

DURECT CORP  
Form S-3/A  
March 10, 2009  
Table of Contents

As filed with the Securities and Exchange Commission on March 10, 2009

Registration No. 333-155042

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**PRE-EFFECTIVE AMENDMENT NO. 1 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

Edgar Filing: DURECT CORP - Form S-3/A

(State or other jurisdiction of

(I.R.S. Employer

incorporation or organization)

Identification No.)

2 Results Way, 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**

**2 Results Way, 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**

**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.

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, please 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.

## Edgar Filing: DURECT CORP - Form S-3/A

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer   
 Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered (1)	Amount to be Registered (1)(2)(3)	Proposed Maximum Offering Price Per Unit (1)	Proposed Maximum Aggregate Offering Price (1)(2)(3)	Amount of Registration Fee (4)
Common Stock, par value \$0.0001 per share (5)				
Preferred Stock, par value \$0.0001 per share				
Debt Securities				
Warrants				
Units				
Total			\$ 75,000,000	\$ 2,947.51

- (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 \$75,000,000, 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) Calculated pursuant to Rule 457(o) under the Securities Act. Pursuant to Rule 457(p) under the Securities Act of 1933, the registrant hereby offsets the entire registration fee of \$2,947.51 required in connection with this registration statement by \$4,028.25 that was previously paid with respect to \$34,224,774 aggregate offering price of common stock that was registered by DURECT Corporation pursuant to a prior registration statement (File No. 333-128979), originally filed on October 13, 2005, that has not yet been issued and sold. The remaining unused \$1,080.74 from the prior registration statement may be used to offset future registration fees in accordance with Rule 457(p).
- (5) Associated with the common stock are series A participating preferred stock purchase rights that will not be exercisable or be evidenced separately from the common stock prior to the occurrence of certain events. Prior to the occurrence of certain events, the series A participating preferred stock purchase rights will not be exercisable or evidenced separately from the registrant's common stock and have no value except as reflected in the market price of the shares to which they are attached.

**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.**



**Table of Contents**

**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 MARCH 10, 2009**

PROSPECTUS

**\$75,000,000**

**DURECT CORPORATION**

**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, ANY ACCOMPANYING PROSPECTUS SUPPLEMENT AND IN THE DOCUMENTS INCORPORATED BY REFERENCE INTO THIS PROSPECTUS. 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 \$75,000,000.

Our common stock trades on the NASDAQ Global Market under the symbol DRRX. On March 9, 2009, the last reported sale price of the common stock on the NASDAQ Global Market was \$1.44 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 \_\_\_\_\_, 2009

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>About This Prospectus</u>	1
<u>About DURECT</u>	2
<u>Risk Factors</u>	3
<u>Cautionary Note Regarding Forward Looking Information</u>	20
<u>Ratio of Earnings to Fixed Charges and</u>	
<u>Ratio of Earnings to Combined Fixed Charges and Preferred Dividend Requirements</u>	20
<u>Use of Proceeds</u>	21
<u>Description of Capital Stock</u>	21
<u>Additional Information Concerning Our Capital Stock</u>	24
<u>Description of Debt Securities</u>	25
<u>Description of Warrants</u>	30
<u>Description of Units</u>	31
<u>Legal Ownership of Securities</u>	32
<u>Plan of Distribution</u>	35
<u>Legal Matters</u>	36
<u>Experts</u>	36
<u>Where You Can Find More Information</u>	37
<u>Information Not Required in Prospectus</u>	II-1

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.

POSIDUR<sup>®</sup>, SABER<sup>®</sup>, ELADUR<sup>®</sup>, TRANSDUR<sup>®</sup>, ORADDERIN<sup>®</sup>, CHRONOGESI<sup>®</sup>, MICRODUR<sup>®</sup>, ALZET<sup>®</sup> and LACTEL<sup>®</sup> are trademarks of DURECT Corporation. Other trademarks referred to belong to their respective owners. REMOXY is a trademark of Pain Therapeutics, Inc. DUROS is a trademark of ALZA Corporation, a Johnson & Johnson Company. Memryte is a trademark of Voyager Pharmaceutical Corp. Other trademarks referred to belong to their respective owners.

**Table of Contents**

**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 \$75,000,000.

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 Securities and Exchange Commission (the SEC) website or at the SEC offices mentioned under the heading **Where You Can Find More Information**.

**Table of Contents**

**ABOUT DURECT**

We are a pharmaceutical company developing therapies based on our proprietary drug formulations and delivery platform technologies. We have several products under development by ourself and with third party pharmaceutical and biotechnology company collaborators. 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 for pharmaceutical and medical device clients for use as raw materials in their products.

We were incorporated in Delaware in February 1998. Our principal executive offices are located at 2 Results Way, Cupertino, California 95014 and our telephone number at that address is (408) 777-1417. Our website is [www.durect.com](http://www.durect.com). The information contained or incorporated in our website is not part of this registration statement.

*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 \$75,000,000 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.



## **Table of Contents**

### **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.

#### **Risks Related To Our Business**

*Development of our pharmaceutical systems is not complete, and we cannot be certain that our pharmaceutical systems will be able to be commercialized*

To be profitable, we or our third-party collaborators must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our pharmaceutical systems under development. For each pharmaceutical system that we or our third-party collaborators intend to commercialize, we must successfully meet a number of critical developmental milestones for each disease or medical condition targeted, including:

selecting and developing drug delivery platform technology to deliver the proper dose of drug over the desired period of time;

determining the appropriate drug dosage for use in the pharmaceutical system;

developing drug compound formulations that will be tolerated, safe and effective and that will be compatible with the system;

demonstrating the drug formulation will be stable for commercially reasonable time periods;

demonstrating through clinical trials that the drug and system combination is safe and effective in patients for the intended indication; and

completing the manufacturing development and scale-up to permit manufacture of the pharmaceutical system in commercial quantities and at acceptable prices.

The time frame necessary to achieve these developmental milestones for any individual product is long and uncertain, and we may not successfully complete these milestones for any of our products in development. We have not yet selected the drug dosages nor finalized the formulation or the system design of POSIDUR, TRANSDUR-Sufentanil, ELADUR, our ORADUR-based drug candidates other than Remoxy, and Memryte, and we have limited experience in developing such products. We may not be able to finalize the design or formulation of any of these pharmaceutical systems. In addition, we may select components, solvents, excipients or other ingredients to include in our pharmaceutical systems that have not been previously approved for use in pharmaceutical products, which may require us or our collaborators to perform additional studies and may delay clinical testing and regulatory approval of our pharmaceutical systems. Even after we complete the design of a pharmaceutical system, the pharmaceutical system must still complete required clinical trials and additional safety testing in animals before approval for commercialization. We are continuing testing and development of our pharmaceutical systems and may explore possible design or formulation changes to address issues of safety, manufacturing efficiency and performance. We and our collaborators may not be able to complete development of any pharmaceutical systems that will be safe and effective and that will have a commercially reasonable treatment and storage period. If we or our third-party collaborators are unable to complete development of POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and our ORADUR-based drug candidates other than Remoxy, Memryte or other pharmaceutical systems, we will not be able to earn revenue from them, which would materially harm our business.



---

## **Table of Contents**

*We or our third-party collaborators must conduct and satisfactorily complete required laboratory performance and safety testing, animal studies and clinical trials for our pharmaceutical systems before they can be sold*

Before we or our third-party collaborators can obtain government approval to sell any of our pharmaceutical systems, we or they, as applicable, must demonstrate through laboratory performance studies and safety testing, nonclinical (animal) studies and clinical (human) trials that each system is safe and effective for human use for each targeted indication. The clinical development status of our publicly announced development programs is as follows:

**Remoxy** In December 2007, Pain Therapeutics and King reported positive results from the pivotal Phase III trial submitted under an approved Special Protocol Assessment (SPA) with the FDA; the NDA was submitted to the FDA in June 2008, and in August 2008, the NDA was accepted by the FDA and granted priority review. In December 2008, Pain Therapeutics received a Complete Response Letter for its NDA for Remoxy in which the FDA determined that the NDA was not approved. According to Pain Therapeutics, the FDA indicated that additional non-clinical data will be required to support the approval of Remoxy, but the FDA has not requested or recommended additional clinical efficacy studies prior to approval. Pain Therapeutics has indicated that they plan to meet with the FDA in the second quarter of 2009 regarding the NDA for Remoxy, and they believe this FDA meeting will provide them with a more reliable context in which to make projections about Remoxy.

**POSIDUR** A successful Phase IIb clinical trial in hernia surgery was completed and an end-of-Phase II meeting has been held with the FDA. We are currently in dialogue with the FDA regarding our Phase III program. In parallel with these discussions, we are conducting a 60-patient Phase IIb study in Australia in shoulder surgery in order to allow us to confirm aspects of our clinical study design and conduct. Additionally, Nycomed is commencing Phase IIb studies in surgical procedures in Europe.

**TRANSDUR-Sufentanil Patch** Endo recently successfully completed a Phase II program for TRANSDUR- Sufentanil in which they evaluated the conversion of patients on oral and transdermal opioids to TRANSDUR-Sufentanil. The most recent Phase II study met its primary and secondary objectives of establishing a successful dose-titration regimen and dose potency relationships, demonstrating safety and tolerability at the therapeutic dose, and achieving effective analgesic pain control. The Phase II data, extensive non-clinical data that had been generated by Endo and detailed proposed protocols for Phase III were reviewed with the FDA at an end-of-Phase II meeting on February 19, 2009. On February 26, 2009, Endo notified us that it was terminating its license agreement for TRANSDUR-Sufentanil and thereby returning to us Endo's rights to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada effective August 26, 2009.

**ELADUR** A Phase IIa clinical trial was completed and positive results were reported in the fourth quarter of 2007. In 2008, we conducted manufacturing scale-up and processing activities to secure additional Phase II and Phase III supplies, and developed our clinical and regulatory strategy for further development of this program. In September 2008, we entered into a development and license agreement with Alpharma Ireland Ltd., an affiliate of Alpharma Inc., granting such party the exclusive worldwide rights to develop and commercialize ELADUR. The agreement became effective in October 2008 upon clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR). Alpharma was acquired by King Pharmaceuticals in December 2008 and, as a result, the rights and obligations of the agreement are now controlled by King.

**Second and third ORADUR-Opioid Drug Candidates under Pain Therapeutics/King alliance** We also have two other ORADUR-based drug candidates for which Phase I clinical trials have been completed. According to Pain Therapeutics, the data from these Phase I trials indicate that these drug candidates are safe and well-tolerated with a release profile that appears well suited to use with a chronic pain population. The active ingredients in these two drug candidates are opioids whose identities have not been publicly disclosed.

We are currently in the clinical, preclinical or research stages with respect to all our other pharmaceutical systems under development. We plan to continue extensive and costly tests, clinical trials and safety studies in animals to assess the safety and effectiveness of our pharmaceutical systems. These studies include laboratory performance studies and safety testing, clinical trials and animal toxicological studies necessary to support regulatory approval of development products in the United States and other countries of the world. These studies are costly, complex and last for long durations, and may not yield the data required for regulatory approval. We and our collaborators may not be permitted to begin or continue our planned clinical trials for our potential pharmaceutical systems. If our trials are permitted, our potential pharmaceutical systems

## Edgar Filing: DURECT CORP - Form S-3/A

may not prove to be safe or produce their intended effects. In addition, we or our collaborators may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our pharmaceutical systems which we have not planned or anticipated. For example, according to Pain Therapeutics, the FDA has indicated that additional non-clinical data will be required prior to regulatory approval for Remoxy. This additional data could delay commercialization of such pharmaceutical systems and harm our business and financial condition.

