

ACORDA THERAPEUTICS INC  
Form S-3ASR  
August 06, 2008

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As filed with the Securities and Exchange Commission on August 6, 2008

Registration No. 333-

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM S-3**

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)

**13-3831168**

(I.R.S. Employer Identification Number)

**15 Skyline Drive  
Hawthorne, New York 10532  
(914) 347-4300**

(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 LLP  
The New York Times Building  
620 Eighth Avenue  
New York, NY 10018  
(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 as determined by the registrant.

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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<br>filer <input checked="" type="checkbox"/> | Accelerated<br>filer <input type="checkbox"/> | Non-accelerated filer <input type="checkbox"/><br>(Do not check if a<br>smaller reporting company) | Smaller reporting<br>company <input type="checkbox"/> |
|--|---|--|---|

### Calculation of Registration Fee

| Title of each class of securities to be registered(1)           | Amount to be registered | Proposed maximum offering price per unit | Proposed maximum aggregate offering price | Amount of registration fee |
|---|-------------------------|--|---|----------------------------|
| Common Stock, Preferred Stock, Debt Securities, Warrants, Units | (2)                     | (2)                                      | \$150,000,000                             | \$5895                     |

(1) An indeterminate amount of securities of each identified class is being registered as may from time to time be offered, reoffered or resold hereunder at indeterminate prices, along with an indeterminate number of securities that may be issued upon exercise, settlement, exchange, conversion, exercise or exchange or conversion of securities offered or sold hereunder.

(2) The proposed maximum per unit price per class of security will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered under this registration statement. The information is not required to be included in accordance with General Instruction II.E of Form S-3.

**ACORDA THERAPEUTICS, INC.**

**15 Skyline Drive  
Hawthorne, New York 10532  
(914) 347-4300**

**Common Stock  
Preferred Stock  
Debt Securities  
Warrants  
Units**

We may offer under this prospectus from time to time, at prices and on terms to be determined by market conditions at the time we make the offer, our:

common stock, par value \$0.001 per share;

preferred stock, par value \$0.001 per share;

debt securities;

warrants to purchase common stock or preferred stock, or debt securities; or

any combination of the above, separately or as units.

This prospectus may not be used to sell our securities unless accompanied by a prospectus supplement. Before you invest in our securities, you should carefully read both this prospectus and the prospectus supplement related to the offering of the securities.

Our common stock is listed on the Nasdaq Stock Market LLC under the symbol "ACOR." On August 5, 2008, the last reported sales price for our common stock was \$30.54 per share.

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.

**Investing in our securities involves a high degree of risk. You should purchase the securities only if you can afford a complete loss of your investment. See "Risk Factors" beginning on page 6 of this prospectus.**

If we sell securities through agents or underwriters, we will include their names and the fees, commissions and discounts they will receive, as well as the net proceeds to us, in the applicable prospectus supplement.

The date of this prospectus is August 6, 2008

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You should rely only on the information contained in or incorporated by reference in this prospectus, the related prospectus supplement or any free writing prospectus by or on behalf of us. 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 or incorporated by reference in this prospectus is accurate as of the date on the front of this prospectus or incorporated document only, as the case may be. Our business, financial condition, results of operations and prospects may have changed since that date.

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## PROSPECTUS 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 approved by the U.S. Food and Drug Administration, or FDA, for the management of spasticity. Our lead product, Fampridine-SR, is designed to improve walking ability in people with MS. In June 2008, we reported positive results from our second Phase 3 clinical trial of Fampridine-SR. (We reported positive results from our first Phase 3 clinical trial of Fampridine S-R in September 2006.) We intend to submit a New Drug Application, or NDA, for Fampridine-SR to the FDA in the first quarter of 2009. 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 to 750,000 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. We launched Zanaflex Capsules, a new capsule formulation of tizanidine, in April 2005.

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

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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 more than doubled the size of our internal specialty sales force between 2006 and 2007. As of July 1, 2008, our internal specialty sales force consisted 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 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.

