
**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, 2023

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)

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.

The information contained in Item 8.01 of this Current Report is incorporated into this Item 2.02 by reference.

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 into any registration statement or other document filed under the Securities Act of 1933, as amended (the “Securities Act”) or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On February 3, 2023, DURECT Corporation (“DURECT”), posted an update to its corporate presentation (the “Corporate Presentation”) on its website, <https://www.durect.com/investors/>. A copy of the Corporate Presentation is attached hereto as Exhibit 99.1.

The information set forth in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

In connection with updating its Corporate Presentation, DURECT has announced that it expects to report that it had approximately \$43.6 million in cash, cash equivalents and investments and approximately \$21.2 million in outstanding debt at December 31, 2022. Additionally, DURECT had approximately 22.8 million outstanding shares of common stock at December 31, 2022. These amounts comprise forward-looking statements based on preliminary unaudited information and estimates for the year ended December 31, 2022, are not comprehensive statements of DURECT’s financial results for this period, and are 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. This preliminary estimate may change. DURECT’s expectation with respect to its cash, cash equivalents and investments and debt at December 31, 2022, is based upon management estimates and is the responsibility of management. 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.

Updated Risk Factor

DURECT is also providing an updated risk factor 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.

We will require, and may have difficulty or be unsuccessful in raising needed capital in the future, to continue to operate as a going concern.

As of September 30, 2022, we had cash, cash equivalents and investments of \$52.0 million. Our accumulated deficit as of September 30, 2022 was \$550.9 million. We have incurred significant net losses since inception, and expect to incur continuing losses and negative cash flows from operations for the foreseeable future. In addition, our debt repayment obligations under the Loan and Security Agreement (as amended, the “Loan Agreement”) with Oxford Finance LLC may prove a burden to us as such repayment obligations become due, particularly following the expiration of the interest-only period. Such increased payment requirements, currently expected to commence in June 2023, will increase our cash expenditures. Furthermore, over the next twelve months, we anticipate a decline in revenues. As a result of the forgoing conditions, we believe that absent raising additional capital to fund our

operations, our existing cash, cash equivalents and investments will not be sufficient to fund our current business plan for twelve months from the date of this prospectus supplement and therefore raises substantial doubt regarding our ability to continue as a going concern for a period of one year from the issuance of this prospectus supplement.

Because we continue to experience negative cash flows from operations, our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources. In addition, we may decide to raise additional capital through a variety of sources in the short-term and in the long-term, including from sales of shares of our common stock through our Controlled Equity OfferingSM Sales Agreement, dated July 30, 2021, by and between us and Cantor Fitzgerald & Co., or other equity offerings in the public markets, private equity financings, collaborative arrangements or public or private debt, which, in each case, may be dilutive to existing stockholders, and may cause the price of our common stock to decline. Our continued negative cash flows from operations increase the difficulty in securing alternative sources of funding, and there can be no assurances that we will be able to obtain any future funding on favorable terms or at all. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Our ability to obtain additional financing in the debt and equity capital markets is subject to several factors, including market and economic conditions, our performance and investor sentiment with respect to us and our industry.

If we are unable to obtain sufficient financing, we plan to address our operating cash flow requirements by modifying our current business plan to significantly reduce or refocus our operations, renegotiate or refinance the Loan Agreement, seek to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, or liquidate our assets, all of which could have a material adverse effect on our business, financial condition and results of operations. In addition, if our modification efforts are insufficient, future reports of our independent registered public accounting firm may contain statements expressing substantial doubt about our ability to continue as a going concern.

Cautionary Note Regarding Forward-looking Statements

Certain statements in this Current Report on Form 8-K related to DURECT constitute “forward-looking information” within the meaning of applicable securities laws and are prospective in nature. Forward-looking information is not based on historical facts, but rather on current expectations and projections about future events and is therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as “will”, “may”, “should”, “could”, “intend”, “estimate”, “plan”, “anticipate”, “expect”, “believe”, “potential” or “continue”, or the negative thereof or similar variations. Forward-looking information in this Current Report on Form 8-K includes, but is not limited to, the uncertainties related to the sufficiency of DURECT’s cash resources, anticipated capital requirements and capital expenditures, DURECT’s ability to comply with covenants of the Loan Agreement, DURECT’s need or desire for additional financing, and DURECT’s ability to continue to operate as a going concern. There are numerous risks and uncertainties that could cause actual results and DURECT’s plans and objectives to differ materially from those expressed in the forward-looking information, such as those risks discussed or referred to herein and the risks described in DURECT’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and its Quarterly Report on Form 10-Q for the period ended September 30, 2022 and other filings and furnishings made by DURECT with the SEC on EDGAR at www.sec.gov. Except as required by law, DURECT undertakes no duty or obligation to update any forward-looking statements contained in this Current Report on Form 8-K as a result of new information, future events, changes in expectations or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor Presentation, dated February 3, 2023.
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: February 3, 2023

By: /s/ Timothy M. Papp

Timothy M. Papp

Chief Financial Officer