---

**Table of Contents**

The length of clinical trials will depend upon, among other factors, the rate of trial site and patient enrollment and the number of patients required to be enrolled in such studies. We or our third-party collaborators may fail to obtain adequate levels of patient enrollment in our clinical trials. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials, which could have a material adverse effect on us. In addition, even if we or our third-party collaborators enroll the number of patients we expect in the time frame we expect, such clinical trials may not provide the data necessary to support regulatory approval for the pharmaceutical systems for which they were conducted. Additionally, we or our third-party collaborators may fail to effectively oversee and monitor these clinical trials, which would result in increased costs or delays of our clinical trials. Even if these clinical trials are completed, we or our third-party collaborators may fail to complete and submit a new drug application as scheduled. The Food and Drug Administration (FDA) may not clear any such application in a timely manner or may deny the application entirely. Data already obtained from preclinical studies and clinical trials of our pharmaceutical systems do not necessarily predict the results that will be obtained from later preclinical studies and clinical trials. Moreover, preclinical and clinical data such as ours are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a pharmaceutical system under development could delay or prevent regulatory clearance of the potential pharmaceutical system, resulting in delays to the commercialization of our pharmaceutical system, and could materially harm our business. Clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our pharmaceutical systems, and thus our pharmaceutical systems may not be approved for marketing.

*Regulatory action or failure to obtain product approvals could delay or limit development and commercialization of our pharmaceutical systems and result in failure to achieve anticipated revenues*

The manufacture and marketing of our pharmaceutical systems and our research and development activities are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. We or our third-party collaborators must obtain clearance or approval from applicable regulatory authorities before we or they, as applicable, can perform clinical trials, market or sell our development products in the United States or abroad. Clinical trials, manufacturing and marketing of products are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. In particular, recent recalls of and reported adverse side effects of marketed drugs have made regulatory agencies, including the FDA, increasingly focus on the safety of drug products. Regulatory agencies are requiring more extensive and ever increasing showings of safety at every stage of drug development and commercialization from initial clinical trials to regulatory approval and beyond. These rigorous and evolving standards may delay and increase the expenses of our development efforts. The FDA or other foreign regulatory agency may, at any time, halt our and our collaborators' development and commercialization activities due to safety concerns, in which case our business will be harmed. In addition, the FDA or other foreign regulatory agency may refuse or delay approval of our or our collaborators' drug candidates for failure to collect sufficient clinical or animal safety data, and require us or our collaborators to conduct additional clinical or animal safety data which may cause lengthy delays and increased costs to our programs. For example, Pain Therapeutics has announced that the FDA indicated that additional non-clinical data will be required to support the approval of Remoxy.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. These laws and regulations are complex and subject to change. Furthermore, these laws and regulations may be subject to varying interpretations, and we may not be able to predict how an applicable regulatory body or agency may choose to interpret or apply any law or regulation to our pharmaceutical systems. As a result, clinical trials and regulatory approval can take a number of years to accomplish and require the expenditure of substantial resources. We or our third-party collaborators, as applicable, may encounter delays or rejections based upon administrative action or interpretations of current rules and regulations. We or our third-party collaborators, as applicable, may not be able to timely reach agreement with the FDA on our clinical trials or on the required clinical or animal data we or they must collect to continue with our clinical trials or eventually commercialize our pharmaceutical systems.

We or our third-party collaborators, as applicable, may also encounter delays or rejections based upon additional government regulation from future legislation, administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We or our third-party collaborators, as applicable, may encounter similar delays in foreign countries. Sales of our pharmaceutical systems outside the United States are subject to foreign

**Table of Contents**

regulatory standards that vary from country to country. The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We or our third-party collaborators, as applicable, may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the clinical uses that we specify. If we or our third-party collaborators, as applicable, fail to obtain timely clearance or approval for our development products, we or they will not be able to market and sell our pharmaceutical systems, which will limit our ability to generate revenue.

*Many of our drug candidates under development including Remoxy and TRANSDUR-Sufentanil are subject to mandatory Risk Evaluation and Mitigation Strategy (REMS) programs, a new requirement by the FDA, which could delay the approval of these drug candidates and increase the cost, burden and liability associated with the commercialization of these drug candidates*

On February 6, 2009, the Food and Drug Administration (FDA) sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The FDA has authority to require a REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) when necessary to ensure that the benefits of a drug outweigh the risks.

According to the FDA, opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients. Opioid drugs have serious risks when used improperly. The FDA, drug manufacturers, and others have taken a number of steps in the past to prevent misuse, abuse and accidental overdose of these drugs, including providing additional warnings in product labeling, implementing risk management plans, conducting inter-agency collaborations, and issuing direct communications to both prescribers and patients. Despite these efforts, the rates of misuse and abuse, and of accidental overdose of opioids, have risen over the past decade. The FDA believes that establishing a REMS for opioids will reduce these risks, while still ensuring that patients with legitimate need for these drugs will continue to have appropriate access.

According to the FDA, it recognizes the need to achieve balance between appropriate access and risk mitigation, and believes an effective strategy would benefit from input from industry, patient advocacy groups, the pain and addiction treatment communities, the general public, and other stakeholders. In the first of a series of meetings with stakeholders, the FDA invited those companies that market the affected opioid drugs to a meeting with the agency on March 3, 2009 to discuss REMS development. Additional steps will include discussions with other federal agencies and non-government institutions, including patient and consumer advocates, representatives of the pain and addiction treatment communities, other health care professionals, and other interested parties. FDA is planning a public meeting in late spring or early summer to allow for broader public input and participation. Through this process, FDA hopes to gain valuable information that will lead to practical and effective solutions for development of a REMS and for appropriate use of these opioid drug products.

Many of our drug candidates including Remoxy, our other ORADUR-opioid drug candidates and TRANSDUR-Sufentanil are subject to the REMS requirement. Until the contours of required REMS programs are established by the FDA and understood by drug developers and marketers such as ourselves and our collaborators, there may be delays in marketing approvals for these drug candidates. In addition, there may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of drug candidates subject to the REMS requirement, which could negatively impact the commercial benefits to us and our collaborators from the sale of these drug candidates.

*We depend to a large extent on third-party collaborators, and we have limited or no control over the development, sales, distribution and disclosure for our pharmaceutical systems which are the subject of third-party collaborative or license agreements*

Our performance depends to a large extent on the ability of our third-party collaborators to successfully develop and obtain approvals for our pharmaceutical systems. We have entered into an agreement with Endo related to the development, promotion and distribution of TRANSDUR-Sufentanil in the United States and Canada, which agreement will terminate effective August 26, 2009. In addition, we have entered into agreements with Pain Therapeutics, Nycomed, Alharma (acquired by King in December 2008) and Voyager under which we granted such third parties the right to develop, apply for regulatory approval for, market, promote or distribute Remoxy and other ORADUR-based products incorporating specified opioids, POSIDUR, ELADUR and Memryte, respectively, subject to payments to us in the form of product royalties and other payments. We have limited or no control over the expertise or resources that any collaborator may devote to the development, clinical trial strategy, regulatory approval, marketing or sale of these pharmaceutical systems, or the timing of

---

**Table of Contents**

their activities. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. They may also conduct their activities in a manner that is different from the manner we would have chosen, had we been developing such pharmaceutical systems ourselves. Further, our collaborators may elect not to develop or commercialize pharmaceutical systems arising out of our collaborative arrangements or not devote sufficient resources to the development, clinical trials, regulatory approval, manufacture, marketing or sale of these pharmaceutical systems. If any of these events occur, we may not recognize revenue from the commercialization of our pharmaceutical systems based on such collaborations. In addition, these third parties may have similar or competitive products to the ones which are the subject of their collaborations with us, or relationships with our competitors, which may reduce their interest in developing or selling our pharmaceutical systems. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

*Our near-term revenues depend on collaboration agreements with other companies. These agreements subject us to obligations which must be fulfilled and also make our revenues dependent on the performance of such third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements or enter into additional collaboration agreements or if our existing collaborations are terminated, our revenues may decrease*

Our near-term revenues are based to a significant extent on collaborative arrangements with third parties, pursuant to which we receive payments based on our performance of research and development activities set forth in the agreements. We may not be able to fulfill our obligations or attain milestones set forth in any specific agreement, which could cause our revenues to fluctuate or be less than anticipated and may expose us to liability for contractual breach. In addition, these agreements may require us to devote significant time and resources to communicating with and managing our relationships with such collaborators and resolving possible issues of contractual interpretation which may detract from time our management would otherwise devote to managing our operations. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations. Such disputes can delay or prevent the development of potential new pharmaceutical systems, or can lead to lengthy, expensive litigation or arbitration. In general, our collaboration agreements, including our agreements with Endo with respect to TRANSDUR-Sufentanil (which will terminate effective August 26, 2009), Pain Therapeutics with respect to Remoxy and other ORADUR-based products incorporating specified opioids, Nycomed with respect to POSIDUR, Alpharma (acquired by King) with respect to ELADUR, and Voyager with respect to Memryte, may be terminated by the other party at will or upon specified conditions including, for example, if we fail to satisfy specified performance milestones or if we breach the terms of the agreement.

If any of our collaborative agreements are terminated, our revenues may be reduced or not materialize, and our development products related to those agreements may not be commercialized.

*Our near-term revenues also depend on milestone payments based on achievements by our third-party collaborators. Failure of such collaborators to attain such milestones would result in our not receiving additional revenues.*

In addition to payments based on our performance of research and development activities, our revenues also depend on the attainment of milestones set forth in our collaboration agreements. Such milestones are typically related to clinical trial developments, regulatory approvals or sales accomplishments. To the extent third-party collaborators do not achieve such milestones, we will not receive the associated revenues, which could harm our financial condition and may cause us to defer or cut-back development activities or forego the exploitation of opportunities in certain geographic territories, any of which could have a material adverse effect on our business.

*Our business strategy includes the entry into additional collaborative agreements. We may not be able to enter into additional collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements*

Our current business strategy includes the entry into additional collaborative agreements for the development and commercialization of our pharmaceutical systems. The negotiation and consummation of these type of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development, legal, and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well the collaborators' own internal product opportunities. We may not be able to consummate additional collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements. If we do not consummate additional collaborative agreements, we may have to consume money more rapidly on our product development efforts, defer development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business.





**Table of Contents**

*We may have difficulty raising needed capital in the future*

Our business currently does not generate sufficient revenues to meet our capital requirements and we do not expect that it will do so in the near future. We have expended and will continue to expend substantial funds to complete the research, development and clinical testing of our pharmaceutical systems. We will require additional funds for these purposes, to establish additional clinical- and commercial-scale manufacturing arrangements and facilities and to provide for the marketing and distribution of our pharmaceutical systems. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially harm our business, financial condition and results of operations.