Zanaflex Capsules are protected by a U.S. patent that expires in 2021. Zanaflex tablets lost compound patent protection in 2002 and both products now compete with 12 generic versions of tizanidine tablets. In August 2007, the Company received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. for patent infringement in relation to the filing of the ANDA by Apotex, Inc. If the FDA approves the ANDA and Apotex Corp. and Apotex Inc. are successful in challenging the validity of the patent, Apotex Corp. and Apotex Inc. could be permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex tablets.

### ***Fampridine-SR***

Our lead product candidate, Fampridine-SR, completed its second successful Phase 3 clinical trial for improvement of walking ability in people with MS, MS-F204, in June 2008. A significantly greater proportion of people taking Fampridine-SR in the trial had a consistent improvement in walking speed compared to people taking placebo (42.9% vs. 9.3%), as measured by the timed 25-foot walk. Consistent improvement in walking speed was the primary endpoint of the study as outlined in the Special Protocol Assessment, or SPA, with the FDA. Under the SPA, the FDA agreed that this trial, if successful, together with our first Phase 3 trial, would be adequate to support the efficacy requirements in an NDA for Fampridine-SR. 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, although it was not part of the SPA or the statistical analysis plan. These results were consistent with those of the Phase 3 trial. An increased response rate on the timed 25-foot walk was seen across all four types of MS.

The trial's only prospectively defined secondary outcome measure, leg strength, showed a statistically significant increase in the Fampridine-SR timed walk responders compared to placebo. There was a small improvement in leg strength for Fampridine-SR timed walk non-responders compared to placebo that was not statistically significant.

We expect to submit a New Drug Application, or NDA, for Fampridine-SR to the FDA in the first quarter of 2009. Earlier this year, we submitted a request to the FDA for Fast Track designation for Fampridine-SR, which the FDA did not grant. We plan to request consideration for Priority Review at the time we file our NDA and will submit additional data analyses at that time in support of this request. Fast Track provides for additional interactions with the FDA during drug development and the option of submitting an NDA in sections rather than all components simultaneously. Priority Review provides for a six month rather than a ten month FDA review period for an NDA.

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Fampridine-SR completed its first Phase 3 clinical trial for improvement of walking ability in people with MS, MS-F203, in September 2006. In this trial, statistical significance was achieved on all three efficacy criteria defined in a SPA issued by the FDA. A significantly greater proportion of people taking Fampridine-SR in this trial had a consistent improvement in walking speed on a timed 25-foot walk, the trial'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 timed walk responders compared to timed walk non-responders in the 12-Item MS Walking Scale.

As of July 18, 2008, 177 subjects from our MS-F202 Phase 2 clinical trial of Fampridine-SR in MS had been enrolled in an extension trial and 101, or approximately 57%, remained active in the trial, with duration of treatment ranging from 3.8 to 4.4 years. As of the same date, 269 patients from MS-F203 had been enrolled in a separate extension study and 203 of these, or approximately 75%, remained active, with duration of treatment ranging from 1.8 to 2.6 years. Also, as of this same date, 214 patients from MS-F204 had been enrolled in a third extension study and 194, or approximately 89%, remained active, with a duration of treatment ranging from one to 11 months. The total exposure to Fampridine-SR in our MS studies to date, including both double-blind and open label studies, is over 1,200 patient-years.

In January 2008, we announced the results of a Thorough QT cardiac study of Fampridine-SR, an FDA-required study that evaluated the potential of Fampridine-SR to cause an increase in the electrocardiographic QT interval. This study found that Fampridine-SR, at both therapeutic and suprathreshold doses, was no different than placebo.

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 is the first potential therapy in late-stage clinical development for MS that seeks to improve the function of damaged nerve fibers. We have obtained Orphan Drug designations from the FDA for Fampridine in MS. We plan to commercialize Fampridine-SR in MS, if approved, using our own sales force in the United States and are exploring options for commercializing this product, if the appropriate regulatory approvals are obtained, outside the United States. We also have obtained orphan drug designation from the FDA for incomplete SCI, although we do not have any ongoing studies for that indication.

