

DURECT CORP
Form S-3/A
September 28, 2018

As filed with the Securities and Exchange Commission on September 28, 2018

Registration No. 333-226518

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 2 TO

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

DURECT CORPORATION

(Exact name of registrant as specified in its charter)

Delaware 94-3297098
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)

10260 Bubb Road
Cupertino, California 95014
(408) 777-1417

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

James E. Brown

Chief Executive Officer

DURECT Corporation

10260 Bubb Road

Cupertino, California 95014

(408) 777-1417

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Stephen B. Thau

Alfredo B.D. Silva

Morrison & Foerster LLP

755 Page Mill Road

Palo Alto, CA 94304

(650) 813-5600

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement as determined by the Registrant

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer
 Non-accelerated filer Smaller reporting company
 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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

| Title of Each Class of | Amount | Proposed Maximum Offering Price | Proposed Maximum Aggregate | Amount of |
|--------------------------------------------------|-------------------------|------------------------------------------|----------------------------------|----------------------|
| Registered (1) | Registered (1)(2)(3)(4) | Per Unit (1) | Offering Price (1)(2)(3)(4) | Registration Fee (5) |
| Common Stock, par value \$0.0001 per share | | | | |
| Preferred Stock, par value \$0.0001 per share | | | | |
| Debt Securities | | | | |
| Warrants | | | | |
| Units | | | | |
| Total | | | \$175,000,000 | \$21,788 (6) |

(1)Not specified as to each class of securities to be registered pursuant to General Instruction II.D of Form S-3 under the Securities Act of 1933, as amended, or the Securities Act.

(2)

The registrant is hereby registering an indeterminate amount and number of each identified class of the identified securities up to a proposed maximum aggregate offering price of \$175,000,000, which may be offered from time to time at indeterminate prices, including securities that may be purchased by underwriters. The registrant has estimated the proposed maximum aggregate offering price solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act. Securities registered hereunder may be sold separately, together or as units with other securities registered hereunder.

- (3) The registrant is hereby registering an indeterminate amount and number of each identified class of the identified securities as may be issued upon conversion, exchange, exercise or settlement of any other securities that provide for such conversion, exchange, exercise or settlement.
- (4) Pursuant to Rule 429 under the Securities Act and as further described below under the heading "Statement Pursuant to Rule 429(b)," this registration statement covers up to a maximum aggregate offering price of \$175,000,000 of the registrant's common stock, preferred stock, debt securities, warrants and/or units, including \$68,263,783 of such securities registered on the registrant's Registration Statement on Form S-3 first filed on November 3, 2015 (File No. 333-207776) (the "Prior Registration Statement"), which was declared effective on November 25, 2015, that have not yet been sold and are included in this registration statement.
- (5) Calculated pursuant to Rule 457(o) under the Securities Act. Pursuant to Rule 457(p) under the Securities Act, the registrant is applying \$6,874.16 of the registration fee paid in connection with the Prior Registration Statement, representing the aggregate total amount of the filing fee associated with the unsold securities registered on the Prior Registration Statement, to offset \$6,874.16 of the registration fee due hereunder.
- (6) Previously paid.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

STATEMENT PURSUANT TO RULE 429(b)

The registrant is filing a single base prospectus in this registration statement pursuant to Rule 429 under the Securities Act, in order to satisfy the requirements of the Securities Act and the rules and regulations thereunder for (i) the offering, issuance and sale by the registrant of up to a maximum aggregate offering price of \$106,736,217 of the registrant's common stock, preferred stock, debt securities, warrants and/or units being registered in this new registration statement and (ii) the offering, issuance and sale by the registrant of up to a maximum aggregate offering price of \$68,263,783 of the registrant's common stock, preferred stock, debt securities, warrants and/or units registered in the Prior Registration Statement, to enable an aggregate of \$175,000,000 of securities to be offered pursuant to the combined base prospectus. The combined base prospectus in this registration statement, which is a new registration statement, also constitutes a post-effective amendment to the Prior Registration Statement. Such post-effective amendment shall hereafter become effective concurrently with the effectiveness of this registration statement and in accordance with Section 8(c) of, and Rule 429 under, the Securities Act.