We believe that our cash, cash equivalents and investments, will be adequate to satisfy our capital needs for at least the next 12 months. However, our actual capital requirements will depend on many factors, including:

continued progress and cost of our research and development programs;

the continuation of our collaborative agreements that provide financial funding for our activities;

success in entering into collaboration agreements and meeting milestones under such agreements;

progress with preclinical studies and clinical trials;

the time and costs involved in obtaining regulatory clearance;

costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

costs of developing sales, marketing and distribution channels and our ability and that of our collaborators to sell our pharmaceutical systems;

costs involved in establishing manufacturing capabilities for clinical and commercial quantities of our pharmaceutical systems;

competing technological and market developments;

market acceptance of our pharmaceutical systems;

costs for recruiting and retaining employees and consultants; and

unexpected legal, accounting and other costs and liabilities related to our business.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through equity or debt financings, convertible debt financings, collaborative arrangements with corporate

collaborators or other sources, which may be dilutive to existing stockholders and may cause the price of our common stock to decline. In addition, in the event that additional funds are obtained through arrangements with collaborators or other sources, we may have to relinquish rights to some of our technologies or pharmaceutical systems that we would otherwise seek to develop or commercialize ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs, and reduced revenues.

*We and our third-party collaborators may not be able to manufacture sufficient quantities of our pharmaceutical systems and components to support the clinical and commercial requirements of our collaborators and ourselves at an acceptable cost or in compliance with applicable government regulations, and we have limited manufacturing experience*

We or our third-party collaborators to whom we have assigned such responsibility must manufacture our pharmaceutical systems and components in clinical and commercial quantities, either directly or through third parties, in compliance with regulatory requirements and at an acceptable cost. The manufacturing processes associated with our pharmaceutical systems are complex. Except with respect to Remoxy, we and our third-party collaborators, where relevant, have not yet completed development of the manufacturing process for any pharmaceutical systems or components including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Memryte, and other ORADUR-based drug candidates. If we and our third-party collaborators, where relevant, fail to timely complete the development of the manufacturing process for our pharmaceutical systems, we and our third-party collaborators, where relevant, will not be able to timely produce product for clinical trials and commercialization of our pharmaceutical systems. We have also committed to manufacture and supply

---

## Table of Contents

pharmaceutical systems or components under a number of our collaborative agreements with third-party companies. We have limited experience manufacturing pharmaceutical products, and we may not be able to timely accomplish these tasks. If we and our third-party collaborators, where relevant, fail to develop manufacturing processes to permit us to manufacture a pharmaceutical system or component at an acceptable cost, then we and our third-party collaborators may not be able to commercialize that pharmaceutical system or we may be in breach of our supply obligations to our third-party collaborators.

Our manufacturing facility in Cupertino is a multi-disciplinary site that we have used to manufacture only research and clinical supplies of several of our pharmaceutical systems under good manufacturing practices (GMP), including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and additional ORADUR-based drug candidates, and Memryte. We have not manufactured commercial quantities of any of our pharmaceutical systems. In the future, we intend to develop additional manufacturing capabilities for our pharmaceutical systems and components to meet our demands and those of our third-party collaborators by contracting with third-party manufacturers and by construction of additional manufacturing space at our current facilities in Cupertino, CA, Vacaville, CA and Pelham, AL. We have limited experience building and validating manufacturing facilities, and we may not be able to accomplish these tasks in a timely manner.

If we and our third-party collaborators, where relevant, are unable to manufacture pharmaceutical systems or components in a timely manner or at an acceptable cost, quality or performance level, and attain and maintain compliance with applicable regulations, the clinical trials and the commercial sale of our pharmaceutical systems and those of our third-party collaborators could be delayed. Additionally, we may need to alter our facility design or manufacturing processes, install additional equipment or do additional construction or testing in order to meet regulatory requirements, optimize the production process, increase efficiencies or production capacity or for other reasons, which may result in additional cost to us or delay production of product needed for the clinical trials and commercial launch of our pharmaceutical systems and those of our third-party collaborators.

We have entered into a supply agreement with Corium International, Inc. for clinical and commercial supplies of ELADUR and a supply agreement with Hospira Worldwide, Inc. for clinical and commercial supplies of POSIDUR. These third parties are currently our sole source for drug product required for development and commercialization of these drug candidates. Furthermore, we and our third-party collaborators, where relevant, may also need or choose to subcontract with additional third-party contractors to perform manufacturing steps of our pharmaceutical systems or supply required components for our pharmaceutical systems. Where third party contractors perform manufacturing services for us, we will be subject to the schedule, expertise and performance of third parties as well as incur significant additional costs. Failure of third parties to perform their obligations could adversely our operations, development timeline and financial results. Under our development and commercialization agreement with ALZA, we cannot subcontract the manufacture of subassemblies of the DUROS system components of our DUROS-based pharmaceutical systems to third parties which have not been approved by ALZA.

If we or our third-party collaborators cannot manufacture pharmaceutical systems or components in time to meet the clinical or commercial requirements of our collaborators or ourselves or at an acceptable cost, our operating results will be harmed.

*Failure to comply with ongoing governmental regulations for our pharmaceutical systems could materially harm our business in the future*

Marketing or promoting a drug is subject to very strict controls. Furthermore, clearance or approval may entail ongoing requirements for post-marketing studies. The manufacture and marketing of drugs are subject to continuing FDA and foreign regulatory review and requirements that we update our regulatory filings. Later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing full commercial use of our pharmaceutical systems, which in turn would materially harm our business, financial condition and results of operations:

failure to obtain or maintain requisite governmental approvals;

failure to obtain approvals for clinically intended uses of our pharmaceutical systems under development; or

FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our pharmaceutical systems.

## Edgar Filing: DURECT CORP - Form S-3/A

Manufacturers of drugs must comply with the applicable FDA good manufacturing practice regulations, which include production design controls, testing, quality control and quality assurance requirements as well as the corresponding

---

**Table of Contents**

maintenance of records and documentation. Compliance with current good manufacturing practices regulations is difficult and costly. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they can be used for the commercial manufacture of our development products. We and/or our present or future suppliers and distributors may be unable to comply with the applicable good manufacturing practice regulations and other FDA regulatory requirements. We have not been subject to a good manufacturing regulation inspection by the FDA relating to our pharmaceutical systems. If we, our third-party collaborators or our respective suppliers do not achieve compliance for our pharmaceutical systems we or they manufacture, the FDA may refuse or withdraw marketing clearance or require product recall, which may cause interruptions or delays in the manufacture and sale of our pharmaceutical systems.

*We have a history of operating losses, expect to continue to have losses in the future and may never achieve or maintain profitability*

We have incurred significant operating losses since our inception in 1998 and, as of December 31, 2008, had an accumulated deficit of approximately \$283.6 million. We expect to continue to incur significant operating losses over the next several years as we continue to incur significant costs for research and development, clinical trials, manufacturing, sales, and general and administrative functions. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of our proposed pharmaceutical systems, obtain the required regulatory clearances, and manufacture and market our proposed pharmaceutical systems. Development of pharmaceutical systems is costly and requires significant investment. In addition, we may choose to license from third parties either additional drug delivery platform technology or rights to particular drugs or other appropriate technology for use in our pharmaceutical systems. The license fees for these technologies or rights would increase the costs of our pharmaceutical systems.

To date, we have not generated significant revenue from the commercial sale of our pharmaceutical systems and do not expect to do so in the near future. Our current product revenues are from the sale of the ALZET product line and the sale of LACTEL biodegradable polymers, and from payments under collaborative research and development agreements with third parties. We do not expect our product revenues to increase significantly in the near future, and we do not expect that collaborative research and development revenues will exceed our actual operating expenses. We do not anticipate meaningful revenues to derive from the commercialization and marketing of our pharmaceutical systems in development in the near future, and therefore do not expect to generate sufficient revenues to cover expenses or achieve profitability in the near future.

*We may develop our own sales force to market POSIDUR but we have limited sales experience and may not be able to do so effectively*

We may choose to develop our own sales force to market POSIDUR in the United States if POSIDUR is approved for marketing by the FDA. Developing a sales force will require substantial expenditures. DURECT has limited sales and marketing experience, and may not be able to effectively recruit, train or retain sales personnel. We may not be able to effectively sell our pharmaceutical systems, if approved, and our failure to do so could limit or materially harm our business.

*We and our third-party collaborators may not sell our pharmaceutical systems effectively*

We and our third-party collaborators compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts and those of our third-party collaborations may be unable to compete successfully against these other companies. We and our third-party collaborators, if relevant, may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all. We and our third-party collaborators, if relevant, may be unable to engage qualified distributors. Even if engaged, these distributors may:

fail to satisfy financial or contractual obligations to us;

fail to adequately market our pharmaceutical systems;

cease operations with little or no notice to us;

offer, design, manufacture or promote competing product lines;

fail to maintain adequate inventory and thereby restrict use of our pharmaceutical systems; or

build up inventory in excess of demand thereby limiting future purchases of our pharmaceutical systems resulting in significant quarter-to-quarter variability in our sales.

---

## **Table of Contents**

The failure of us or our third-party collaborators to effectively develop, gain regulatory approval for, sell, manufacture and market our pharmaceutical systems will hurt our business and financial results.

*We rely heavily on third parties to support development, clinical testing and manufacturing of our pharmaceutical systems*

We rely on third-party contract research organizations, service providers and suppliers to provide critical services to support development, clinical testing, and manufacturing of our pharmaceutical systems. For example, we currently depend on third-party vendors to manage and monitor our clinical trials and to perform critical manufacturing steps for our pharmaceutical systems. These third parties may not execute their responsibilities and tasks competently or in a timely fashion. We rely on third-parties to manufacture or perform manufacturing steps relating to our pharmaceutical systems or components. We anticipate that we will continue to rely on these and other third-party contractors to support development, clinical testing, and manufacturing of our pharmaceutical systems. Failure of these contractors to provide the required services in a competent or timely manner or on reasonable commercial terms could materially delay the development and approval of our development products, increase our expenses and materially harm our business, financial condition and results of operations.

*Key components of our pharmaceutical systems are provided by limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs*

Certain components and drug substances used in our pharmaceutical systems (including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and our additional ORADUR-based drug candidates, and Memryte) are currently purchased from a single or a limited number of outside sources. In particular, Eastman Chemicals is the sole supplier, pursuant to a supply agreement entered into in December 2005, of our requirements of sucrose acetate isobutyrate, a necessary component of POSIDUR, Remoxy, our additional ORADUR-opioids and certain other pharmaceuticals systems we have under development. The reliance on a sole or limited number of suppliers could result in:

delays associated with redesigning a pharmaceutical system due to a failure to obtain a single source component;

an inability to obtain an adequate supply of required components; and

reduced control over pricing, quality and delivery time.