### ***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. In Q1 2008, we began work with a contract manufacturer to scale up manufacturing of GGF-2 under good manufacturing practices in preparation for a potential Investigational New Drug (IND) application to support human clinical trials, which is planned for late 2009. In July 2008, we presented data on GGF-2 demonstrating improved cardiac function in preclinical models of heart failure. In preclinical

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testing, neuregulins have shown the potential to reduce and even reverse dysfunction of congestive heart failure by strengthening and protecting heart muscle cells.

*Remyelinating antibodies.* This program is based on research performed at the Mayo Clinic, with whom we have a license agreement. 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 treat MS or other demyelinating conditions that repairs or replaces myelin. We have begun work with a contract manufacturer to scale up manufacturing of one of these antibodies under good manufacturing practices, and expect to complete this scale up process by the end of 2008, in preparation for an IND application to support human clinical trials, which is planned for late 2009.

*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 neuregulins, remyelinating antibodies and chondroitinase 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:

obtain regulatory approval for Fampridine-SR in MS;

maximize our revenue from Zanaflex Capsules and tablet commercial operations, which we expect to be cash flow positive in 2008;

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 increase shareholder value.

We have established a team of advisors and a 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 40 MS 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.



### **Risk Factors Associated with Our Business**

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" in this prospectus. We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. Those reasons could include delays in obtaining, or a failure to obtain, regulatory approval for Fampridine-SR, or obtaining approval for a narrow set of uses or with restricted distributions or other burdensome post-approval requirements and limitations; failure to successfully promote Zanaflex Capsules and any other future marketed products; 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 June 30, 2008, we had an accumulated deficit of approximately \$305.3 million. We expect to incur losses for at least the next several years. We had net losses of \$38.0 million, \$60.0 million and \$60.4 million for the years ended December 31, 2007, 2006 and 2005, respectively, and a net loss of 18.8 for the three-month period ended June 30, 2008. 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](http://www.acorda.com). Please note that all references to "[www.acorda.com](http://www.acorda.com)" in this prospectus and documents incorporated by reference herein are inactive textual references only and that the information contained on Acorda's website is neither incorporated by reference nor intended to be used in connection with this offering.

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**

This prospectus is part of a registration statement on Form S-3ASR that we filed with the Securities and Exchange Commission utilizing a "shelf" registration process. Under this process, we may sell any combination of the securities described in this prospectus in one or more offerings. This prospectus provides you with a general description of the securities that we may offer. Each time we offer to sell securities under this prospectus, we will provide a prospectus supplement containing specific information about the terms of that offering. A prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any information we provide in a prospectus supplement is inconsistent with information in this prospectus, the information in the prospectus supplement will modify or supersede this prospectus. You should read both this prospectus and any prospectus supplement together with the additional information described under the headings "Where You Can Find More Information" and "Incorporation of Information by Reference."

## 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 and the documents incorporated by reference herein 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. Our business and financial results could be adversely affected in a material way 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 June 30, 2008, we had an accumulated deficit of approximately \$305.3 million. We had net losses of \$35.3 million, \$38.0 million, \$60.0 million and \$60.4 million for the six-month period ended June 30, 2008 and the years ended December 31, 2007, 2006 and 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 increasing shareholder value.

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

***If 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 materially adversely affected.***

We have reported positive results from two Phase 3 clinical trials of Fampridine-SR for the improvement of walking in patients with MS, most recently in June 2008. Both trials were conducted pursuant to SPAs from the FDA. The FDA has informed us that positive results from at least two successful Phase 3 clinical trials will be needed to support the filing of an NDA with the FDA. If the FDA determines that there is a new substantial scientific issue regarding walking in the MS population or Fampridine-SR, the FDA may alter its opinion expressed in the prior SPAs regarding the adequacy of the Phase 3 studies. The FDA also required us to execute a Thorough QT study of cardiac safety which was completed in January 2008. Although our QT consultants concluded that this study showed no safety signal for a risk of cardiac QT prolongation with Fampridine-SR at a therapeutic or supra-therapeutic dose, the FDA will make its own evaluation of the data when it is submitted as part of the NDA application and its interpretation of the results may differ.