EXPLANATORY NOTE

This registration statement contains two prospectuses:

- a base prospectus which covers the offering, issuance and sale by the registrant of up to a maximum aggregate offering price of \$175,000,000 of the registrant's common stock, preferred stock, debt securities, warrants and/or units; and
- a prospectus supplement covering the offering, issuance and sale by the registrant of up to a maximum aggregate offering price of \$75,000,000 of the registrant's common stock that may be issued and sold under a sales agreement with Cantor Fitzgerald & Co.

The base prospectus immediately follows this explanatory note. The supplemental prospectus immediately follows the base prospectus. The common stock that may be offered, issued and sold by the registrant under the supplemental prospectus is included in the \$175,000,000 of securities that may be offered, issued and sold by the registrant under the base prospectus.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED SEPTEMBER 28, 2018

PROSPECTUS

\$175,000,000

Common Stock

Preferred Stock

Debt Securities

Warrants

Units

Investing in our securities involves a high degree of risk. You should carefully read and consider the risk factors described in this prospectus supplement, any accompanying prospectus supplement and in the documents incorporated by reference into this prospectus supplement. See "Risk Factors" beginning on page 3.

From time to time, we may offer and sell, in one or more offerings, in amounts, at prices and on terms determined at the time of any such offering, common stock, preferred stock, debt securities, warrants, either individually or in units, with a total value of up to \$175,000,000.

Our common stock trades on the NASDAQ Global Market under the symbol "DRRX." On September 26, 2018, the last reported sale price of the common stock on the NASDAQ Global Market was \$1.20 per share.

We will provide specific terms of these securities in supplements to this prospectus. The prospectus supplement will also describe the specific manner in which we will offer the securities and may also supplement, update or amend information contained in this document. You should read this prospectus and any supplement carefully before you purchase any of our securities.

THIS PROSPECTUS MAY NOT BE USED TO OFFER AND SELL SECURITIES UNLESS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

We may offer the securities in amounts, at prices and on terms determined at the time of offering. We may sell the securities directly to you, through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers to sell the securities, we will name them and describe their compensation in a prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2018

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No person has been authorized to give any information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus and any accompanying prospectus supplement in connection with the offering described in this prospectus and any accompanying prospectus supplement, and, if given or made, such information or representations must not be relied upon as having been authorized by us. Neither this prospectus nor any prospectus supplement shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation. Neither the delivery of this prospectus or any prospectus supplement nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference in this prospectus or in any prospectus supplement is correct as of any date subsequent to the date of this prospectus supplement or of any prospectus supplement.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a “shelf” registration process. Under this shelf registration process, we may, from time to time, issue and sell to the public any part of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$175,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell the securities, we will provide a prospectus supplement containing specific information about the terms of that offering. The prospectus supplement may also add, update or change information in this prospectus or in documents incorporated by reference in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus or in documents incorporated by reference in this prospectus, the statements made or incorporated by reference in this prospectus will be deemed modified or superseded by those made in the prospectus supplement. You should carefully read both this prospectus and any prospectus supplement together with the additional information described under the heading “Where You Can Find More Information” before buying any securities offered in this offering.

THIS PROSPECTUS MAY NOT BE USED TO OFFER AND SELL SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

The registration statement containing this prospectus, including exhibits to the registration statement, provides additional information about us and the securities offered under this prospectus. The registration statement can be read at the SEC’s website or at the SEC offices mentioned under the heading “Where You Can Find More Information.”

