

ACORDA THERAPEUTICS INC
Form POS AM
March 29, 2007

As filed with the Securities and Exchange Commission on March 29, 2007

Registration No. 333-138842

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST EFFECTIVE AMENDMENT NO. 1

ON

FORM S-3

TO

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ACORDA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2836
(Primary Standard Industrial
Classification Code Number)
15 Skyline Drive
Hawthorne, New York 10532
(914) 347-4300

13-3831168
(I.R.S. Employer
Identification Number)

(Address, Including Zip Code, and Telephone Number,
Including Area Code, of Registrant's Principal Executive Offices)

Ron Cohen
Chief Executive Officer
15 Skyline Drive
Hawthorne, New York 10532
(914) 347-4300

(Name, Address, Including Zip Code, and Telephone Number,
Including Area Code, of Agent For Service)

Copy To:
Ellen B. Corenswet
Covington & Burling
1330 Avenue of the Americas
New York, New York 10019
(212) 841-1000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the securities being registered on this form are being offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

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If this form is filed to register additional securities for an offering pursuant to Rule 462(b) 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 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 post-effective amendment filed pursuant to Rule 462(d) 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 delivery of the prospectus is expected to be made pursuant to Rule 434 under the Securities Act, please check the following box.

This Registration Statement on Form S-3 constitutes a post-effective amendment to the Company's Registration Statement on Form S-1 (Registration No. 333-138842). Pursuant to Rule 401(c) under the Securities Act, the Company is filing this post-effective amendment on Form S-3.

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, or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Prospectus

3,230,769 Shares

ACORDA THERAPEUTICS, INC.

Common Stock

We are registering our common stock, par value \$0.001 per share, for resale by the selling stockholders identified in this prospectus. We are not selling any shares of our common stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders. Specifically, this prospectus relates to the resale of 3,230,769 shares of our common stock. The selling stockholders acquired their shares from us in a private placement that closed on October 6, 2006.

For a description of the plan of distribution of the resale shares, see page 24 of this prospectus.

Our common stock is listed on the Nasdaq Global Market under the symbol ACOR. On March 28, 2007, the last reported sales price for our common stock was \$18.69 per share.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 5.

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

The date of this Prospectus is March 29, 2007

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. We are not making offers to sell or seeking offers to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information contained in this prospectus is accurate as of the date on the front of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

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SUMMARY

This summary highlights information contained elsewhere in this prospectus and may not contain all of the information that is important to you. We encourage you to read this prospectus in its entirety, including the Risk Factors section and the documents incorporated by reference herein. As used in this prospectus, unless otherwise specified or the context requires otherwise, the terms Acorda, we, our, and us refer to Acorda Therapeutics, Inc.

Overview

We are a commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis, or MS, spinal cord injury, or SCI, and other disorders of the central nervous system, or CNS. Our marketed product, Zanaflex Capsules, is FDA-approved for the management of spasticity. Our lead product candidate, Fampridine-SR, has completed a positive Phase 3 clinical trial for the improvement of walking ability in people with MS and we expect to initiate a second phase 3 clinical trial in the second quarter of 2007. Our preclinical programs also target other aspects of MS, as well as SCI and other CNS disorders, including stroke and traumatic brain injury.

Approximately 650,000 people in the United States suffer from MS or SCI and the combined annual cost of treatment for these conditions exceeds \$13 billion. It is estimated that a total of approximately 10 million people live with the long-term consequences of traumatic brain injury and stroke in the United States.

Our goal is to continue to grow as a fully-integrated biopharmaceutical company by commercializing pharmaceutical products, developing our product candidates and advancing our preclinical programs for these large and underserved markets.

Our Product Pipeline

Zanaflex

Our products, Zanaflex Capsules and Zanaflex tablets, are FDA-approved for the management of spasticity, a symptom of conditions such as MS and SCI that is commonly characterized by stiffness and rigidity, restriction of movement and painful muscle spasms. Zanaflex Capsules and Zanaflex tablets contain tizanidine hydrochloride, or tizanidine, one of the two leading treatments currently used for the management of spasticity. We acquired Zanaflex Capsules and Zanaflex tablets from a wholly-owned subsidiary of Elan Corporation, plc, or Elan, in July 2004. This strategic acquisition provided us with the opportunity to build a commercial infrastructure, develop sales and marketing expertise and create a foundation for future product launches, in addition to generating product revenue.

In April 2005, we launched Zanaflex Capsules, a new capsule formulation of tizanidine. This product is protected by an issued U.S. patent. Zanaflex tablets lost compound patent protection in 2002 and both products now compete with 12 corporations' generic versions of tizanidine tablets.

We believe that Zanaflex Capsules offer important benefits over Zanaflex tablets and generic tizanidine tablets. When taken with food, Zanaflex Capsules have a different blood absorption profile, referred to as pharmacokinetic profile, than Zanaflex tablets and generic tizanidine tablets, generally resulting in a lower level and more gradual rise of peak levels of tizanidine in a patient's blood. As a result of this different pharmacokinetic profile, Zanaflex tablets and generic tizanidine tablets are not equivalent, or AB-rated, with Zanaflex Capsules. Therefore, under state pharmacy laws, prescriptions written for Zanaflex Capsules may not properly be filled by the pharmacist with Zanaflex tablets or generic tizanidine tablets. Zanaflex Capsules are also available in a higher dose strength, which gives patients and prescribers an additional choice in dosing and an opportunity to reduce the number of pills a person must take daily. In addition, people who have difficulty swallowing may find Zanaflex Capsules easier to take.