We have supply agreements in place for certain components of our pharmaceuticals systems, but do not have in place long term supply agreements with respect to all of the components of any of our pharmaceutical system candidates. Therefore the supply of a particular component could be terminated at any time without penalty to the supplier. In addition, we may not be able to procure required components or drugs from third-party suppliers at a quantity, quality and cost acceptable to us. Any interruption in the supply of single source components could cause us to seek alternative sources of supply or manufacture these components internally. Furthermore, in some cases, we are relying on our third-party collaborators to procure supply of necessary components. If the supply of any components for our pharmaceutical systems is interrupted, components from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels within required timeframes, if at all, to meet our needs or those of our third-party collaborators. This could delay our ability to complete clinical trials and obtain approval for commercialization and marketing of our pharmaceutical systems, causing us to lose sales, incur additional costs, delay new product introductions and could harm our reputation.

*If we are unable to adequately protect or enforce our intellectual property rights or secure rights to third-party patents, we may lose valuable assets, experience reduced market share or incur costly litigation to protect our rights or our third-party collaborators may choose to terminate their agreements with us*

Our success will depend in part on our ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of others. As of February 27, 2009, we held 55 issued U.S. patents and 356 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 99 pending U.S. patent applications and have filed 107 patent applications under the Patent Cooperation Treaty, from which 549 national phase applications are currently pending in Europe, Australia, Japan, Canada and other countries. Our patents expire at various dates starting in the year 2012.

Under our agreement with ALZA, we must assign to ALZA any intellectual property rights relating to the DUROS system and its manufacture and any combination of the DUROS system with other components, active agents, features or processes. In addition, ALZA retains the right to

enforce and defend against infringement actions relating to the DUROS system, and if ALZA exercises these rights, it will be entitled to the proceeds of these infringement actions.



---

## Table of Contents

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications or those that are licensed to us may not issue into patents, and any issued patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

The patent laws of the U.S. have recently undergone changes through court decisions which may have significant impact on us and our industry. The recent decisions of the U.S. Supreme Court (e.g., *KSR v. Teleflex*, *EBay v. MercExchange*) and other courts (e.g., *In re Seagate*) with respect to the standards of patentability, enforceability, availability of injunctive relief and damages may make it more difficult for us to procure, maintain and enforce patents. In addition, bills are pending before the U.S. Congress including the Patent Reform Act of 2007 that may fundamentally change the patent laws of the U.S. on issues ranging from priority entitlement, filing and prosecution matters to enforcement and damages. These changes and proposed reforms have introduced significant uncertainty in the patent law landscape and may potentially negatively impact our ability to procure, maintain and enforce patents to provide exclusivity for our products.

We are party to several collaborative agreements. Our third-party collaborators have entered into these agreements based on the exclusivity that our intellectual property rights confer on the products being developed. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration requiring us to devote management time and resources to such dispute which we would otherwise spend on our business. To the extent that our agreements call for future royalties to be paid conditional on our having patents covering the royalty-bearing subject matter, the decision by the Supreme Court in the case of *MedImmune, Inc. v. Genentech, Inc.* could encourage our licensees to challenge the validity of our patents and thereby seek to avoid future royalty obligations without losing the benefit of their license. Should they be successful in such a challenge, our ability to collect future royalties could be substantially diminished.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference proceedings declared by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

*We may be sued by third parties which claim that our pharmaceutical systems infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents*

We and our collaborators may be exposed to future litigation by third parties based on claims that our pharmaceutical systems or activities infringe the intellectual property rights of others or that we or our collaborators have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us or our collaborators, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. We also may not have sufficient funds to litigate against parties with substantially greater resources. In addition, pursuant to our collaborative agreements, we have provided our collaborators with the right, under specified circumstances, to defend against any claims of infringement of the third party intellectual property rights, and such collaborators may not defend against such claims adequately or in the manner that we would do ourselves. Intellectual property litigation or claims could force us or our collaborators to do one or more of the following, any of which could harm our business or financial results:

## Edgar Filing: DURECT CORP - Form S-3/A

cease selling, incorporating or using any of our pharmaceutical systems that incorporate the challenged intellectual property, which would adversely affect our revenue;

---

**Table of Contents**

obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or

redesign our pharmaceutical systems, which would be costly and time-consuming.

*We may be required to obtain rights to certain drugs*

Some of the pharmaceutical systems that we may choose to develop may include proprietary drugs to which we do not have commercial rights. To complete the development and commercialization of pharmaceutical systems containing drugs to which we do not have commercial rights, we will be required to obtain rights to those drugs. We may not be able to do this at an acceptable cost, if at all. If we are not able to obtain required rights to commercialize certain drugs, we may not be able to complete the development of pharmaceutical systems which require use of those drugs. This could result in the cessation of certain development projects and the potential write-off of certain assets.

*Technologies and businesses which we have acquired may be difficult to integrate, disrupt our business, dilute stockholder value or divert management attention. We may also acquire additional businesses or technologies in the future, which could have these same effects*

We may acquire technologies, products or businesses to broaden the scope of our existing and planned product lines and technologies. Future acquisitions expose us to:

increased costs associated with the acquisition and operation of the new businesses or technologies and the management of geographically dispersed operations;

the risks associated with the assimilation of new technologies, operations, sites and personnel;

the diversion of resources from our existing business and technologies;

the inability to generate revenues to offset associated acquisition costs;

the requirement to maintain uniform standards, controls, and procedures; and

the impairment of relationships with employees and customers or third party collaborators as a result of any integration of new management personnel.

Acquisitions may also result in the issuance of dilutive equity securities, the incurrence or assumption of debt or additional expenses associated with the amortization of acquired intangible assets or potential businesses. Past acquisitions, such as our acquisitions of IntraEAR, ALZET, SBS and APT, as well as future acquisitions, may not generate any additional revenue or provide any benefit to our business.

*Some of our pharmaceutical systems contain controlled substances, the making, use, sale, importation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies*

Some of our pharmaceutical systems currently under development contain, and our products in the future may contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation and distribution. The TRANSDUR-Sufentanil patch, Remoxy and our additional ORADUR-based drug candidates, and other pharmaceutical systems we have under development contain active ingredients which are classified as controlled substances under the regulations of the U.S. Drug Enforcement Agency. For our pharmaceutical systems containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation and distribution of controlled substances. These regulations are extensive and include regulations governing manufacturing, labeling, packaging, testing, dispensing,

## Edgar Filing: DURECT CORP - Form S-3/A

production and procurement quotas, record keeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of drug candidates including controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our pharmaceutical systems containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our pharmaceutical systems containing controlled substances.

---

**Table of Contents**

*Write-offs related to the impairment of long-lived assets and other non-cash charges, as well as stock-based compensation expenses may adversely impact or delay our profitability*

We may incur significant non-cash charges related to impairment write-downs of our long-lived assets, including goodwill and other intangible assets. We will continue to incur non-cash charges related to amortization of other intangible assets. For example, we had a \$13.5 million non-cash write down of deferred royalties and commercial rights related to CHRONOGESIC in the fourth quarter of 2008, which impacted our financial statements. We are required to perform periodic impairment reviews of our goodwill at least annually. To the extent these reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the cost of our long-lived assets, we will be required to measure and record an impairment charge to write down these assets to their realizable values. We completed our last review during the fourth quarter of 2008 and determined that goodwill was not impaired as of December 31, 2008. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it will adversely impact or delay our profitability.

In December 2004, the FASB issued Statement No. 123 (revised 2004, or SFAS 123(R), *Share-Based Payment*, which was originally effective for annual or interim periods beginning after June 15, 2005. SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock purchase plans. We adopted SFAS 123(R) using the modified prospective basis on January 1, 2006. Our adoption of SFAS 123(R) has and will continue to have a material adverse impact on our results of operations and will adversely impact or delay our profitability.

*Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents or short-term investments and our ability to meet our financing objectives.*

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days and less than one year at the time of purchase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments since December 31, 2008, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or short-term investments or our ability to meet our financing objectives.

*We depend upon key personnel who may terminate their employment with us at any time, and we need to hire additional qualified personnel*

Our success will depend to a significant degree upon the continued services of key management, technical and scientific personnel, including Felix Theeuwes, our Chairman and Chief Scientific Officer and James E. Brown, our President and Chief Executive Officer. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to product development or approval, loss of sales and diversion of management resources.

*We may not successfully manage our company through varying business cycles*

Our success will depend on properly sizing our company through growth and contraction cycles caused in part by changing business conditions, which places a significant strain on our management and on our administrative, operational and financial resources. To manage through such cycles, we must expand or contract our facilities, our operational, financial and management systems and our personnel. If we were unable to manage growth and contractions effectively our business would be harmed.

*Our business involves environmental risks and risks related to handling regulated substances*

In connection with our research and development activities and our manufacture of materials and pharmaceutical systems, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and

**Table of Contents**

wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the use, generation and disposal of hazardous materials, including but not limited to certain hazardous chemicals, solvents, agents and biohazardous materials. The extent of our use, generation and disposal of such substances has increased substantially since we started manufacturing and selling biodegradable polymers. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances generated by us, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

*Our corporate headquarters, manufacturing facilities and personnel are located in a geographical area that is seismically active*

Our corporate headquarters, primary manufacturing facilities and personnel are located in a geographical area that is known to be seismically active and prone to earthquakes. Should such a natural disaster occur, our ability to conduct our business could be severely restricted, and our business and assets, including the results of our research, development and manufacturing efforts, could be destroyed.

**Risks Related To Our Industry**

*The market for our pharmaceutical systems is rapidly changing and competitive, and new products or technologies developed by others could impair our ability to grow our business and remain competitive*

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our pharmaceutical systems under development or technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

We may face competition from other companies in numerous industries including pharmaceuticals, medical devices and drug delivery. POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and other ORADUR-based opioids, and Memryte, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, and implantable and external infusion pumps which can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Purdue Pharma, King, Knoll, Janssen, Medtronic, Endo Pharmaceuticals, AstraZeneca, Arrow International, Tricumed, I Flow and others. Numerous companies are applying significant resources and expertise to the problems of drug delivery and several of these are focusing or may focus on delivery of drugs to the intended site of action, including Alkermes, Pacira Pharmaceuticals, EpiCept, Innocoll, Inovio, Nektar, Focal, I-Flow, Anesiva, NeurogesX, Alexza, Cadence Pharmaceuticals, Javelin Pharmaceuticals and others. Some of these competitors may be addressing the same therapeutic areas or indications as we are. Our current and potential competitors may succeed in obtaining patent protection or commercializing products before us. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources.

We are engaged in the development of novel therapeutic technologies. Our resources are limited and we may experience technical challenges inherent in such novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our pharmaceutical systems. Our competitors may develop products that are safer, more effective or less costly than our pharmaceutical systems and, therefore, present a serious competitive threat to our product offerings.

---

## **Table of Contents**

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our pharmaceutical systems even if commercialized. Chronic and post-operative pain are currently being treated by oral medication, transdermal drug delivery systems, such as drug patches, and implantable drug delivery devices which will be competitive with our pharmaceutical systems. These treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our pharmaceutical systems to receive widespread acceptance if commercialized.

*We could be exposed to significant product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage*

The testing, manufacture, marketing and sale of our pharmaceutical systems involve an inherent risk that product liability claims will be asserted against us. Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our pharmaceutical systems, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our pharmaceutical systems, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our pharmaceutical systems. A product liability claim could also significantly harm our reputation and delay market acceptance of our pharmaceutical systems.