The FDA may also identify a need for further studies in order to confirm efficacy or to examine safety or other properties or characteristics of Fampridine-SR. For example, in October 2007, we met with the FDA to discuss the completed preclinical studies proposed for the NDA for Fampridine-SR and the FDA asked us to complete a series of bridging studies to bring our older preclinical toxicology studies to current scientific standards. This included a requirement to complete new studies to fully characterize the toxicokinetics of fampridine in the blood of experimental animals given doses that were

used in the full range of our previously performed preclinical toxicology studies, so the FDA can evaluate the suitability of those doses and routes of administration of drug in its evaluation of safety. We may also determine, on our own, to conduct additional studies from time to time to support our filing of an NDA or to otherwise provide additional data regarding the safety or efficacy of Fampridine-SR. If the studies that we are required to conduct, or any studies that we determine, on our own, to conduct, cause us to incur unanticipated expenses or delays, or yield unfavorable results, our ability to obtain regulatory approval of Fampridine-SR could be seriously delayed or impaired, in which case our business prospects will be materially adversely affected.

Earlier this year, we submitted a request to the FDA for Fast Track designation for Fampridine-SR. The FDA did not grant our request, stating that we had not at this time demonstrated that Fampridine-SR addresses an unmet medical need under the criteria for Fast Track designation. We will present additional information on the ways in which Fampridine-SR improves walking ability in patients with MS and differs in its effects from existing MS therapies as part of our request for Priority Review of the NDA under the FDA's standards for designating NDAs for either Priority or Standard review. We may not be able to convince the FDA that Fampridine-SR addresses an unmet medical need for MS patients, in which case we would not receive Priority Review and our NDA would be subject to FDA's normal 10 month review time under the Prescription Drug User Free Act rather than an expedited review time of six months.

Notwithstanding the results of our clinical trials and pre-clinical studies, 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 materially 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. However, 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 materially adversely affected.

*We expect to further increase our sales force in anticipation of the possible launch of Fampridine-SR and sales of Zanaflex Capsules may not grow sufficiently, or Fampridine-SR may not get approved, to offset the increased costs associated with this expansion.*

Between 2006 and 2007, we expanded our internal sales force from 32 to 65 people as part of our strategy to increase sales of Zanaflex Capsules, which increased our fixed expenses significantly. If we file an NDA with the FDA for Fampridine-SR for the improvement of walking in patients with MS, we expect to further increase our sales force in anticipation of the possible launch of Fampridine-SR, if approved. If we expand our sales force and an NDA is not approved by the FDA, or, if approved, we are not able to achieve our expected level of sales of Zanaflex Capsules and Fampridine-SR, our cash flow and our prospects for achieving profitability will be adversely affected. 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, 2007, 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, such as government health administrative authorities, including Medicaid and Medicare, private health insurers and other such organizations 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 continue to generate meaningful revenue from this product will be adversely affected.

*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 our product candidates 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.

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. Although we do not have any such agreements with private third-party payors and only a small number of such agreements with government payors, as sales of Zanaflex Capsules continue to increase, we expect increasing pressure 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. Third-party payors may also require prior authorization for, or even refuse to provide, reimbursement for drugs for which there are competing lower-priced drugs. 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 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 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 January 1, 2008, 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 June 30, 2008, we had approximately \$149.0 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 into the fourth quarter of 2009 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 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 less 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 the Zanaflex 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 interest 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, or (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. For example, we are required to inform the FDA if certain issues arise in the manufacturing or packaging of our commercialized products. In December 2007, we filed a field alert with the FDA notifying them that two bottles of Zanaflex Capsules were packaged without the required lot and expiration date information on their labels. We worked with the packager of Zanaflex Capsules to identify and correct any issues that could have caused this, but there can be no assurance that other bottles of Zanaflex Capsules are or will be labeled properly or that other similar issues will not occur.

## Edgar Filing: ACORDA THERAPEUTICS INC - Form S-3ASR

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 provided retrospective pediatric safety data to the FDA in April 2007. However, we were not able to complete the pediatric pharmacokinetic study by the February 2007 deadline due to delays in investigator recruitment and obtaining Institutional Review Board approvals. The study was completed and the final report submitted to the FDA in April 2008. The FDA reviewed our response to the 2002 outstanding pediatric commitments based on the new standards set out in the 2007 FDA Act Amendments and found that it does not fulfill them. We have withdrawn our submission and plan to meet with FDA to determine how best to bring our submission into compliance with the revised standards. This could include conducting additional studies. Such additional studies could be more extensive and more costly than the recently completed 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 laws 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. 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.