To support and increase sales of Zanaflex Capsules, we have more than doubled the size of our internal specialty sales force since early 2006. Our internal specialty sales force consists of 65 sales professionals who call on neurologists, other specialists, and primary care physicians who treat patients with conditions that involve spasticity. Members of this sales force also call on managed care organizations, pharmacists and wholesale drug distribution customers. We also engage a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care physicians, specialty physicians and pharmacists. We believe that our expanded sales and marketing infrastructure enables us to efficiently reach virtually all high-volume prescribers of Zanaflex tablets and generic tizanidine. We believe that many of these prescribers are also potential high-volume prescribers for our lead product candidate, Fampridine-SR, if approved.

Fampridine-SR

Our lead product candidate, Fampridine-SR, completed a positive Phase 3 clinical trial for improvement of walking ability in people with MS in September 2006. In this trial, statistical significance was achieved on all three efficacy criteria defined in the SPA. A significantly greater proportion of people taking Fampridine-SR had a consistent improvement in walking speed, the study's primary outcome, compared to people taking a placebo. In addition, the effect was maintained throughout the 14-week treatment period, and there was a statistically significant improvement among responders compared to non-responders in the 12-Item MS Walking Scale, a self-rated assessment of walking disability. We expect to initiate a second Phase 3 trial in the second quarter of 2007.

Fampridine-SR is a small molecule drug contained in a sustained release tablet form. Laboratory studies have shown that fampridine, the active ingredient in Fampridine-SR, improves impulse conduction in nerve fibers in which the insulating outer layer, called the myelin sheath, has been damaged. This damage may be caused by the body's own immune system, in the case of MS, or by physical trauma, in the case of SCI.

We believe that Fampridine-SR could represent a fundamental shift in the treatment of people with MS because it may improve neurological function rather than treating the symptoms or slowing the progression of disease, as current treatments do. We have obtained Orphan Drug designations from the FDA for Fampridine in both MS and incomplete SCI.

Preclinical programs

We have three preclinical programs focused on novel approaches to repair damaged components of the CNS:

- *Neuregulins.* This program is based on using GGF-2, a neuregulin growth factor to stimulate remyelination, or repair of the myelin sheath. In published studies, GGF-2 has been shown to stimulate remyelination in animal models of MS and to have other effects in neural protection and repair. In addition, the neuregulins have been shown to have potential cardiovascular applications, promoting the growth of heart muscle cell and reversing signs and symptoms in animal models of cardiac damage, such as congestive heart failure.
- *Remyelinating antibodies.* This program is based on research performed at the Mayo Clinic. Studies have demonstrated the ability of this family of antibodies to stimulate remyelination in three different animal models of MS. Currently, there is no available therapy indicated to repairs myelin that has been destroyed in MS of other demyelinating diseases.
- *Chondroitinase.* This program is based on the concept of breaking down the matrix of scar tissue that develops as a result of an injury to the CNS. Published research has demonstrated that this scar matrix is partly responsible for limiting the regeneration of nerve fibers in the CNS and restricting

their ability to modify existing neural connections. Independent academic laboratories have also published animal studies showing that application of chondroitinase results in recovery of function following injuries to various areas of the brain or spinal cord.

We believe all of our preclinical programs chondroitinase, neuregulins and remyelinating antibodies have broad applicability and have the potential to be first-in-class therapies. While these programs have initially been focused on MS and SCI, we believe they may be applicable across a number of CNS disorders, including stroke and traumatic brain injury, because many of the mechanisms of tissue damage and repair are similar. In addition, we believe that these programs have applicability beyond the nervous system, including in such fields as cardiology, oncology, orthopedics and ophthalmology.

Our Strategy

Our strategy is to continue to grow as a fully-integrated biopharmaceutical company focused on the identification, development and commercialization of a range of nervous system therapeutics. We are using our scientific, clinical and commercial expertise in MS and SCI as strategic points of access to additional CNS markets, including stroke and traumatic brain injury. Key aspects of our strategy are to:

- complete the clinical development of and obtain regulatory approval for Fampridine-SR in MS;
- maximize our revenue from Zanaflex Capsules;
- leverage the commercial presence of Zanaflex Capsules for the potential launch of Fampridine-SR;
- advance our pipeline of preclinical programs to clinical trials; and
- explore alternatives to maximize shareholder value.

We have established an advisory team and network of well-recognized scientists, clinicians and opinion leaders in the fields of MS and SCI. Depending on their expertise, these advisors provide assistance in trial design, conduct clinical trials, keep us apprised of the latest scientific advances and help us identify and evaluate business development opportunities. In addition, we have recruited over 35 MS centers and 80 SCI rehabilitation centers in the United States and Canada to conduct our clinical trials. Our clinical management team has extensive experience in the areas of MS and SCI and works closely with this network.

Risks Associated with our Business

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. Those reasons could include failure to successfully promote Zanaflex Capsules and any other future marketed products; delays in obtaining, or a failure to obtain, regulatory approval for Fampridine-SR or any of our future product candidates; and failure to maintain and to protect our proprietary intellectual property assets, among others. The information about our preclinical and clinical trials may be useful to you in evaluating our company's current stage of development and our near-term and long-term prospects; however, you should note that of the large number of drugs in development, only a small percentage successfully complete the FDA regulatory approval process and are commercialized.