*Acceptance of our pharmaceutical systems in the marketplace is uncertain, and failure to achieve market acceptance will delay our ability to generate or grow revenues*

Our future financial performance will depend upon the successful introduction and customer acceptance of our future products, including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and other ORADUR-based drug candidates, and Memryte. Even if approved for marketing, our pharmaceutical systems may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

the receipt of regulatory clearance of marketing claims for the uses that we are developing;

the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products, including oral medication, transdermal drug delivery products such as drug patches, or external or implantable drug delivery products; and

pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products. If we are unable to obtain regulatory approval, commercialize and market our future products when planned and achieve market acceptance, we will not achieve anticipated revenues.

*If users of our products are unable to obtain adequate reimbursement from third-party payors, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues*

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and third-party collaborators and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care, and the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

## Edgar Filing: DURECT CORP - Form S-3/A

The successful commercialization of our pharmaceutical systems will depend in part on the extent to which appropriate reimbursement levels for the cost of our pharmaceutical systems and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly limiting



## **Table of Contents**

payments or reimbursement for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may limit reimbursement or payment for our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

*If we or our third-party collaborators are unable to train physicians to use our pharmaceutical systems to treat patients' diseases or medical conditions, we may incur delays in market acceptance of our products*

Broad use of our pharmaceutical systems will require extensive training of numerous physicians on the proper and safe use of our pharmaceutical systems. The time required to begin and complete training of physicians could delay introduction of our products and adversely affect market acceptance of our products. We or third parties selling our pharmaceutical systems may be unable to rapidly train physicians in numbers sufficient to generate adequate demand for our pharmaceutical systems. Any delay in training would materially delay the demand for our pharmaceutical systems and harm our business and financial results. In addition, we may expend significant funds towards such training before any orders are placed for our products, which would increase our expenses and harm our financial results.

*Potential new accounting pronouncements and legislative actions are likely to impact our future financial position or results of operations*

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, PCAOB pronouncements and NASDAQ Global Market rules, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

## **Risks Related To Our Common Stock**

*Our operating history makes evaluating our stock difficult*

Our quarterly and annual results of operations have historically fluctuated and we expect will continue to fluctuate for the foreseeable future. We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies with no approved pharmaceutical products, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery and biotechnology. To address these risks, we must, among other things, obtain regulatory approval for and commercialize our pharmaceutical systems, which may not occur. We may not be successful in addressing these risks and difficulties. We may require additional funds to complete the development of our pharmaceutical systems and to fund operating losses to be incurred in the next several years.

*Investors may experience substantial dilution of their investment*

Investors may experience dilution of their investment if we raise capital through the sale of additional equity securities or convertible debt securities or grant additional stock options to employees and consultants. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices for our common stock.

*The price of our common stock may be volatile*

The stock markets in general, and the markets for pharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

**Table of Contents**

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

failure of our third-party collaborators (such as Endo, Pain Therapeutics or its commercialization sublicensee King Pharmaceuticals, Nycomed, Alpharma (now owned by King) or Voyager) to develop and commercialize successfully the respective pharmaceutical systems they are developing;

adverse results (including adverse events) or delays in our clinical and non-clinical trials of POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy, our additional ORADUR-based drug candidates, Memryte or other pharmaceutical systems;

announcements of FDA non-approval of our pharmaceutical systems, or delays in the FDA or other foreign regulatory agency review process;

adverse actions taken by regulatory agencies with respect to our pharmaceutical systems, clinical trials, manufacturing processes or sales and marketing activities, or those of our third party collaborators;

announcements of technological innovations, patents or new products by our competitors;

regulatory developments in the United States and foreign countries;

any lawsuit involving us or our pharmaceutical systems including intellectual property infringement or product liability suits;

announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;

developments concerning our strategic alliances or acquisitions;

actual or anticipated variations in our operating results;

changes in recommendations by securities analysts or lack of analyst coverage;

deviations in our operating results from the estimates of analysts;

sales of our common stock by our executive officers or directors or sales of substantial amounts of common stock by others;

changes in accounting principles; and

## Edgar Filing: DURECT CORP - Form S-3/A

loss of any of our key scientific or management personnel.

The market price of our common stock may fluctuate significantly in response to factors which are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of technology and pharmaceutical companies have also been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management's attention and our company's resources.

*We have broad discretion over the use of our cash and investments, and their investment may not always yield a favorable return*

Our management has broad discretion over how our cash and investments are used and may from time to time invest in ways with which our stockholders may not agree and that do not yield favorable returns.

*Executive officers, directors and principal stockholders have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders*

Our directors, executive officers and principal stockholders, together with their affiliates, have substantial control over us. The interests of these stockholders may differ from the interests of other stockholders. As a result, these stockholders, if acting together, would have the ability to exercise control over all corporate actions requiring stockholder approval irrespective of how our other stockholders may vote, including:

the election of directors;

**Table of Contents**

the amendment of charter documents;

the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets; or

the defeat of any non-negotiated takeover attempt that might otherwise benefit the public stockholders.

Our certificate of incorporation, our bylaws, Delaware law and our stockholder rights plan contain provisions that could discourage another company from acquiring us.

Provisions of Delaware law, our certificate of incorporation, bylaws and stockholder rights plan may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

authorizing the issuance of blank check preferred stock without any need for action by stockholders;

providing for a dividend on our common stock, commonly referred to as a poison pill, which can be triggered after a person or group acquires 17.5% or more of common stock;

providing for a classified board of directors with staggered terms;

requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;

eliminating the ability of stockholders to call special meetings of stockholders;

**Table of Contents**

prohibiting stockholder action by written consent; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

prohibiting stockholder action by written consent; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

**CAUTIONARY NOTE REGARDING FORWARD LOOKING INFORMATION**

All statements included or incorporated by reference in this prospectus, other than statements of historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward looking statements. Such statements are typically characterized by terminology such as believe, anticipate, should, intend, plan, will, expect, estimate, project, strategy, and similar expressions. 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 progress of our third-party collaborations, including estimated milestones;

the progress and results of our research and development programs;

the results and timing of clinical trials and the commencement of future clinical trials;

submission and timing of applications for regulatory approval;

the impact of FDA and other government regulation on our business;

uncertainties associated with obtaining and protecting patents and other intellectual property rights;

products and companies that will compete with the products we license to third-party collaborators;

our intention to commercialize our own products and to build up our commercial, sales and marketing capabilities and other required infrastructure in focused speciality areas; and

future performance, sufficiency of our cash resources, anticipated capital requirements and our need for additional financing.

Any such forward looking statements are not guarantees of future performance and actual results, developments and business decisions may differ from those contemplated by such forward looking statements. We disclaim any duty to update any forward looking statements. You should also carefully consider other information set forth in reports or other documents that we file with the Securities and Exchange Commission.

**RATIO OF EARNINGS TO FIXED CHARGES AND**

**RATIO OF EARNINGS TO COMBINED FIXED CHARGES AND PREFERRED DIVIDEND REQUIREMENTS**

For purposes of computing the ratio of earnings to fixed charges and the ratio of earnings to combined fixed charges and preferred dividend requirements, earnings consist of net loss plus fixed charges. Fixed charges consist of interest expense, amortization of debt expense and discount or premium related to indebtedness, whether expensed or capitalized, and that portion of rental payments under operating leases we believe to be representative of interest. Preferred dividend requirements consist of the amount required to meet dividend requirements on our preferred stock for the periods indicated, and during the periods indicated, we did not have any preferred dividend requirements. Earnings were insufficient to cover fixed charges and preferred dividend requirements for these periods. The amount of the coverage deficiency was \$43.9 million, \$24.3 million, \$33.3 million, \$18.1 million and \$27.6 million for the years ended December 31, 2008, 2007, 2006, 2005 and 2004, respectively.

**Table of Contents**

The following table sets forth the computation of our ratio of earnings to fixed charges and our ratio of earnings to combined fixed charges and preferred dividend requirements for the periods indicated:

	Year ended December 31,				
	2008	2007	2006	2005	2004
Ratio of earnings to fixed charges					
Ratio of combined fixed charges and preferred dividend requirements to earnings					

**USE OF PROCEEDS**

Unless otherwise indicated in a prospectus supplement, the net proceeds from the sale of securities offered by this prospectus will be used for general corporate purposes, including clinical trials, research and development activities, capital expenditures, facilities expansion and to meet working capital needs. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. Pending such uses, we may invest the net proceeds in investment grade interest-bearing securities.

The amounts actually expended for each purpose may vary significantly depending upon numerous factors, including the amount and timing of the proceeds from this offering and progress with the commercial development of our products as well as our clinical development programs. Expenditures will also depend upon the establishment of collaborative arrangements with other companies, the availability of additional financing and other factors. Investors will be relying on the judgment of our management regarding the application of the proceeds of any sale of securities.

**DESCRIPTION OF CAPITAL STOCK**

This section describes the general terms and provisions of the shares of our common stock, \$0.0001 par value per share, and preferred stock, \$0.0001 par value per share, that we may issue. This description is only a summary. Our certificate of incorporation and our bylaws have been filed as exhibits to our periodic reports filed with the SEC, which are incorporated by reference into this prospectus. You should read our certificate of incorporation and our bylaws for additional information before you buy any of our securities. See [Where You Can Find More Information](#).

**Common Stock**

*General.* We are authorized to issue up to 110,000,000 shares of common stock. As of February 27, 2009, there were 82,025,921 shares of common stock issued and outstanding.

*Voting Rights.* The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose.

*Dividends.* Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably dividends, if any, as may be declared by our board of directors out of funds legally available therefor. We have not declared any dividends and have no current plans to do so.

*Other Rights.* Upon our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock offered, when issued, will be, fully paid and nonassessable.

**Transfer Agent and Registrar for Common Stock**

The transfer agent and registrar for our common stock is Computershare. Its offices are located at 250 Royall Street, Canton, MA 02021, and its telephone number is (781) 575-3452.





**Table of Contents**

**Preferred Stock**

*General.* We are authorized to issue up to 10,000,000 shares of preferred stock. As of February 27, 2009, no shares of preferred stock were issued and outstanding. Our board of directors has the authority, without further action by our stockholders, to issue from time to time the preferred stock in one or more series, and to fix the number of shares, designations, preferences, powers, and other rights and qualifications, limitations or restrictions as our board of directors may authorize, including:

the distinctive designation of each series and the number of shares that will constitute the series;

the purchase price;

the voting rights, if any, of shares of the series and the terms and conditions of the voting rights;

the dividend rate on the shares of the series, the dates on which dividends are payable, any restriction, limitation or condition upon the payment of dividends, whether dividends will be cumulative, and the dates from and after which dividends shall accumulate;

the prices at which, and the terms and conditions on which, the shares of the series may be redeemed, if the shares are redeemable;

the procedures for any auction or remarketing, if any;

the terms and conditions of a sinking or purchase fund for the purchase or redemption of shares of the series, if such a fund is provided;

any preferential amount payable upon shares of the series in the event of the liquidation, dissolution or winding up of, or upon the distribution of any of our assets;

any listing of the preferred stock on any securities exchange or market;

preemption rights, if any;

restrictions on transfer, sale or other assignment, if any;

the prices or rates of conversion or exchange at which, and the terms and conditions on which, the shares of the series may be converted or exchanged into other securities, if the shares are convertible or exchangeable; and

any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

When we issue shares of preferred stock, the shares will be fully paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

## Edgar Filing: DURECT CORP - Form S-3/A

Delaware General Corporation Law ( DGCL ) provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to holders of common stock or adversely affect the rights and powers, including voting rights, of the holders of common stock. The issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company, which could depress the market price of our common stock.

