
**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**

Date of Report (Date of earliest event reported): February 3, 2021

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	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)
Preferred Share Purchase Rights		

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 2.02 Results of Operations and Financial Condition.**Recent Developments*****Certain Preliminary Financial Results as of December 31, 2020***

In connection with a proposed registered offering of common stock, DURECT Corporation ("DURECT") has announced that it expects to report that it had approximately \$56.9 million in cash, cash held in escrow (approximately \$15 million related to the sale of its LACTEL polymer product line) and investments at December 31, 2020. This amount comprises forward-looking statements based on preliminary unaudited information and management estimates for the year ended December 31, 2020, is not a comprehensive statement of DURECT's financial results for this period, and is subject to change pending completion of DURECT's financial closing procedures, final adjustments, completion of the audit of DURECT's financial statements and other developments that may arise between now and the time such audit is completed. Additional information and disclosures would be required for a more complete understanding of DURECT's financial position and results of operations as of December 31, 2020. DURECT's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, these preliminary estimates. DURECT expects the audit of its financial statements for the year ended December 31, 2020, to be completed subsequent to the completion of the proposed registered offering. It is possible that DURECT or its independent registered public accounting firm may identify items that require them to make adjustments to the preliminary estimated cash, cash held in escrow and investments balance set forth above and those changes could be material.

The information in this Item 2.02 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.***Updated Risk Factors***

In connection with a proposed registered offering of common stock, DURECT is providing the updated risk factors set forth below.

All references below to "we," "us," "our" and similar references refer to DURECT, except where the context otherwise requires or as otherwise indicated.

Additional Risks Related to Our Business***The outbreak of the novel coronavirus disease, COVID-19, has and will adversely impact our business.***

The global COVID-19 pandemic has disrupted our operations and delayed our clinical trials. In particular, the COVID-19 pandemic has delayed initiation of our AHFIRM Phase 2b clinical trial to evaluate the safety and efficacy of DUR-928 in severe alcohol-associated hepatitis (AH) patients, and it may delay enrollment of this trial and other clinical trials. As a result of the COVID-19 pandemic, there are also supply shortages of components needed for commercialization supplies of POSIMIR, which are adversely affecting the timing for the commercial launch of POSIMIR, and there has been reduced demand for our ALZET products, which are used in scientific and pre-clinical research. In addition, COVID-19 may have an adverse impact on the economies and financial markets of many countries, resulting in a severe and prolonged global economic downturn that could continue to affect demand for our ALZET product lines and POSIMIR and impact our operating results. We also need to raise additional capital to provide sufficient funding to continue our product development efforts, including clinical trials. COVID-19 initially had an adverse impact on the capital markets and could again, which would make it more difficult for companies such as ours to access capital. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. As a

result of the COVID-19 pandemic, we may continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints, the ability to collect, ship and analyze biological samples from clinical trial patients due to concerns about potential contamination of samples and/or exposure of clinical staff to patients with the COVID-19;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- disruption or delays in manufacturing of clinical and commercial supplies due to issues experienced by our contract manufacturing organizations and or shortages and delays in obtaining raw materials and supplies required in the manufacturing processes;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at laboratory facilities;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- material delays and complications with respect to our research and development programs.

The approval of COVID-19 vaccines and alternative therapies may limit enrollment of the clinical trial of DUR-928 in COVID-19 patients with acute liver or kidney injury, and we may discontinue this trial.

Since we initiated a clinical trial of DUR-928 in patients with COVID-19 with acute liver or kidney injury, several vaccines for COVID-19 have been approved and are being deployed worldwide. During this period, treatment regimens for patients with COVID-19 have evolved and more additional therapies have entered clinical trials. Consequently, despite the increasing number of confirmed COVID-19 patients, there may be a decreasing number of patients eligible or willing to enroll in our trial of DUR-928 in COVID-19 patients with acute liver or kidney injury. If we are unable to obtain sufficient enrollment in this trial in a reasonable period of time, we may elect to discontinue it.

We intend to seek a commercialization partner for POSIMIR and may be unable to do so.

We intend to license POSIMIR to a third party for commercialization. We had previously entered into a license agreement with Sandoz AG for commercialization of POSIMIR, but Sandoz terminated that agreement. There can be no assurance that we will be able to enter into an agreement with a third party for the commercialization of POSIMIR at all, or that any agreement we enter into will result in material payments to us. If we are not able to enter into such an agreement, or if such agreement does not result in material payments to us, our financial prospects may be harmed.

Fast Track designation of DUR-928 by the FDA may not actually lead to a faster development or regulatory review or approval process.

The FDA grants Fast Track designation to therapies that are considered capable of addressing unmet medical needs and possess the potential to treat serious or life-threatening disease conditions in order to facilitate its development and expedite the review procedure. Even though DUR-928 has received Fast Track designation for the treatment of alcoholic hepatitis, we may not experience a faster development process, review or approval, or receive FDA approval at all, in that indication or any other compared to conventional FDA procedures. A Fast Track designation does not change the standards for approval. The FDA may also withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Our revenues may decrease and our losses may increase compared to prior years as a result of the sale of the LACTEL® polymer product line.

In December 2020 we completed the sale of our LACTEL polymer product line to Evonik for approximately \$15 million. Sales of LACTEL polymers contributed to our product revenues and earnings, and the loss of these revenues and earnings will make future period financial results less comparable to those of prior periods.

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: February 3, 2021

By: /s/ Michael H. Arenberg

Michael H. Arenberg

Chief Financial Officer