We have a limited operating history and, as of December 31, 2006, had an accumulated deficit of approximately \$232.1 million. We expect to incur losses for at least the next several years. We had net losses of \$60.0 million and \$60.4 million for the year ended December 31, 2006 and 2005, respectively. We are unable to predict the extent of future losses or when we will become profitable, if at all. Even if we succeed in promoting Zanaflex Capsules and developing and commercializing one or more of our product candidates, we may never generate sufficient sales revenue to achieve and sustain profitability.

Corporate Information

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 15 Skyline Drive, Hawthorne, New York 10532. Our telephone number is (914) 347-4300. Our website is *www.acorda.com*. The information on our website is not part of this prospectus.

Our logo, Acorda Therapeutics , Zanaflex and Zanaflex Capsules are registered trademarks that we own. Other trademarks, trade names and service marks used in this prospectus are the property of their respective owners.

THE OFFERING

Common stock covered hereby 3,230,769 shares

Use of proceeds We will not receive any proceeds from the sale or other disposition of the shares of our common stock by the selling stockholders. See Use of Proceeds.

Nasdaq Global Market symbol ACOR

Risk factors See Risk Factors and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should consider carefully the following risk factors and the other information contained in this prospectus before you decide to purchase our common stock. Additional risks that are not currently known or foreseeable to us may materialize at a future date. The trading price of our common stock could decline if any of these risks or uncertainties occur and you might lose all or part of your investment.

Risks Related To Our Business

We have a history of operating losses and we expect to continue to incur losses and may never be profitable.

As of December 31, 2006, we had an accumulated deficit of approximately \$232.1 million. We had net losses of \$60.0 million and \$60.4 million for the year ended December 31, 2006 and the year ended December 31, 2005, respectively. We have had operating losses since inception as a result of our significant clinical development, research and development, general and administrative, sales and marketing and business development expenses. We expect to incur losses for at least the next several years as we expand our sales and marketing capabilities and continue our clinical trials and research and development activities.

Our prospects for achieving profitability will depend primarily on how successful we are in executing our business plan to:

- obtain FDA approval for and commercialize Fampridine-SR;
- increase sales of Zanaflex Capsules;
- continue to develop our preclinical product candidates and advance them into clinical trials; and
- evaluate and act on appropriate opportunities for maximizing shareholder value.

If we are not successful in executing our business plan, we may never achieve or may not sustain profitability.

If additional studies required by the FDA for Fampridine-SR do not yield favorable results or we are unable to obtain regulatory approval for Fampridine-SR, or any approval is unduly limited in scope or delayed, our business prospects will be adversely affected.

In September 2006, we announced positive results from our Phase 3 clinical trial of Fampridine-SR for the improvement of walking in patients with MS, which was performed under a SPA from the FDA. Although statistical significance was achieved on all three efficacy criteria defined in the SPA, positive results from at least one other Phase 3 clinical trial will be needed to support the filing of an NDA with the FDA. Based on our December 2006 meeting with the FDA, we will be required to design and conduct an additional Phase 3 trial of Fampridine-SR in people with MS. In addition, we will be required to execute a QT safety cardiac study in accordance with the FDA's October 2005 guidance, "Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs". We cannot predict how long these two studies, or any additional studies that might be required by the FDA, will take, whether any such studies will yield favorable results, or what the cost will be. In addition, if the FDA determines that a new substantial scientific issue regarding the safety or efficacy of Fampridine-SR is identified, the FDA may alter its conclusion, expressed in the SPA, regarding the adequacy of the Phase 3 protocol. The FDA may also identify a need for studies in addition to the second Phase 3 trial and the QT safety cardiac study to confirm efficacy that would examine safety or other properties or characteristics of Fampridine-SR.

Notwithstanding the results of our clinical trials, the FDA could determine that the overall balance of risks and benefits for Fampridine-SR is not adequate to support approval, or only justifies approval for a narrow set of uses or approval with restricted distribution or other burdensome post-approval requirements and limitations. Subjects taking Fampridine-SR have experienced adverse events, including falls, urinary tract infection, insomnia, dizziness, asthenia, headache, fatigue, nausea and balance disorder. A small number of subjects have also experienced seizures while taking Fampridine-SR, and there is a possibility that additional seizures will occur even at low doses of the drug. If the FDA denies approval of Fampridine-SR in MS, if FDA approval is substantially delayed, if approval is granted on a narrow basis or with restricted distribution or other burdensome post-approval requirements, or if the Fampridine-SR program is terminated, our business prospects will be adversely affected.

In March 2004, we completed two Phase 3 clinical trials of Fampridine-SR in SCI in which our results failed to reach their primary endpoints. We may resume development of Fampridine-SR for SCI after we have completed further development of the drug for MS. We cannot predict whether future clinical trials of Fampridine-SR in SCI will achieve their primary endpoints, how long these clinical trials will take or how much they will cost.

We will be substantially dependent on sales of one product, Zanaflex Capsules, to generate revenue for the foreseeable future.