*Series A Participating Preferred Stock.* Of the 10,000,000 shares of preferred stock currently authorized, we have designated 100,000 shares as series A participating preferred stock. As of February 27, 2009, no shares of series A participating preferred stock were issued and outstanding.

*Voting Rights.* The holders of our series A participating preferred stock are entitled to 1,000 votes, subject to certain adjustments, for each share held of record on all matters submitted to a vote of the stockholders. Except as otherwise provided, holders of shares of series A participating preferred stock and the holders of shares of common stock shall vote together as one class on all matters submitted to a vote of the stockholders.

*Dividends.* Subject to preferences that may be applicable to any then outstanding preferred stock, holders of series A participating preferred stock are entitled to receive ratably dividends, if any, as may be declared by our board of directors out of funds legally available therefor, to be paid on a quarterly basis in an amount per share equal to, subject to certain adjustments, 1,000 times the aggregate per share amount of all cash dividends and 1,000 times the aggregate per share amount of all non-cash dividends or other distributions other than a dividend payable in shares of common stock or a subdivision of the outstanding shares of common stock. We will not declare any dividend on, make any distribution on or

---

## **Table of Contents**

redeem or purchase or otherwise acquire for consideration any shares of common stock after the first issuance of a share or fraction of a share of series A participating preferred stock unless we concurrently declare a dividend on the series A participating preferred stock. When dividends payable to holders of series A participating preferred stock are in arrears, we will not take certain actions until such all accrued and unpaid dividends and distributions on shares of series A participating preferred stock are paid in full. We have not declared any dividends and have no plans to do so.

*Other Rights.* Upon our liquidation, dissolution or winding up, no distribution shall be made to the holders of shares ranking junior to the series A participating preferred stock unless the holders of series A participating preferred stock have received an amount equal to the accrued and unpaid dividends and distributions, whether or not declared, to the date of such payment plus an amount equal to the greater of (i) \$1,000 per share, or an adjusted amount if we do not have sufficient assets, and (ii) 1,000 times the aggregate per share amount to be distributed to the holders of common stock, subject to certain adjustments. Upon a consolidation, merger, combination or other transaction in which shares of our common stock are exchanged for or changed into other stock or securities, cash and/or any other property, each share of series A participating preferred stock shall be exchanged or changed in an amount equal to 1,000 times the aggregate amount of stock, securities, cash and/or any other property into which or for which each share of common stock is changed or exchanged, subject to certain adjustments. Holders of series A participating preferred stock have no redemption rights. All outstanding shares of series A participating preferred stock, when issued, will be fully paid and nonassessable.

### **Stockholder Rights Plan**

On July 6, 2001, our board of directors adopted a stockholder rights plan. The stockholder rights plan was adopted to give our board of directors increased power to negotiate in our best interests and to discourage appropriation of control of us at a price that is unfair to our stockholders. It is not intended to prevent fair offers for acquisition of control determined by our board of directors to be in the best interest of us and our stockholders, nor is it intended to prevent a person or group from obtaining representation on or control of our board of directors through a proxy contest, or to relieve our board of directors of its fiduciary duty to consider any proposal for our acquisition in good faith.

The material provisions of the rights plan are summarized below. However, since the terms of our rights agreement are complex, this summary may not contain all the information that is important to you. For more information, you should obtain a copy of the agreement, which is filed as an exhibit with the SEC. See [Where You Can Find More Information](#) for information on how to obtain a copy.

Under the rights agreement, we will issue one right with respect to each share of common stock that is issued prior to the distribution date described below. Except as set forth below, each right, when exercisable, entitles the holder to purchase from us one one-thousandth of a share of our series A participating preferred stock at a price of \$120.00, subject to adjustment. The rights trade in tandem with the common stock until, and become exercisable following, a distribution date. Our board of directors retains the right to amend the stockholder rights plan in any respect until 10 days following our announcement of the occurrence of any such triggering event, as defined below, leading to a distribution. Until a right is exercised, the holder of the right, as such, will have no rights as a stockholder of ours and will not have the right to vote or to receive dividends.

In general, the rights separate from the common stock and a distribution date will occur upon the earlier of:

the close of business on the tenth day (or such later date as may be determined by a majority of our board of directors) following a public announcement that a person or group of affiliated or associated persons has acquired, or obtained the right to acquire, beneficial ownership of 17.5% or more of the outstanding common stock; or

the close of business on the tenth day (or such later date as may be determined by a majority of our board of directors) following the commencement of a tender offer or exchange offer, the consummation of which would result in the beneficial ownership by a person or group of 17.5% or more of the outstanding Common Shares.

If a person or group acquires 17.5% or more of our common stock, all rightholders except the buyer will be entitled to acquire our common stock at a discount and, under certain circumstances, to acquire shares of the acquiring company at a discount. Also, in the event our board of directors may authorize the exchange of all or part of the then outstanding and exercisable rights for shares of our common stock at a rate of one share of our common stock per right if the buyer has not acquired 50% or more of our common stock.

Our board of directors may authorize the redemption of the rights, at a price of \$0.01 per right, at any time before a person or group acquires 17.5% or more of our common stock. The rights will expire on July 6, 2011.



## **Table of Contents**

### **ADDITIONAL INFORMATION CONCERNING OUR CAPITAL STOCK**

#### **Anti-Takeover Effects of Our Certificate of Incorporation and Bylaws**

Our certificate of incorporation and by-laws include a number of provisions that may have the effect of encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions:

authorizing the issuance of blank check preferred stock without any need for action by stockholders;

providing for a classified board of directors with staggered terms;

requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and by-laws;

eliminating the ability of stockholders to call special meetings of stockholders;

prohibiting stockholder action by written consent; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could discourage, delay or prevent certain types of transactions involving an actual or potential change in control of us, including transactions in which stockholders might otherwise receive a premium for their shares over current market prices.

#### **Anti-Takeover Effects of Provisions of Delaware Law**

We are subject to the provisions of Section 203 of the DGCL. In general, the statute prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date that person became an interested stockholder, unless the business combination was approved in a prescribed manner. A business combination includes a merger, asset sale or other transaction resulting in a financial benefit to an interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns, or, within the three years prior to the determination of interested stockholder status, owned, 15% or more of our outstanding voting stock.

Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period. This statute could prohibit or delay mergers or other takeover or change in control attempts not approved in advance by our board of directors, and as a result could discourage attempts to acquire us, which could depress the market price of our common stock.

#### **Limitation of Liability and Indemnification**

To the fullest extent permitted by the Delaware law, our certificate of incorporation provides that directors shall not be personally liable to us or any of our stockholders for monetary damages for breach of fiduciary duty as a director. However, this provision does not eliminate the duty of care, and in appropriate circumstances, equitable remedies such as injunctive or other forms of nonmonetary relief that will remain available under Delaware law. In addition, each director will continue to be subject to liability for (i) breach of the directors duty of loyalty to us or our stockholders, (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) violating Section 174 of the DGCL or (iv) any transaction from which the director derived an improper personal benefit. The provision also does not affect a director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

## Edgar Filing: DURECT CORP - Form S-3/A

Our bylaws provide that we shall, to the maximum extent and in the manner permitted by the Delaware law, indemnify each of our directors and officers against expenses (including attorneys' fees), judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of our company. Our bylaws also provide that we shall have the power to, to the maximum extent and in the manner permitted by the Delaware law, indemnify each of our employees and agents against expenses (including attorneys' fees), judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of our company. Our bylaws provide that expenses incurred in defending any such action or proceeding shall be paid in advance of the final disposition of such action or proceeding upon the receipt of an undertaking by or on behalf of the indemnified party to repay such amount if it shall be ultimately determined that the indemnified party is not entitled to be indemnified as authorized by our bylaws. The indemnification provided by our bylaws shall not be deemed exclusive of any other rights to which those seeking indemnification may have been entitled under any bylaw, agreement, vote of shareholders or disinterested directors or otherwise, to the extent that such additional rights to indemnification are authorized in our certificate of incorporation.

## **Table of Contents**

We also maintain liability insurance for our officers and directors and have entered into indemnification agreements with them.

### **DESCRIPTION OF DEBT SECURITIES**

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we offer under a prospectus supplement may differ from the terms we describe below.

The following summary description, together with the additional information we may include in any applicable prospectus supplements does not purport to be complete and is subject to, and qualified in its entirety by reference to, the forms of indenture, notes and supplemental agreements relating to each series of debt securities that will be incorporated by reference as exhibits to the registration statement that includes this prospectus or as exhibits to a current report on Form 8-K if we offer debt securities.

We will issue the senior debt securities under the senior indenture that we will enter into with the trustee named in the senior indenture. We will issue the subordinated debt securities under the subordinated indenture that we will enter into with the trustee named in the subordinated indenture. We may file the forms of these documents as exhibits to the registration statement which includes this prospectus or incorporate them by reference in a current report on Form 8-K. We use the term `indentures` in this prospectus to refer to both the senior indenture and the subordinated indenture.

The indentures will be qualified under the Trust Indenture Act of 1939, as amended. We use the term `debenture trustee` to refer to either the trustee under the senior indenture or the trustee under the subordinated indenture, as applicable.

The following summaries of material provisions of the senior debt securities, the subordinated debt securities and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements related to the debt securities that we sell under this prospectus, as well as the indenture that would contain the terms of the debt securities. Except as we may otherwise indicate, the terms of the senior indenture and the subordinated indenture would be identical.

#### **General**

We will describe in each prospectus supplement the following terms relating to a series of debt securities:

the title;

the principal amount being offered, and if a series, the total amount authorized and the total amount outstanding;

any limit on the amount that may be issued;

whether or not we will issue the series of debt securities in global form, the terms and who the depository will be;

the maturity date;

whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a U.S. person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;

## Edgar Filing: DURECT CORP - Form S-3/A

the annual interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;

whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;

the terms of the subordination of any series of subordinated debt;

the place where payments will be payable;



**Table of Contents**

restrictions on transfer, sale or other assignment, if any;

our right, if any, to defer payment of interest and the maximum length of any such deferral period;

the date, if any, after which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemptions provisions;

the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;

whether the indenture will restrict our ability and/or the ability of our subsidiaries to:

incur additional indebtedness;

issue additional securities;

create liens;

pay dividends and make distributions in respect of our capital stock and the capital stock of our subsidiaries;

redeem capital stock;

place restrictions on our subsidiaries' ability to pay dividends, make distributions or transfer assets;

make investments or other restricted payments;

sell or otherwise dispose of assets;

enter into sale-leaseback transactions;

engage in transactions with stockholders and affiliates;

issue or sell stock of our subsidiaries; or

effect a consolidation or merger;

whether the indenture will require us to maintain any interest coverage, fixed charge, cash flow-based, asset-based or other financial ratios;

a discussion of any material or special U.S. federal income tax considerations applicable to the debt securities;

information describing any book-entry features;

provisions for a sinking fund purchase or other analogous fund, if any;

whether the debt securities are to be offered at a price such that they will be deemed to be offered at an original issue discount as defined in paragraph (a) of Section 1273 of the Internal Revenue Code;

the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof; and

any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, including any additional events of default or covenants provided with respect to the debt securities, and any terms that may be required by us or advisable under applicable laws or regulations.