*Fulfilling our obligations pursuant to compliance with the Sarbanes-Oxley Act of 2002 will be expensive and time consuming.*

The Sarbanes-Oxley Act of 2002 requires that we maintain certain corporate governance practices and adhere to a variety of reporting requirements, including with respect to internal controls over financial reporting. Compliance with these requirements has increased our general and administrative costs. In addition, these requirements could make it more difficult and more expensive for us to obtain director and officer liability insurance, and more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

#### **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, facilities for production and packaging of Zanaflex Capsules, Zanaflex tablets or Fampridine-SR. We rely and expect to continue to rely on third parties for the production and packaging of our commercial 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 for our supply requirements of 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. We have recently received FDA approval for a tizanidine manufacturer, Farmak, that will supply the active pharmaceutical ingredient for Zanaflex Capsules. However, we are still required to obtain FDA approval for a new supplier of the tizanidine needed for the production of Zanaflex tablets. Elan has agreed to supply us with Novartis-manufactured tizanidine for the production of Zanaflex tablets until a new manufacturer is approved.

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 of supply. We may not be able to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements. We could experience substantial delays before we are able to qualify any new supplier and transfer the required manufacturing technology to that supplier.

Beginning in May 2007, the chemical stability of Elan's inventory of Novartis-manufactured tizanidine must be retested within 30 days of each manufacturing run. If Elan's tizanidine inventory fails its retest prior to FDA approval of a new supplier for Zanaflex tablets, a delay or interruption in our supply of our Zanaflex tablets could result.

We also rely exclusively on Elan to supply us with our requirements for Fampridine-SR. Elan relies on a single third-party manufacturer to supply fampridine, the active pharmaceutical ingredient in Fampridine-SR. Under our supply agreement with Elan, we are obligated to purchase at least 75% of our yearly supply of Fampridine-SR from Elan, and we are required to make compensatory payments if we do not purchase 100% of our requirements from Elan, subject to certain exceptions. We and Elan have agreed that we may purchase up to 25% of our annual requirements from Patheon, a mutually agreed-upon and qualified second manufacturing source, with compensatory payment.

Our dependence on others to manufacture our marketed products and clinical trial materials may adversely affect our ability to develop and commercialize our products on a timely and competitive basis.

***If third-party contract research organizations do not perform in an acceptable and timely manner, our preclinical testing or clinical trials could be delayed or unsuccessful.***

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We rely and will continue to rely on clinical investigators, third-party contract research organizations and consultants to perform some or all of the functions associated with preclinical testing and clinical trials. The failure of any of these vendors to perform in an acceptable and timely manner in the future, including in accordance with any applicable regulatory requirements, such as good clinical and laboratory practices, or preclinical testing or clinical trial protocols, could cause a delay or other adverse effect on our preclinical testing or clinical trials and ultimately on the timely advancement of our development programs.

**Risks related to our intellectual property**

*If we cannot protect our intellectual property, our ability to develop and commercialize our products will be severely limited.*

Our success will depend in part on our and our licensors' ability to obtain, maintain and enforce patent protection for the technologies, compounds and products, if any, resulting from our licenses and development programs. Without protection for the intellectual property we use, other companies could offer substantially identical products for sale without incurring the sizable discovery, development and licensing costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished.

We have in-licensed or are the assignee of over 25 U.S. patents, over 60 foreign patents and over 65 patent applications pending in the United States or abroad for our own technologies and for technologies from our in-licensed programs. The process of obtaining patents can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent may not issue or it may not have sufficient scope or strength to protect the technology it was intended to protect or to provide us with any commercial advantage. We may never be certain that we were the first to develop the technology or that we were the first to file a patent application for the particular technology because U.S. patent applications are confidential until they are published, and publications in the scientific or patent literature lag behind actual discoveries. The degree of future protection for our proprietary rights will remain uncertain if our pending patent applications are not approved for any reason or if we are unable to develop additional proprietary technologies that are patentable. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents or the patents of our licensors.

