, in the United States.

"We are excited to license the U.S. development and commercialization rights for POSIMIR to Innocoll, whose dedicated hospital sales and marketing organization is deeply committed to providing non-opioid analgesia products to patients in the post-surgical setting," said James E. Brown, President and Chief Executive Officer of DURECT Corporation. "Completing this POSIMIR deal is another important step in the continued transformation of DURECT as we continue to focus on larsucosterol, our lead epigenetic regulator, which is in late-stage clinical development for alcohol-associated hepatitis."

"We believe that POSIMIR has the potential to become a cornerstone of multi-modal post-operative pain management as well as an important contributor to the on-going efforts to provide safe and effective alternatives to opioid-based medications following surgery," added Louis Pascarella, Chief Executive Officer of Innocoll. "Innocoll is now the only company with two bupivacaine-based, sustained-release, non-opioid products, that are FDA approved and indicated for relief of post-surgical pain in specified surgical procedures. We are currently on track to launch POSIMIR in the second quarter of 2022, subject to commercial supply timelines."

Terms of the Collaboration
Under the terms of the agreement, Innocoll will make near-term payments to DURECT of $6 million, consisting of a $4 million license fee and a $2 million payment upon first commercial sale, with the potential for up to an additional $130 million in commercial, regulatory and

intellectual property milestone payments as well as tiered, low to mid double-digit royalties on net product sales in the United States.

Innocoll has been granted the exclusive right to develop and commercialize POSIMIR in the United States. Innocoll has also been granted the right to conduct additional development activities to expand the approved indications for POSIMIR, and DURECT's contract manufacturing supply agreement for POSIMIR has been assigned to Innocoll. DURECT retains all commercial rights to POSIMIR throughout the rest of the world.

Conference Call
DURECT will host a conference call today to discuss the license agreement with Innocoll:

Wednesday, December 22 @ 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time
Toll Free: 877-869-8261
International: 201-689-8261
Conference ID: 13725862
Webcast: https://themediaframe.com/mediaframe/webcast.html?webcastid=86LaZ3eE

The conference call will also be available by webcast on DURECT's homepage at www.durect.com under the "Investors" tab. If you are unable to participate during the webcast, the call will be archived on DURECT's website under "Event Calendar" in the "Investors" section.

About Innocoll
Innocoll Biotherapeutics plc is a global specialty pharmaceutical company headquartered in Athlone, Ireland. Innocoll Biotherapeutics plc and its subsidiaries Innocoll Holdings Limited and Innocoll Pharmaceuticals Limited, are focused on the development and commercialization of pharmaceutical technologies to meet some of today's most important healthcare challenges. Innocoll Biotherapeutics plc is a portfolio business of Gurnet Point Capital. www.innocoll.com

About POSIMIR
POSIMIR® (bupivacaine solution) for infiltration use is a novel and proprietary product that combines the strength of 660 mg of bupivacaine base with the innovative SABER® platform technology, enabling continuous sustained delivery of a non-opioid local analgesic over 3 days in adults. POSIMIR contains more bupivacaine than any other approved single-dose sustained-release bupivacaine product. At the end of surgery, POSIMIR is administered into the subacromial space under direct arthroscopic visualization, where it continuously releases bupivacaine for 72 hours or more.

Indications and Usage
POSIMIR® (bupivacaine solution) for infiltration use is indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.

Limitations of Use
Safety and effectiveness have not been established in other surgical procedures, including soft tissue surgical procedures, other orthopedic procedures, including for intra-articular administration, and boney procedures, or when used for neuraxial or peripheral nerve blockade.

Full Prescribing Information, including the Boxed Warning, is available at www.POSIMIR.com

Important Safety Information

BOXED WARNING: RISK OF POTENTIAL ADVERSE EMBOLIC EFFECTS RESULTING FROM INADVERTENT INTRAVASCAULAR INJECTION. Inadvertent intravascular injection could cause POSIMIR droplets to be deposited in the pulmonary and other capillary beds. Administer POSIMIR into the subacromial space at the end of arthroscopic shoulder surgery. Direct arthroscopic visualization must be used to confirm proper placement of the needle tip before injecting POSIMIR.

In POSIMIR clinical studies, no inadvertent intravascular injections were observed. Do not inject POSIMIR intravascularly.