We currently derive substantially all of our revenue from the sale of Zanaflex Capsules and Zanaflex tablets, which are our only FDA-approved products. Although we currently distribute Zanaflex tablets, our marketing efforts are focused on Zanaflex Capsules and we do not, and do not intend to, actively promote Zanaflex tablets. As a result, prescriptions for Zanaflex tablets have declined and we expect that they will continue to decline. Our goal is to convert sales of Zanaflex tablets and generic tizanidine tablets to sales of Zanaflex Capsules. We believe that sales of Zanaflex Capsules will constitute a significant portion of our total revenue for the foreseeable future. If we are unable to convert tablet sales to capsule sales or are otherwise unable to increase our revenue from the sale of this product, our business, financial condition and results of operations could be adversely affected.

We have recently expanded our sales force and sales of Zanaflex Capsules may not grow sufficiently to offset the increased costs associated with this expansion.

In the past year, we expanded our internal sales force from 32 to 65 people as part of our strategy to increase sales of Zanaflex Capsules. The expansion of our sales force has increased our fixed expenses significantly and there can be no assurances that we will be able to increase our sales of Zanaflex Capsules sufficiently to justify the expense associated with our expanded sales force. This in turn would adversely affect our cash flow and our prospects for achieving profitability. In addition, we may not be able to train and retain skilled sales and marketing personnel, in a timely manner or at all, or integrate and manage our larger sales and marketing organization.

There are currently 12 companies with generic versions of tizanidine tablets on the market and they are significantly cheaper than either Zanaflex Capsules or Zanaflex tablets. As of December 31, 2006, these generic versions of tizanidine tablets constituted approximately 93% of tizanidine sales in the United States. Although Zanaflex Capsules have a different pharmacokinetic profile when taken with food and are available in a higher dose than Zanaflex tablets and their generic equivalents, we may be unsuccessful in convincing prescribers, patients and third-party payors that these differences justify the higher price of Zanaflex Capsules. Despite our increased investment in sales personnel, we may be unable to convert a significant additional number of current users of Zanaflex tablets or generic tizanidine tablets to Zanaflex Capsules. If that is the case, our ability to generate meaningful revenue from this product will be adversely affected.

We had previously planned to target potential high-prescribing primary care physicians using a contract sales representative company, initially, Cardinal Health PTS, LLC and, later, Innovex, Inc., that we hired to provide sales representatives targeting the primary care market. We now intend to address that market through our expanded sales force. There can be no assurances that our sales force will be effective in reaching the primary care market.

Our product candidates must undergo rigorous clinical testing, the results of which are uncertain and could substantially delay or prevent us from bringing them to market.

Before we can obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory agencies. Clinical trials of new product candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete, and the outcome of such trials is uncertain.

Clinical development of any product candidate that we determine to take into clinical trials may be curtailed, redirected, delayed or eliminated at any time for some or all of the following reasons:

- negative or ambiguous results regarding the efficacy of the product candidate;
- undesirable side effects that delay or extend the trials, or other unforeseen or undesirable safety issues that make the product candidate not medically or commercially viable;
- inability to locate, recruit and qualify a sufficient number of patients for our trials;
- difficulty in determining meaningful end points or other measurements of success in our clinical trials;
- regulatory delays or other regulatory actions, including changes in regulatory requirements;
- difficulties in obtaining sufficient quantities of the product candidate manufactured under current good manufacturing practices;
- delays, suspension or termination of the trials imposed by us, an independent institutional review board for a clinical trial site, or clinical holds placed upon the trials by the FDA;
- FDA approval of new drugs that are more effective than our product candidates;
- change in the focus of our development efforts or a re-evaluation of our clinical development strategy; and
- a change in our financial position.

A delay in or termination of any of our clinical development programs could have an adverse effect on our business.

Our other drug development programs are in early stages of development and may never be commercialized.

All of our development programs other than Fampridine-SR are in the preclinical phase. Our future success depends, in part, on our ability to select successful product candidates, complete preclinical development of these product candidates and advance them to clinical trials. These product candidates will require significant development, preclinical studies and clinical trials, regulatory clearances and substantial additional investment before they can be commercialized.

Our preclinical programs may not lead to commercially viable products for several reasons. For example, we may fail to identify promising product candidates, our product candidates may fail to be safe and effective in preclinical tests or clinical trials, or we may have inadequate financial or other resources to pursue discovery and development efforts for new product candidates. In addition, because we have

limited resources, we are focusing on product candidates that we believe are the most promising. As a result, we may delay or forego pursuit of opportunities with other product candidates. From time to time, we may establish and announce certain development goals for our product candidates and programs; however, given the complex nature of the drug discovery and development process, it is difficult to predict accurately if and when we will achieve these goals. If we are unsuccessful in advancing our preclinical programs into clinical testing or in obtaining regulatory approval, our long-term business prospects will be harmed.

The pharmaceutical industry is subject to stringent regulation and failure to obtain regulatory approval will prevent commercialization of our product candidates.

Our research, development, preclinical and clinical trial activities, as well as the manufacture and marketing of any products that we may successfully develop, are subject to an extensive regulatory approval process by the FDA and other regulatory agencies abroad. The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain, and any regulatory approvals may contain limitations on the indicated usage of a drug, distribution restrictions or may be conditioned on burdensome post-approval study or other requirements, including the requirement that we institute and follow a special risk management plan to monitor and manage potential safety issues, all of which may eliminate or reduce the drug's market potential. Post-market evaluation of a product could result in marketing restrictions or withdrawal from the market.