We may initiate actions to protect our intellectual property and in any litigation in which our patents or our licensors' patents are asserted, a court may determine that the patents are invalid or unenforceable. Even if the validity or enforceability of these patents is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by the patent claims. In addition, effective intellectual property enforcement may be unavailable or limited in some foreign countries. From time to time we may receive notices from third parties alleging infringement of their intellectual property rights. Any litigation, whether to enforce our rights to use our or our licensors' patents or to defend against allegations that we infringe third party rights, would be costly, time consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research areas that are similar to those areas in which they were involved at their former employers, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs and be a distraction to management and which could have an adverse effect on us, even if we are successful in defending such claims.

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, those agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements or that our trade secrets become known or

independently discovered by competitors, could adversely affect us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it filed an ANDA with the FDA to market generic versions of each of the three Zanaflex Capsules dosage strengths marketed by us. In response to that Notice, in October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, "Apotex") in the United States District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557 relating to methods of reducing drowsiness in patients with immediate release multiparticulate tizanidine formulations, including those sold by us as Zanaflex Capsules. This patent expires in 2021.

In November 2007, Apotex filed an answer to our complaint, asserting affirmative defenses of invalidity and non-infringement of U.S. Patent No. 6,455,557, and also filed counterclaims for declaratory judgment of invalidity and non-infringement. Apotex's defenses or counterclaims may change during the course of the litigation and its arguments and/or the underlying bases for its arguments may change. Although we intend to vigorously defend our intellectual property rights related to Zanaflex Capsules, there is no assurance that we will prevail or that the ANDA filed by Apotex Inc. will not be approved by the FDA. The resolution of this patent litigation could be lengthy and at substantial cost, even if resolved in our favor, and could absorb significant management time, all of which may materially and adversely affect our financial position and results of operations. In addition, if Apotex is successful in challenging our patent, and if the FDA approves that ANDA, it could be permitted to sell a generic tizanidine hydrochloride capsule. Further, other third parties may bring similar claims. We would face significant competition from any generic brand of tizanidine hydrochloride capsule, which would cause significant declines in our revenue and profit margin.

***If third parties successfully claim that we infringed their patents or proprietary rights, our ability to continue to develop and successfully commercialize our product candidates could be delayed.***

Third parties may claim that we or our licensors or suppliers are infringing their patents or are misappropriating their proprietary information. In the event of a successful claim against us or our licensors or suppliers for infringement of the patents or proprietary rights of others relating to any of our marketed products or product candidates, we may be required to:

pay substantial damages;

stop using our technologies;

stop certain research and development efforts;

develop non-infringing products or methods, which may not be feasible; and

obtain one or more licenses from third parties.

In addition, from time to time, we become aware of third parties who have, or claim to have, intellectual property rights covering matters such as methods for doing business, conducting research, diagnosing diseases or prescribing medications that are alleged to be broadly applicable across sectors of the industry, and we may receive assertions that these rights apply to us. The existence of such intellectual property rights could present a risk to our business.

A license required under any patents or proprietary rights held by a third party may not be available to us, or may not be available on acceptable terms. If we or our licensors or suppliers are



sued for infringement we could encounter substantial delays in, or be prohibited from developing, manufacturing and commercializing our product candidates and advancing our preclinical programs.

*We are dependent on our license agreements and if we fail to meet our obligations under these license agreements, or our agreements are terminated for any reason, we may lose our rights to our in-licensed patents and technologies.*

We are dependent on licenses for intellectual property related to Zanaflex, Fampridine-SR and all of our preclinical programs. Our failure to meet any of our obligations under these license agreements could result in the loss of our rights to this intellectual property. If we lose our rights under any of these license agreements, we may be unable to commercialize a product that uses licensed intellectual property.