POSIMIR is contraindicated in patients with a known hypersensitivity to any amide local anesthetic, or other components of POSIMIR, as well as in patients undergoing obstetrical paracervical block anesthesia. There is a risk of joint cartilage necrosis with unapproved intra-articular use of POSIMIR. Unintended intravascular injection of POSIMIR may be associated with systemic toxicities, including CNS or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. As with other local anesthetics, patients should be monitored for central nervous system, cardiovascular, and allergic reactions. Avoid additional use of local anesthetics within 168 hours following administration of POSIMIR. Cases of methemoglobinemia have been reported in association with use of local anesthetics. There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use. POSIMIR should be used cautiously in patients with impaired hepatic and cardiovascular function. Adverse events reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in shoulder surgery were dizziness, dysgeusia, dysuria, headache, hypoesthesia, paresthesia, tinnitus, and vomiting. Adverse events reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in soft tissue surgical procedures were anemia, bradycardia, constipation, C-reactive protein increased, diarrhea, dizziness, dysgeusia, headache, nausea, oropharyngeal pain, post-procedural contusion (bruising), procedural pain, pruritus, pyrexia, somnolence, surgical site bleeding, visible bruising and vomiting.

To report SUSPECTED ADVERSE REACTIONS, contact DURECT Corporation at 1-844-767-4647 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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. Larsucosterol (also known as DUR-928), DURECT's lead drug candidate, binds to and inhibits the activity of DNA methyltransferases (DNMTs), epigenetic enzymes which are elevated and associated with hypermethylation found in alcohol-associated hepatitis (AH) patients. Larsucosterol is in clinical development for the potential treatment of AH, for which FDA has granted a Fast Track Designation; non-alcoholic steatohepatitis (NASH) is also being explored. In addition, POSIMIR® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABER® platform technology, is FDA-approved and has been exclusively licensed to Innocoll Pharmaceuticals for development and commercialization in the United States. Full prescribing information about POSIMIR, including the Boxed Warning, can be found at www.posimir.com. For more information about DURECT, please visit www.durect.com and follow us on Twitter https://twitter.com/DURECTCorp.

DURECT Forward-Looking Statement. This press release contains forward-looking statements relating to, among other things, DURECT's relationship with Innocoll; milestone and royalty payments that may be potentially paid to DURECT under the license agreement with Innocoll, Innocoll's ability to achieve regulatory and commercial milestones or DURECT's ability to achieve intellectual property milestones, in each case, under the license agreement with DURECT; statements about the potential launch of POSIMIR in the second quarter of 2022, statements about the use of POSIMIR to treat post-operative pain, statements about POSIMIR's potential as an alternative to opioid-based medications following surgery, the commercial potential of POSIMIR, statements about the potential for larsucosterol (also known as DUR-928) to treat patients with AH, NASH, multiple acute organ injury, chronic liver diseases and other diseases, ongoing clinical trials of larsucosterol, and the potential benefits of Fast Track Designation. Any statements contained in this press release 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 DURECT'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 launch POSIMIR as planned or commercialize POSIMIR successfully, if at all; Innocoll's ability to obtain supplies of POSIMIR; marketplace acceptance of POSIMIR; the risk that Innocoll may terminate the license agreement under conditions specified in the license agreement; the risk that the clinical trial of larsucosterol in AH takes longer to conduct than anticipated due to COVID-19 or other factors; the risk that clinical trials of larsucosterol, including AHFIRM, do not confirm the results from earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy or the lifesaving potential of larsucosterol in a statistically significant manner; the risk that Fast Track Designation for larsucosterol in AH may not lead to faster FDA review or an approval; risks related to DURECT's ability to obtain capital to fund operations and expenses; risks related to market competition, and other risks described in the "Risk Factors" section of DURECT's Quarterly Report on Form 10-Q for the period ended September 30, 2021 filed with the Securities and Exchange Commission (the "SEC") on November 3, 2021, and in other filings filed from time to time with the SEC. DURECT 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.
NOTE: POSIMIR® is a trademark of Innocoll Pharmaceuticals, Ltd. in the U.S. and a trademark of DURECT Corporation outside of the U.S. SABER® is a trademark of DURECT Corporation. Other referenced trademarks belong to their respective owners. Larsucosterol (DUR-928) is an investigational drug candidate under development and has not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities for any indication.

SOURCE: DURECT Corporation

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