The results of preclinical and Phase 1 and Phase 2 clinical studies are not necessarily indicative of whether a product will demonstrate safety and efficacy in larger patient populations, as evaluated in Phase 3 clinical trials. Additional adverse events that could impact commercial success, or even continued regulatory approval, might emerge with more extensive post-approval patient use. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

In order to conduct clinical trials to obtain FDA approval to commercialize any product candidate, an IND application must first be submitted to the FDA and must become effective before clinical trials may begin. Subsequently, an NDA must be submitted to the FDA, including the results of adequate and well-controlled clinical trials demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. In addition, the manufacturing facilities used to produce the products must comply with current good manufacturing practices and must pass a pre-approval FDA inspection. Extensive submissions of preclinical and clinical trial data are required to demonstrate the safety, efficacy, potency and purity for each intended use. The FDA may refuse to accept our regulatory submissions for filing if they are incomplete.

Clinical trials are subject to oversight by institutional review boards and the FDA to ensure compliance with the FDA's good clinical practice requirements, as well as other requirements for the protection of clinical trial participants. We depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices required by regulators. If any such standards are not complied with in our clinical trials, the resulting data from the clinical trial may not be usable or we, an institutional review board or the FDA may suspend or terminate such trial, which would severely delay our development and possibly end the development of such product candidate. We also depend upon third party manufacturers of our products to qualify for FDA approval and to comply with good manufacturing practices required by regulators. We cannot be certain that our present or future manufacturers and suppliers will comply with current good manufacturing practices. The failure to comply with good manufacturing practices may result in the termination of clinical studies, restrictions in the sale of, or withdrawal of the products from the market. Compliance by third parties with these standards and practices is outside of our direct control. For

example, we and other pharmaceutical companies recently received notification from the FDA regarding the FDA's concerns with the reliability of certain study analyses conducted by MDS Pharma Services, or MDS Pharma, at its St. Laurent (Montreal) and Blainville (Quebec) Canada sites from 2000 through 2004. MDS Pharma helped conduct the studies submitted to FDA for the approval of Zanaflex Capsules. The MDS Pharma facility involved was in Ireland, not Canada, and MDS Pharma's role in the studies did not include performing the types of analyses that the FDA identified in its recent notice as being of concern. Nonetheless, if the FDA's concerns extend to other MDS Pharma facilities or activities, the reliability of the studies that MDS Pharma assisted on for Zanaflex Capsules could be called into question, and we might have to confirm or repeat the studies.

In addition, we are subject to regulation under other state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other local, state, federal and foreign regulations. We cannot predict the impact of such regulations on us, although it could impose significant restrictions on our business and additional expenses to comply with these regulations.

Our products and product candidates may not gain market acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenue.

Market acceptance of our products and product candidates will depend on the benefits of our products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness and our ability to demonstrate these benefits to physicians and patients. We believe market acceptance also depends on the pricing of our products and the reimbursement policies of government and third-party payors, as well as on the effectiveness of our sales and marketing activities. Physicians may not prescribe our products, and patients may determine, for any reason, that our products are not useful to them. For example, physicians may not believe that the benefits of Zanaflex Capsules outweigh their higher cost in relation to Zanaflex tablets or generic tizanidine tablets. The failure of any of our products or product candidates, once approved, to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

Our potential products may not be commercially viable if we fail to obtain an adequate level of reimbursement for these products by Medicaid, Medicare or other third-party payors.

Our commercial success will depend in part on third-party payors, such as government health administrative authorities, including Medicaid and Medicare, private health insurers and other such organizations, agreeing to reimburse patients for the cost of our products. Significant uncertainty exists as to the reimbursement status of newly-approved healthcare products. Our business would be materially adversely affected if the Medicaid program, Medicare program or other third-party payors were to deny reimbursement for our products or provide reimbursement only on unfavorable terms. Our business could also be adversely affected if the Medicaid program, Medicare program or other reimbursing bodies or payors limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate.

Third-party payors frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. At present we do not have any such agreements with private third-party payors and only a small number of such agreements with government payors. If sales of Zanaflex Capsules increase we may need to offer larger discounts or discounts to a greater number of third-party payors to maintain acceptable reimbursement levels. If we were required to negotiate such agreements, there is no guarantee that we would be able to negotiate them at price levels that are profitable to us, or at all. If we are unsuccessful in maintaining reimbursement for our products at acceptable levels, our business will be adversely affected. In addition, if our competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products,

this may result in a greater level of reimbursement for their products relative to our products, which would reduce our sales and adversely affect our results of operations. We may experience pressure to lower prices on our approved products due to new and/or proposed federal legislation.

Federal legislation enacted in December 2003 added an outpatient prescription drug benefit to Medicare. The benefit is provided primarily through private entities, which attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations increase pressure to lower prescription drug prices. While the new law specifically prohibits the U.S. government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the U.S. government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating de facto price controls on prescription drugs. In addition, the new law contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include limitations on prescription drug prices. This Medicare prescription drug coverage legislation, as well as additional healthcare legislation that may be enacted at a future date, could reduce our sales and adversely affect our results of operations.

If our competitors develop and market products that are more effective, safer or more convenient than our approved products, or obtain marketing approval before we obtain approval of future products, our commercial opportunity will be reduced or eliminated.