We could lose our rights to Fampridine-SR under our license agreement with Elan in countries in which we have a license, including the United States, if we fail to file regulatory approvals within a commercially reasonable time after completion and receipt of positive data from all preclinical and clinical studies required for the related NDA, or any NDA-equivalent. We could also lose our rights under our license agreement with Elan if we fail to launch a product in such countries, within 180 days of NDA or equivalent approval. Elan could also terminate our license agreement if we fail to make payments due under the license agreement. If we lose our rights to Fampridine-SR our prospects for generating revenue and recovering our substantial investment in the development of this product would be materially harmed.

#### **Risks relating to our common stock**

*Our stock price may be volatile and you may lose all or a part of your investment.*

Prior to our initial public offering in February 2006, you could not buy or sell our common stock publicly. While our common stock is listed on the Nasdaq Global Market, an active public market for our common stock may not be sustained. You may not be able to sell your shares quickly or at the current market price if trading in our stock is not active. Our stock price could fluctuate significantly due to a number of factors, including:

achievement or rejection of regulatory approvals by us or by our competitors;

publicity regarding actual or potential clinical trial results or updates relating to products under development by us or our competitors;

announcements of new corporate partnerships, alliances, financings or other transactions, or of technological innovations or new commercial products by our competitors or by us;

developments concerning proprietary rights, including patents;

developments concerning our collaborations;

economic or other crises or other external factors;

conditions or trends in the pharmaceutical or biotechnology industries;

litigation and other developments relating to our patents or other proprietary rights or those of our competitors;

governmental regulation and legislation in the United States and foreign countries;

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changes in securities analysts' estimates of our performance or our failure to meet analysts' expectations;

sales of substantial amounts of our stock;

delay or failure in initiating, completing or analyzing pre-clinical trials or unsatisfactory design or result of these trials;

variations in product revenue and profitability;

variations in our anticipated or actual operating results; and

delays in completing Phase IV trials if required by the FDA.

Many of these factors are beyond our control, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues, if any, in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

In addition, the stock markets in general, and the Nasdaq Global Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations recently. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

***Future sales of our common stock could cause our stock price to decline.***

If our existing stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. Sales of substantial amounts of shares of our common stock in the public market by our executive officers, directors, 5% or greater shareholders or other shareholders, or the prospect of such sales, could adversely affect the market price of our common stock. As of July 31, 2008, we have outstanding 33,038,025 shares of voting common stock. We have registered 6,625,910 shares of common stock that are authorized for issuance under our equity compensation plans, including outstanding options to acquire 3,256,370 shares of common stock outstanding as of July 31, 2008, exercisable at an average exercise price of \$12.74 per share. To the extent that option holders exercise outstanding options, there may be further dilution and the sales of shares issued upon such exercises could cause our stock price to drop further.

***If our officers, directors and largest stockholders choose to act together, they may be able to control the outcome of stockholder vote.***

As of July 31, 2008, our officers, directors and holders of 5% or more of our outstanding common stock beneficially own approximately 58.2% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval or mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

*Certain provisions of Delaware law, our certificate of incorporation and our bylaws may delay or prevent an acquisition of us that stockholders may consider favorable or may prevent efforts by our stockholders to change our directors or our management, which could decrease the value of your shares.*

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us, and may have the effect of preventing or hindering any attempt by our stockholders to replace our current directors or officers. These provisions include:

Our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors.

Our board of directors may issue, without stockholder approval, shares of preferred stock with rights, preferences and privileges determined by the board of directors. The ability to authorize and issue preferred stock with voting or other rights or preferences makes it possible for our board of directors to issue preferred stock with super voting, special approval, dividend or other rights or preferences on a discriminatory basis that could impede the success of any attempt to acquire us.

Our board of directors is divided into three classes, each with staggered three-year terms. As a result, only one class of directors will be elected at each annual meeting of stockholders, and each of the two other classes of directors will continue to serve for the remainder of their respective three-year terms, limiting the ability of stockholders to reconstitute the board of directors.

The vote of the holders of 75% of the outstanding shares of our common stock is required in order to take certain actions, including amendment of our bylaws, removal of directors for cause and certain amendments to our certificate of incorporation.