#### **Conversion or Exchange Rights**

We will set forth in the prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

#### **Consolidation, Merger or Sale**

Any successor to or acquiror of the indentures must assume all of our obligations under the indentures or the debt securities, as appropriate. If the debt securities are convertible for our other securities or securities of other entities, the person with whom we consolidate or merge or to whom we sell all of our property must make provisions for the conversion of the debt securities into securities that the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

## **Table of Contents**

### **Events of Default Under the Indenture**

The following are events of default under the indentures with respect to any series of debt securities that we may issue:

if we fail to pay interest when due and payable and our failure continues for 90 days, or within such other time period as may be specified in the applicable indenture, and the time for payment has not been extended or deferred;

if we fail to pay the principal, premium or sinking fund payment, if any, when due and payable and the time for payment has not been extended or delayed;

if we fail to observe or perform any other covenant contained in the debt securities or the indentures, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days, or within such other time period as may be specified in the applicable indenture, after we receive notice from the debenture trustee or holders of at least 25%, or such other percentage as may be specified in the applicable indenture, in aggregate principal amount of the outstanding debt securities of the applicable series; and

if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the debenture trustee or the holders of at least 25%, or such other percentage as may be specified in the applicable indenture, in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the debenture trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the debenture trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided that:

the direction so given by the holder is not in conflict with any law or the applicable indenture; and

subject to its duties under the Trust Indenture Act of 1939, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

the holder has given written notice to the debenture trustee of a continuing event of default with respect to that series;

the holders of at least 25%, or such other percentage as may be specified in the applicable indenture, in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity to the debenture trustee to institute the proceeding as trustee; and

the debenture trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days, or within such other time period as may be specified in the applicable indenture, after the notice, request and offer.

## **Table of Contents**

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the debenture trustee regarding our compliance with specified covenants in the indentures.

### **Modification of Indenture; Waiver**

We and the debenture trustee may change an indenture without the consent of any holders with respect to specific matters:

to fix any ambiguity, defect or inconsistency in the indenture;

to comply with the provisions described above under Consolidation, Merger or Sale ;

to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act of 1939;

to add to, delete from or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;

to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided under General to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;

to evidence and provide for the acceptance of appointment hereunder by a successor trustee;

to provide for uncertificated debt securities and to make all appropriate changes for such purpose;

to add to our covenants such new covenants, restrictions, conditions or provisions for the protection of the holders, and to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default; or

to change anything that does not materially adversely affect the interests of any holder of debt securities of any series.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, we and the debenture trustee may only make the following changes with the consent of each holder of any outstanding debt securities affected:

extending the fixed maturity of the series of debt securities;

## Edgar Filing: DURECT CORP - Form S-3/A

reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any debt securities; or

reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including obligations to:

register the transfer or exchange of debt securities of the series;

replace stolen, lost or mutilated debt securities of the series;

maintain paying agencies;

hold monies for payment in trust;

recover excess money held by the debenture trustee;

compensate and indemnify the debenture trustee; and

appoint any successor trustee.

---

## **Table of Contents**

In order to exercise our rights to be discharged, we must deposit with the debenture trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

### **Form, Exchange and Transfer**

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company or another depository named by us and identified in a prospectus supplement with respect to that series. See **Legal Ownership of Securities** for a further description of the terms relating to any book-entry securities.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days, or within such other time period as may be specified in the applicable indenture, before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing;  
or

register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

### **Information Concerning the Debenture Trustee**

The debenture trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given him or her by the indentures at the request of any holder of debt securities unless he or she is offered reasonable security and indemnity against the costs, expenses and liabilities that he or she might incur.

### **Payment and Paying Agents**

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will

## Edgar Filing: DURECT CORP - Form S-3/A

mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in a prospectus supplement, we will designate the corporate trust office of the debenture trustee in the City of New York as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.



## **Table of Contents**

All money we pay to a paying agent or the debenture trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

### **Governing Law**

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act of 1939 is applicable.

### **Subordination of Subordinated Debt Securities**

The subordinated debt securities will be unsecured and will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement. The subordinated indenture does not limit the amount of subordinated debt securities that we may issue. It also does not limit us from issuing any other secured or unsecured debt.

### **Outstanding Debt Securities**

We have no outstanding registered debt securities.

## **DESCRIPTION OF WARRANTS**

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. The terms of any warrants offered under that prospectus supplement may differ from the terms described below.

The following summary description, together with the additional information we may include in any applicable prospectus supplements does not purport to be complete and is subject to, and qualified in its entirety by reference to, the form of warrant agreement and form of warrant certificate relating to each series of warrants that will be incorporated by reference as an exhibit to the registration statement that includes this prospectus or as an exhibit to a current report on Form 8-K if we offer warrants.

### **General**

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

the offering price and aggregate number of warrants offered;

the currency for which the warrants may be purchased;

if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;

if applicable, the date on and after which the warrants and the related securities will be separately transferable;

in the case of warrants to purchase common stock, the number of shares of common stock purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;

the terms of any rights to redeem or call the warrants;

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the dates on which the right to exercise the warrants will commence and expire;

the manner in which the warrant agreements and warrants may be modified;

federal income tax consequences of holding or exercising the warrants;

the terms of the securities issuable upon exercise of the warrants; and

any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

---

## **Table of Contents**

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

### **Exercise of Warrants**

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 P.M. Eastern Time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

### **Enforceability of Rights by Holders of Warrants**

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

### **Outstanding Warrants**

As of February 27, 2009, we had an outstanding exercisable warrant to purchase 770 shares of common stock at \$8.50 per share. The warrant was issued in connection with an Exclusive Trademark License and Assignment Agreement. The value of the warrant was immaterial. The warrant expires in 2011.

## **DESCRIPTION OF UNITS**

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below.

The following summary description, together with the additional information we may include in any applicable prospectus supplements does not purport to be complete and is subject to, and qualified in its entirety by reference to, the form of unit agreement and form of unit certificate relating to each series of units that will be incorporated by reference as an exhibit to the registration statement that includes this prospectus or as an exhibit to a current report on Form 8-K if we offer units.

### **General**

We may issue units comprised of common stock, preferred stock, debt securities, debt obligations of third parties, including U.S. treasury securities, warrants or any combination thereof. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.



## **Table of Contents**

We will describe in the applicable prospectus supplement the terms of the series of units, including:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

any provisions of the governing unit agreement that differ from those described below; and

any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units. The provisions described in this section, as well as those described under Description of Capital Stock, Description of Debt Securities and Description of Warrants will apply to each unit and to any common stock, preferred stock, debt security or warrants included in each unit, respectively.

### **Issuance in Series**

We may issue units in such amounts and in such numerous distinct series as we determine.

### **Enforceability of Rights by Holders of Units**

Any unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

### **Title**

We, any unit agents and any of their agents may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purpose and as the person entitled to exercise the rights attaching to the units so requested, despite any notice to the contrary. See Legal Ownership of Securities below.

### **Outstanding Units**

We have no outstanding units.

## **LEGAL OWNERSHIP OF SECURITIES**

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee, depository or warrant agent maintain for this purpose as the holders of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as indirect holders of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

### **Book-Entry Holders**

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depository on behalf of other financial institutions that participate in the depository's book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

## Edgar Filing: DURECT CORP - Form S-3/A

Only the person in whose name a security is registered is recognized as the holder of that security. Securities issued in global form will be registered in the name of the depositary or its participants. Consequently, for securities issued in global form, we will recognize only the depositary as the holder of the securities, and we will make all payments on the securities to the depositary. The depositary passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depositary and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a book-entry security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depositary's book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

## **Table of Contents**

### **Street Name Holders**

We may terminate a global security or issue securities in non-global form. In these cases, investors may choose to hold their securities in their own names or in street name. Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

### **Legal Holders**

Our obligations, as well as the obligations of any applicable trustee and of any third parties employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with depository participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of the indenture or for other purposes. In such an event, we would seek approval only from the holders, and not the indirect holders, of the securities. Whether and how the holders contact the indirect holders is up to the holders.

### **Special Considerations for Indirect Holders**

If you hold securities through a bank, broker or other financial institution, either in book-entry form or in street name, you should check with your own institution to find out:

how it handles securities payments and notices;

whether it imposes fees or charges;

how it would handle a request for the holders' consent, if ever required;

whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;

how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and

if the securities are in book-entry form, how the depository's rules and procedures will affect these matters.

### **Global Securities**

## Edgar Filing: DURECT CORP - Form S-3/A

A global security is a security that represents one or any other number of individual securities held by a depository. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depository. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depository for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depository, its nominee or a successor depository, unless special termination situations arise. We describe those situations below under **Special Situations When a Global Security Will Be Terminated**. As a result of these arrangements, the depository, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depository or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect holder of a beneficial interest in the global security.



## **Table of Contents**

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

### **Special Considerations for Global Securities**

As an indirect holder, an investor's rights relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only in the form of a global security, an investor should be aware of the following:

An investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;

An investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;

An investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;

An investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;

The depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in a global security. We and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in a global security. We and the trustee also do not supervise the depositary in any way;

The depositary may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and

Financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities. There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

### **Special Situations When a Global Security Will Be Terminated**

In a few special situations described below, the global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

The global security will terminate when the following special situations occur:

if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;

if we notify any applicable trustee that we wish to terminate that global security; or

if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived. The prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

**Table of Contents**

**PLAN OF DISTRIBUTION**

We may sell the securities being offered by this prospectus separately or together through any of the following methods:

to or through one or more underwriters or dealers in a public offering and sale by them;

directly to investors;

through agents;

through block trades in which the broker or dealer engaged to handle the block trade will attempt to sell the securities as agent, but may position and resell a portion of the block as principal to facilitate the transaction.

We may sell the securities from time to time in one or more transactions at a fixed price or prices, which may be changed from time to time:

at market prices prevailing at the times of sale;

at prices related to such prevailing market prices; or

at negotiated prices.

We will describe the method of distribution of the securities in the applicable prospectus supplement. We may also determine the price or other terms of the securities offered under this prospectus by use of an electronic auction. We will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the obligations of the underwriter, dealer or agent in the applicable prospectus supplement.

Underwriters, dealers or agents may receive compensation in the form of discounts, concessions or commissions from us or our purchasers (as their agents in connection with the sale of the securities). In addition, underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they act as agent. These underwriters, dealers or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions, or profits on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. The prospectus supplement will identify any such underwriter, dealer or agent, and describe any compensation received by them from us. Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement. Any initial public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

Underwriters, dealers and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments made by the underwriters, dealers or agents, under agreements between us and the underwriters, dealers and agents.