ABOUT DURECT

We are a biopharmaceutical company with research and development programs broadly falling into two categories: (i) new chemical entities derived from our Epigenetic Regulator Program, in which we attempt to discover and develop molecules which have not previously been approved and marketed as therapeutics, and (ii) Drug Delivery Programs, in which we apply our formulation expertise and technologies largely to active pharmaceutical ingredients whose safety and efficacy have previously been established but which we aim to improve in some manner through a new formulation. We also manufacture and sell osmotic pumps used in laboratory research and design, develop and manufacture a wide range of standard and custom biodegradable polymers and excipients for pharmaceutical and medical device clients for use as raw materials in their products. In addition, we conduct research and development of pharmaceutical products in collaboration with third party pharmaceutical and biotechnology companies.

We were incorporated in Delaware in February 1998. We completed our initial public offering on September 28, 2000. Our principal executive offices are located at 10260 Bubb Road, Cupertino, California, 95014. Our telephone number is (408) 777-1417, and our website address is www.durect.com. The information on or accessible through our website does not constitute part of this prospectus supplement or the accompanying prospectus and should not be relied upon in connection with making any investment in our securities. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports available free of charge on our website as soon as reasonably practicable after we file these reports with the Securities and Exchange Commission. Our Code of Ethics can be found on our website.

Securities We Are Offering

We may offer shares of common stock, shares of preferred stock, debt securities, warrants, either individually or in units, with a total value of up to \$175,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of the offering. Our common stock currently is quoted on the NASDAQ Global Market under the symbol "DRRX." Shares of common stock that may be offered in this offering will, when issued and paid for, be fully paid and non-assessable.

We refer to our common stock, preferred stock, debt securities, warrants and units in this prospectus as "securities." This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, as described below under "Plan of Distribution."

RISK FACTORS

Before you invest in our securities, in addition to the other information, documents or reports incorporated by reference in this prospectus and any prospectus supplement or other offering materials, you should carefully consider the risk factors in this section, the section entitled “Risk Factors” in any prospectus supplement as well as our most recent Annual Report on Form 10-K, and in our Quarterly Reports on Form 10-Q filed subsequent to the Annual Report on Form 10-K, which are incorporated by reference into this prospectus and any prospectus supplement in their entirety, as the same may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. Each of the risks described in these sections and documents could materially and adversely affect our business, financial condition, results of operations and prospects, and could result in a partial or complete loss of your investment.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING INFORMATION

This prospectus and the documents we incorporate by reference in this prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical facts, included or incorporated in this prospectus regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. We may, in some cases, use words such as “believe,” “anticipate,” “should,” “intend,” “plan,” “will,” “estimate,” “project,” “expect” and similar expressions. Not all forward-looking statements contain these identifying words. These statements are based on assumptions and assessments made by our management in light of its experience and its perception of historical trends, current conditions, expected future developments and other factors our management believes to be appropriate. These forward-looking statements are subject to a number of risks and uncertainties, including those risks described or incorporated by reference in this prospectus under “Risk Factors” above.

Forward-looking statements included or incorporated by reference in this prospectus include, for example, statements about:

- the clinical trial plans for DUR-928;
- potential regulatory filings for or approval of REMOXY ER, DUR-928, POSIMIR, or any of our or any third parties’ other product candidates;
- the progress of our third-party collaborations, including estimated milestones;
- our intention to seek, and ability to enter into and maintain strategic alliances and collaborations;
- the potential benefits and uses of our products;
- responsibilities of our third-party collaborators, including the responsibility to make cost reimbursement, milestone, royalty and other payments to us, and our expectations regarding our collaborators’ plans with respect to our products and continued development of our products;
- our responsibilities to our third-party collaborators, including our responsibilities to conduct research and development, clinical trials and manufacture products;
- our ability to protect intellectual property, including intellectual property licensed to our collaborators;
- market opportunities for products in our product pipeline;
- the progress and results of our research and development programs and our evaluation of additional development programs;
- requirements for us to purchase supplies and raw materials from third parties, and the ability of third parties to provide us with required supplies and raw materials;
- the results and timing of clinical trials, including for DUR-928, REMOXY ER and POSIMIR, the possible commencement of future clinical trials and announcements of the findings of our clinical trials;
- conditions for obtaining regulatory approval of our product candidates;
- submission and timing of applications for regulatory approval;
-