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, including MS and SCI. We are aware of a company developing a sodium/potassium channel blocker and a second company developing an immediate release form of fampridine, both of which may compete with Fampridine-SR, if approved. In certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis. We are aware that at present compounded fampridine is used by some people with MS or SCI and it is possible that some people will want to continue to use compounded formulations even if Fampridine-SR were approved. Several companies are engaged in developing products that include novel immune system approaches and cell transplant approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Fampridine-SR or our preclinical candidates.

Composition of matter patents on tizanidine, the active ingredient in Zanaflex Capsules and Zanaflex tablets, expired in 2002. As of December 31, 2006, there were 12 companies with generic versions of tizanidine tablets on the market. To the extent that we are not able to differentiate Zanaflex Capsules from Zanaflex tablets and generic tizanidine tablets and/or pharmacists improperly substitute generic tizanidine tablets when filling prescriptions for Zanaflex Capsules, we may be unable to convert additional sales of Zanaflex tablets and generic tizanidine tablets to Zanaflex Capsules and our ability to generate revenue from this product will be adversely affected. Although no other FDA-approved capsule formulation of tizanidine exists, another company could develop a capsule or other formulation of tizanidine that competes with Zanaflex Capsules.

Our competitors may succeed in developing products that are more effective, safer or more convenient than our products or the ones we have under development or that render our approved or proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization before we do. If any of our competitors develops a product that is more effective, safer or more convenient for patients, or is able to obtain FDA approval for commercialization before we do, we may not be able to achieve market acceptance for our products, which would adversely affect our ability to generate revenues and recover the substantial development costs we have incurred and will continue to incur.

Our products may be subject to competition from lower-priced versions of such products and competing products imported into the United States from Canada, Mexico and other countries where there are government price controls or other market dynamics that make the products lower priced.

Our operations could be curtailed if we are unable to obtain any necessary additional financing on favorable terms or at all.

As of December 31, 2006, we had approximately \$53.8 million in cash, cash equivalents and short-term investments. Although we anticipate this will be sufficient to fund our operations and meet our financial obligations through the first quarter of 2008 based on our current projected revenue and spending levels, we have several product candidates in various stages of development, and all will require significant further investment to develop, test and obtain regulatory approval prior to commercialization. We will need to seek additional equity or debt financing or strategic collaborations to continue our product development activities, and could require substantial funding to commercialize any products that we successfully develop. We may seek additional financing in the near future to ensure the completion of Fampridine-SR's clinical development. We may not be able to raise additional capital on favorable terms or at all. To the extent that we are able to raise additional capital through the sale of equity securities, the issuance of those securities would result in dilution to our stockholders. Holders of such new equity securities may also have rights, preference or privileges that are senior to yours. If additional capital is raised through the incurrence of indebtedness, we may become subject to various restrictions and covenants that could limit our ability to respond to market conditions, provide for unanticipated capital investments or take advantage of business opportunities. To the extent funding is raised through collaborations or intellectual property-based financings, we may be required to give up some or all of the rights and related intellectual property to one or more of our products, product candidates or preclinical programs. If we are unable to obtain sufficient financing on favorable terms when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs or devote fewer resources to marketing Zanaflex Capsules.

Under our financing arrangement with the Paul Royalty Fund, or PRF, upon the occurrence of certain events, PRF may require us to repurchase the right to receive revenues that we assigned to it or may foreclose on certain assets that secure our obligations to PRF. Any exercise by PRF of its right to cause us to repurchase the assigned right or any foreclosure by PRF could adversely affect our results of operations and our financial condition.

On December 23, 2005, we entered into a revenue interests assignment agreement with PRF, which was amended on November 28, 2006, pursuant to which we assigned to PRF the right to receive a portion of our net revenues from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex.

Under our arrangement with PRF, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events, transfer any of our interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfer all or substantially all of our assets, or breach certain of the covenants, representations or warranties under the revenue interests assignment agreement, PRF may (i) require us to repurchase the rights we assigned to it at the put/call price in effect on the date such right is exercised or (ii) foreclose on the Zanaflex assets that secure our obligations to PRF. Except in the case of certain bankruptcy events, if PRF exercises its right to cause us to repurchase the rights we assigned to it, PRF may not foreclose unless we fail to pay the put/call price as required. The put/call price on a given date is the greater of (i) 150% of all payments made by PRF to us as of such date, less all payments received by PRF from us as of such date, and (ii) an amount that would generate an internal rate of return to PRF of

25% on all payments made by PRF to us as of such date, taking into account the amount and timing of all payments received by PRF from us as of such date.

If PRF were to exercise its right to cause us to repurchase the right we assigned to it, we cannot assure you that we would have sufficient funds available to pay the put/call price in effect at that time. Even if we have sufficient funds available, we may have to use funds that we planned to use for other purposes and our results of operations and financial condition could be adversely affected. If PRF were to foreclose on the Zanaflex assets that secure our obligations to PRF, our results of operations and financial condition could also be adversely affected. Because PRF's right to cause us to repurchase the rights we assigned to it is triggered by, among other things, a change in control, transfer of any of our interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement) or transfer of all or substantially all of our assets, the existence of that right could discourage us or a potential acquirer from entering into a business transaction that would result in the occurrence of any of those events.

The loss of our key management and scientific personnel may hinder our ability to execute our business plan.