## Edgar Filing: DURECT CORP - Form S-3/A

We may grant underwriters who participate in the distribution of the securities an option to purchase additional securities to cover overallocments, if any, in connection with the distribution. Any underwriter may engage in overallocation, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Overallocation involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the common stock in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the common stock originally sold by the dealer is purchased in a covering transaction to cover short positions. Those activities may cause the price of the common stock to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

**Table of Contents**

Any underwriters who are qualified market makers on the NASDAQ Global Market may engage in passive market making transactions in the common stock on the NASDAQ Global Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded.

Underwriters or agents and their associates may be customers of, engage in transactions with or perform services for us in the ordinary course of business and any such relationships will be described in the applicable prospectus supplement.

**LEGAL MATTERS**

The validity of the securities being offered by this prospectus will be passed upon by Morrison & Foerster LLP of Palo Alto, California.

**EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2008, and the effectiveness of our internal controls over financial reporting as of December 31, 2008, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference rooms at 450 Fifth Street, N.W., Washington, D.C., 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference rooms. Our SEC filings are also available at the SEC's website at [www.sec.gov](http://www.sec.gov) and our website at [www.durect.com](http://www.durect.com). We have not incorporated by reference into this prospectus the information contained on our website and you should not consider it to be part of this prospectus. In addition, you can read and copy our SEC filings at the office of the National Association of Securities Dealers, Inc. at 1735 K Street, Washington, D.C. 20006.

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. In addition, information we file with the SEC in the future will automatically update and supersede information contained in this prospectus and any accompanying prospectus supplement.

This prospectus incorporates by reference the documents set forth below that we have previously filed with the SEC:

our annual report on Form 10-K for the fiscal year ended December 31, 2008 filed with the SEC on March 10, 2009;

our definitive proxy statement dated April 29, 2008 for our annual stockholders' meeting on June 25, 2008;

our current reports on Form 8-K, filed with the SEC on January 15, 2009 and March 4, 2009; and

the description of our common stock in our Registration Statements on Form 8-A filed with the SEC on July 10, 2001, as amended by Amendment No. 1 to Form 8-A filed with the SEC on June 24, 2003.

We also incorporate by reference into this prospectus additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, excluding, in each case, information deemed furnished and not filed until we sell all of the securities we are offering. Any statements contained in a previously filed document incorporated by reference into this prospectus is deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement.

We will provide to you at no cost a copy of any and all of the information incorporated by reference into the registration statement of which this prospectus is a part. You may make a request for copies of this information in writing or by telephone. Requests should be directed to:

DURECT Corporation

2 Results Way

Cupertino, CA 95014

Attn: Investor Relations

(408) 777-1417

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other expenses of issuance and distribution**

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by us in connection with this offering. All the amounts shown are estimates except for the registration fee.

Securities and Exchange Commission registration fee*	\$	0
Legal Fees and Expenses	\$	**
Accountants Fees and Expenses	\$	**
Printing Expenses	\$	**
Miscellaneous Expenses (including any applicable listing fees and transfer agent s fees and expenses)	\$	**
Total	\$	**

\* We are offsetting the entire registration fee of \$2,947.51 required in connection with this registration statement by \$4,028.25 that was previously paid with respect to \$34,224,774 aggregate offering price of common stock that was registered by us pursuant to a prior registration statement (File No. 333 128979), originally filed on October 13, 2005, that has not yet been issued and sold.

\*\* To be filed by amendment.

**Item 15. Indemnification of Directors and Officers**

Our Amended Bylaws provide generally for indemnification of our officers, directors, agents and employees to the extent authorized by the DGCL. Pursuant to Section 145 of the DGCL, a corporation generally has the power to indemnify its present and former directors, officers, employees and agents against expenses incurred by them in connection with any suit to which they are, or are threatened to be made, a party by reason of their serving in such positions so long as they acted in good faith and in a manner they reasonably believed to be in, or not opposed to, the best interests of a corporation, and with respect to any criminal action, they had no reasonable cause to believe their conduct was unlawful. With respect to suits by or in the right of a corporation, however, indemnification is not available if such person is adjudged to be liable for negligence or misconduct in the performance of his duty to the corporation unless the court determines that indemnification is appropriate. In addition, a corporation has the power to purchase and maintain insurance for such person. The statute also expressly provides that the power to indemnify that it authorizes is not exclusive of any rights granted under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise.

As permitted by Section 102 of the DGCL, our stockholders have approved and incorporated provisions into Article XIII of our Amended and Restated Certificate of Incorporation and Article VI of our Amended Bylaws eliminating a director s personal liability for monetary damages to us and our stockholders arising from a breach of a director s fiduciary duty, except for liability under Section 174 of the DGCL or liability for any breach of the director s duty of loyalty to us or its stockholders, for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law or for any transaction in which the director derived an improper personal benefit. DURECT has also entered into agreements with its directors and certain of its officers that will require DURECT, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors to the fullest extent not prohibited by law.

Under Section 145 of the DGCL, we have broad powers to indemnify our directors and officers against liabilities they may incur in such capacities, including liabilities under the Securities Act of 1933, as amended.

We have entered into indemnification agreements with each of our officers and directors in which we agree to indemnify and hold harmless the officer or director to the fullest extent permitted by applicable law in connection with any threatened, pending or completed action, suit or proceeding, or any inquiry or investigation not initiated by the officer or director, by reason of the fact that such person is or was a director, officer, employee, agent or fiduciary of ours, or is or was serving at our request as a director, officer, employee, agent or fiduciary of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against any and all expenses, judgments, penalties, fines and settlement amounts actually and reasonably incurred by such officer or director or on his or her behalf (including mandatory





**Table of Contents**

advancement of expenses), if such person acted in good faith and in a manner which such person believed to be or not opposed to our best interests. The indemnification agreements set forth procedures that apply in the event of a claim for indemnification thereunder.

We also maintain insurance to protect ourselves and our directors, officers, employees and agents against expenses, liabilities and losses incurred by such persons in connection with their service in the foregoing capacities.

**Item 16. Exhibits and Financial Statement Schedules**

(a) The following exhibits are filed herewith or incorporated herein by reference:

<b>Exhibit Number</b>	<b>Description</b>
1.1	Form of Underwriting Agreement*
3.3	Amended and Restated Certificate of Incorporation of the Company (1)
3.5	Amended and Restated Bylaws of the Company (1)
3.8	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock (3)
4.1	Form of Common Stock Certificate (1)
4.2	Second Amended and Restated Investors Rights Agreement (1)
4.3	Preferred Shares Rights Agreement, dated as of July 6, 2001, between the Company and EquiServe Trust Company, N.A. including the Certificate of Designation, the form of the Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B and C, respectively (2)
4.4	Form of Preferred Stock Certificate*
4.7	Form of Warrant Agreement (including warrant certificate)*
4.10	Form of Unit Agreement (including form of unit certificate)*
5.1	Opinion of Morrison & Foerster LLP(4)
12.1	Computation of Ratio of Earnings to Fixed Charges and Ratio of Earnings to Combined Fixed Charges and Preferred Dividend Requirements
23.1	Consent of independent registered public accounting firm
23.2	Consent of Counsel (included in Exhibit 5.1)
24.1	Powers of Attorney (included as part of the signature pages hereto)

\* To be filed by amendment or by a Current Report on Form 8-K and incorporated herein by reference.

(1) Incorporated by reference to our Registration Statement on Form S-1, as amended (File No. 333-35316), originally filed with the SEC on April 20, 2000.

(2) Incorporated by reference to our Registration Statement on Form 8-A (File No. 000-31615), filed with the SEC on July 10, 2001.

(3) Incorporated by reference to our Registration Statement on Form 8-A (File No. 000-31615), filed with the SEC on July 10, 2001 (Exhibit A of Preferred Shares Rights Agreement).

(4) Previously filed.

**Item 17. Undertakings**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

## Edgar Filing: DURECT CORP - Form S-3/A

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental

II-2

**Table of Contents**

change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cupertino, State of California, on the 10th day of March, 2009.

DURECT Corporation.

By: */s/* JAMES E. BROWN  
**James E. Brown President,**

**Chief Executive Officer and Director**

**SIGNATURES AND POWER OF ATTORNEY**

Each person whose signature appears below constitutes and appoints James E. Brown and Felix Theeuwes, and each of them severally, as his true and lawful attorney-in-fact and agent, each acting alone with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign this Registration Statement on Form S-3 to be filed in connection with the offering of securities of DURECT Corporation, and any and all amendments (including post-effective amendments) to this registration statement, and any subsequent registration statement filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same with exhibits thereto, and the other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as they might or could do in person, hereby ratifying and confirming all that said attorney-in-fact or his substitutes, each acting alone, may lawfully do or cause to be done by virtue thereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and as of the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/</i> JAMES E. BROWN <b>James E. Brown</b>	President, Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2009
*	Chairman of the Board and Chief Scientific Officer	March 10, 2009
<b>Felix Theeuwes</b>		
*	Chief Financial Officer (Principal Accounting Officer)	March 10, 2009
<b>Matthew J. Hogan</b>		
*	Director	March 10, 2009
<b>Simon X. Benito</b>		
*	Director	March 10, 2009
<b>Terrence F. Blaschke</b>		

Edgar Filing: DURECT CORP - Form S-3/A

*	Director	March 10, 2009
<b>Michael D. Casey</b>		
*	Director	March 10, 2009
<b>David R. Hoffmann</b>		
*	Director	March 10, 2009
<b>Armand P. Neukermans</b>		
*	Director	March 10, 2009
<b>Jon S. Saxe</b>		

\* By            /s/ James E. Brown  
                  James E. Brown  
                  Attorney-in-Fact

II-4

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
1.1	Form of Underwriting Agreement*
3.3	Amended and Restated Certificate of Incorporation of the Company (1)
3.5	Amended and Restated Bylaws of the Company (1)
3.8	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock (3)
4.1	Form of Common Stock Certificate (1)
4.2	Second Amended and Restated Investors Rights Agreement (1)
4.3	Preferred Shares Rights Agreement, dated as of July 6, 2001, between the Company and EquiServe Trust Company, N.A. including the Certificate of Designation, the form of the Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B and C, respectively (2)
4.4	Form of Preferred Stock Certificate*
4.7	Form of Warrant Agreement (including warrant certificate)*
4.10	Form of Unit Agreement (including form of unit certificate)*
5.1	Opinion of Morrison & Foerster LLP(4)
12.1	Computation of Ratio of Earnings to Fixed Charges and Ratio of Earnings to Combined Fixed Charges and Preferred Dividend Requirements
23.1	Consent of independent registered public accounting firm
23.2	Consent of Counsel (included in Exhibit 5.1)
24.1	Powers of Attorney (included as part of the signature pages hereto)

\* To be filed by amendment or by a Current Report on Form 8-K and incorporated herein by reference.

- (1) Incorporated by reference to our Registration Statement on Form S-1, as amended (File No. 333-35316), originally filed with the SEC on April 20, 2000.
- (2) Incorporated by reference to our Registration Statement on Form 8-A (File No. 000-31615), filed with the SEC on July 10, 2001.
- (3) Incorporated by reference to our Registration Statement on Form 8-A (File No. 000-31615), filed with the SEC on July 10, 2001 (Exhibit A of Preferred Shares Rights Agreement).
- (4) Previously filed.