Our success depends on the continuing contributions of our management team and scientific personnel, and maintaining relationships with our scientific and medical network and the network of centers in the United States and Canada that conducts our clinical trials. We are highly dependent on the services of Dr. Ron Cohen, our President and Chief Executive Officer, as well as the other principal members of our management and scientific staff. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. With the exception of Dr. Ron Cohen, we do not maintain key man life insurance policies on the lives of our officers, directors or employees. The loss of one or more of our key employees, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

We face an inherent risk of liability in the event that the use or misuse of our products results in personal injury or death.

If the use or misuse of Zanaflex Capsules or any other FDA-approved products we may sell in the future harms people, we may be subject to costly and damaging product liability claims brought against us by consumers, healthcare providers, pharmaceutical companies, third-party payors or others. The use of our product candidates in clinical trials could also expose us to product liability claims. We currently maintain a product liability insurance policy that includes coverage of our clinical trials. This insurance policy has a \$10 million per claim limit and the aggregate amount of claims under the policy is also capped at \$10 million. We also maintain separate marketed product liability coverage. We cannot predict all of the possible harms or side effects that may result from the use of our products or the testing of product candidates and, therefore, the amount of insurance coverage we currently have may not be adequate to cover all liabilities or defense costs we might incur. A product liability claim or series of claims brought against us could give rise to a substantial liability that could exceed our resources. Even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

We are subject to various federal and state laws regulating the marketing of Zanaflex Capsules and, if we do not comply with these regulations, we could face substantial penalties.

Our sales, promotion and other activities related to Zanaflex Capsules, or any of our other products under development following their regulatory approval, are subject to regulatory and law enforcement authorities in addition to the FDA, including the Federal Trade Commission, the Department of Justice,

and state and local governments. We are subject to various federal and state laws pertaining to health care fraud and abuse, including both federal and state anti-kickback laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive or pay any remuneration as an inducement for the referral of business, including the use, recommendation, purchase or prescription of a particular drug. The federal government has published regulations that identify safe harbors or exemptions for certain payment arrangements that do not violate the anti-kickback statutes. Although we seek to comply with these statutes, it is possible that our practices, or those of our contract sales force, might be challenged under anti-kickback or similar laws. Violations of fraud and abuse laws may be punishable by civil or criminal sanctions, including fines and civil monetary penalties, and future exclusion from participation in government healthcare programs.

We may be subject to penalties if we fail to comply with post-approval legal and regulatory requirements and our products could be subject to restrictions or withdrawal from the market.

Any product for which we currently have or may obtain marketing approval, along with the associated manufacturing processes, any post-approval clinical data that we might be required to collect and the advertising and promotional activities for the product, are subject to continual recordkeeping and reporting requirements, review and periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, any approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

We have an outstanding FDA commitment, inherited from Elan, to provide an assessment of the safety and effectiveness of Zanaflex Capsules in pediatric patients. This commitment, which is included in the NDA approval for Zanaflex capsules, was to be satisfied by February 2007.

We completed the retrospective pediatric safety data during February 2007 and expect to make it available to the FDA during April 2007. However, we were not able to complete the pediatric pharmacokinetic study by the February 2007 deadline. The delays in initiation of the pediatric pharmacokinetic study have been due to unexpected delays in investigator recruitment and obtaining Institutional Review Board approvals. Depending on the outcome of these studies and whether the FDA considers them adequate to satisfy our PREA commitment, we may be required to conduct additional studies. Such additional studies could be more extensive and more costly than the currently-planned studies. We also may be subject to penalties for non-compliance with PREA, including fines, seizure of product and loss of product approval.

Our advertising and promotion are subject to stringent FDA rules and oversight. In particular, the claims in our promotional materials and activities must be consistent with the FDA approvals for our products, and must be appropriately substantiated and fairly balanced with information on the safety risks and limitations of the products. Any free samples we distribute to physicians must be carefully monitored and controlled, and must otherwise comply with the requirements of the Prescription Drug Marketing Act, as amended, and FDA regulations. We must continually review adverse event information that we receive concerning our drugs and make expedited and periodic adverse event reports to the FDA and other regulatory authorities.

In addition, the research, manufacturing, distribution, sale and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud

and abuse provisions of the Social Security Act, as amended, the False Claims Act, as amended, the privacy provisions of the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We may be slow to adapt, or we may not be able to adapt, to changes in existing regulatory requirements or adoption of new legal or regulatory requirements or policies. Later discovery of previously unknown problems with our products, manufacturing processes, or failure to comply with regulatory requirements, may result in:

- voluntary or mandatory recalls;
- voluntary or mandatory patient or physician notification;
- withdrawal of product approvals;
- product seizures;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on importation of our product candidates;
- fines and injunctions;
- civil and criminal penalties;
- exclusion from participation in government programs; and
- suspension of review or refusal to approve pending applications.

In addition, the FDA or another regulatory agency may conduct periodic unannounced inspections. If they determine that we or any of our manufacturing or other partners are not in compliance with applicable requirements, they may issue a notice of inspectional observations. If the observations are significant, we may have to devote significant resources to respond and undertake appropriate corrective and preventive actions, which could adversely affect our business prospects.

State pharmaceutical marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.

In recent years, several states, including California, Maine, Minnesota, New Mexico, Texas, Vermont and West Virginia, and the District of Columbia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs and file periodic reports with the state on sales, marketing, pricing and other activities. For example, California has enacted a statute requiring pharmaceutical companies to adopt a comprehensive compliance program that is in accordance with the Office of Inspector General of the Department of Health and Human Services Compliance Program Guidance for Pharmaceutical Manufacturers. This compliance program must include policies for compliance with the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, as well as a specific annual dollar limit on gifts or other items given to individual healthcare professionals in California. The law requires posting policies on a company's public web site along with an annual declaration of compliance.

The District of Columbia, Maine, Minnesota, New Mexico, Texas, Vermont and West Virginia have also enacted statutes of varying scope that impose reporting and disclosure requirements upon

pharmaceutical companies pertaining to drug pricing and payments and costs associated with pharmaceutical marketing, advertising and promotional activities, as well as restrictions upon the types of gifts that may be provided to healthcare practitioners. Other states also have laws that regulate, directly or indirectly, various pharmaceutical sales and marketing activities, and new legislation is being considered in many states. Many of the state law requirements are new and uncertain and the penalties for failure to comply with these requirements are unclear. We are not aware of any companies against which fines or penalties have been assessed under these state reporting and disclosure laws to date. We are continually updating our formal compliance infrastructure and standard operating procedures to comply with such laws. Unless we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

If we seek to market our products in foreign jurisdictions, we will need to obtain regulatory approval in those jurisdictions.

In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval procedures vary among countries and can involve additional clinical testing. The time required to obtain approval may differ from that required to obtain FDA approval. Should we decide to market our products abroad, we may fail to obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for, and may not receive, necessary regulatory approvals to commercialize our products in any foreign market, which could adversely affect our business prospects.

If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages.

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials and chemicals that are subject to federal, state and local laws and regulations governing their use, storage, handling and disposal. These materials include ketamine, buprenorphine, sodium pentobarbital, ether, acetonitrile, hexanes, chloroform, xylene, dehydrated alcohol, methanol, ethyl alcohol, isopropanol and formaldehyde. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. If we fail to comply with environmental regulations, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any substantial liability could exceed our resources. We currently maintain a general liability insurance policy that has a \$2 million per claim limit and also caps aggregate claims at \$2 million. In addition, we have an umbrella insurance policy that covers up to \$9 million of liability in excess of the general liability policy's \$2 million limit. This amount of insurance coverage may not be adequate to cover all liabilities or defense costs we might incur. In addition, the cost of compliance with environmental and health and safety regulations may be substantial.

Risks Related to Our Dependence on Third Parties

We currently have no manufacturing capabilities and are substantially dependent upon Elan and other third party suppliers to manufacture Zanaflex Capsules, Zanaflex tablets and Fampridine-SR.

We do not own or operate, and currently do not plan to own or operate, manufacturing facilities for production of Zanaflex Capsules, Zanaflex tablets or Fampridine-SR. We rely and expect to continue to rely on third parties for the production of our products and clinical trial materials.

We rely on a single manufacturer, Elan, for the supply of Zanaflex Capsules. Zanaflex Capsules are manufactured using Elan's proprietary SODAS multiparticulate drug delivery technology. Elan is obligated, in the event of a failure to supply Zanaflex Capsules, to use commercially reasonable efforts to

assist us in either producing Zanaflex Capsules ourselves or in transferring production of Zanaflex Capsules to a third-party manufacturer, provided that such third-party manufacturer is not a technological competitor of Elan. In the event production is transferred to a third party, the FDA may require us to demonstrate through bioequivalence studies and laboratory testing that the product made by the new supplier is equivalent to the current Zanaflex Capsules before we could distribute products from that supplier. The process of transferring the technology and qualifying the new supplier could take a year or more.

Under our supply agreement with Elan, we provide Elan with monthly written 18-month forecasts and with annual written two-year forecasts of our supply requirements for Zanaflex Capsules. In each of the five months following the submission of our written 18-month forecast we are obligated to purchase the quantity specified in the forecast, even if our actual requirements are greater or less. Elan is not obligated to supply us with quantities in excess of our forecasted amounts, although it has agreed to use commercially reasonable efforts to do so. Because we have a limited history of selling Zanaflex Capsules, our forecasts of our supply requirements may be inaccurate. As a result, we may have an excess or insufficient supply of Zanaflex Capsules.

Prior to March 2007, we relied on a single manufacturer, Novartis, for the manufacture of Zanaflex tablets and for the supply of tizanidine, the active pharmaceutical ingredient in Zanaflex Capsules and Zanaflex tablets. Novartis has discontinued production of tizanidine and will no longer supply tizanidine to Elan for the production of Zanaflex Capsules or to us for the production of Zanaflex tablets. In collaboration with Elan, we have identified two tizanidine manufacturers and we are working to have both approved by the FDA as tizanidine suppliers for Zanaflex Capsules and Zanaflex tablets. If we and Elan do not gain FDA approval for at least one of these tizanidine suppliers prior to the depletion of Elan's tizanidine inventory and our Zanaflex Capsules and Zanaflex tablets inventory, we could experience an interruption in our Zanaflex Capsules and Zanaflex tablets supply.

We are currently in contract negotiations with Patheon regarding the manufacture of Zanaflex tablets, and Patheon has agreed to provide us with Zanaflex tablets prior to the contract being executed. If either Elan or Patheon experiences any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or we locate an alternate source o