As a Delaware corporation, we are also subject to certain anti-takeover provisions of Delaware law. Under Delaware law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock unless the holders has held the stock for three years or, among other things, the board of directors has approved the transaction. Our board of directors could rely on Delaware law to prevent or delay an acquisition of us, which could have the effect of reducing your ability to receive a premium on your common stock.

Because we do not intend to pay dividends, you will benefit from an investment in our common stock only if it appreciates in value.

We have not paid cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. The success of your investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares.

#### **Risks relating to an equity offering**

*Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.*

The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. See "Risks relating to our common stock Our stock price may be volatile and you may lose all or a part of your investment".

***We expect to sell additional equity securities, which would cause dilution.***

We expect to sell more equity securities in the future to obtain operating funds. We may sell these securities at a discount to the market price. Any future sales of equity will dilute the holdings of existing stockholders, possibly reducing the value of their investment.

***Investors in an equity offering would suffer immediate dilution.***

As of June 30, 2008, we had a net tangible book value of \$130.2 million which yields a net tangible book value of approximately \$3.97 per share of common stock based on 32,813,251 shares of common stock outstanding, assuming no exercise of any options or conversion of an outstanding convertible promissory note. The net tangible book value per share is substantially less than the current market price per share.

If you pay more than the net tangible book value per share for stock in an equity offering, you will suffer immediate dilution.

***As of July 31, 2008, there were 3,256,370 shares of common stock underlying outstanding options, which if exercised could decrease the value of your shares.***

As of July 31, 2008, holders of our outstanding options had the right to acquire 3,256,370 shares issuable on the exercise their stock options, at an average exercise price of \$12.74 per share.

If the holders exercise those options, or similar dilutive securities we may issue in the future, you may experience dilution in the net tangible book value of your common stock. In addition, the sale or availability for sale of the underlying shares in the marketplace could depress our stock price. We have registered or agreed to register for sale all of the underlying shares listed above. Holders of registered underlying shares could resell the shares immediately upon issuance, resulting in significant downward pressure on our stock.

***We will have considerable discretion over the use of the proceeds of an equity offering and may not realize an adequate return.***

We will have considerable discretion in the application of the net proceeds of an equity offering. We may use the net proceeds for various corporate purposes, including potential acquisitions. We may use the proceeds for purposes that do not yield a significant return, if any, for our stockholders.

### FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated herein by reference contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "continue," or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements, since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could materially affect actual results, levels of activity, performance or achievements. Factors that may cause actual results to differ materially from current expectations, which we describe in more detail elsewhere in this prospectus under the heading "Risk Factors," include, but are not limited to:

- delays in obtaining, or failure to obtain FDA approvals;
- inability to successfully market and sell any approved product;
- unfavorable results of our preclinical or clinical testing;
- increased regulation by the FDA and other agencies;
- the introduction of competitive products;
- impairment of license, patent or other proprietary rights;
- failure to implement our strategy; and
- changes in our financial performance and cash requirements.

If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary significantly from what we projected. Any forward-looking statement you read in this prospectus reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, growth strategy and liquidity. We assume no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

The safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, or PSLRA, protects companies from liability for their forward looking statements if they comply with the requirements of the PSLRA.

**USE OF PROCEEDS**

Unless we state otherwise in a prospectus supplement, we will use the net proceeds from the sale of securities by us under this prospectus for general corporate purposes, including capital expenditures. Until we use net proceeds for these purposes, we intend to invest them in short-term, investment-grade, interest-bearing securities.

## DESCRIPTION OF SECURITIES

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If indicated in the applicable prospectus supplement, the terms of the securities that we offer may differ from the terms summarized below. We will also include information in the prospectus supplement, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may sell, from time to time, in one or more offerings:

common stock;

preferred stock;

debt securities; and

warrants.

### Common Stock

We have the authority to issue 80,000,000 shares of common stock, par value \$0.001 per share. As of June 30, 2008, 33,013,235 shares of our voting common stock were outstanding, and a maximum of 3,270,165 shares of common stock were issuable upon the exercise of outstanding options.

The following description of our common stock is only a summary and is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation. Holders of common stock have one vote per share and have no preemption rights. Holders of common stock have the right to participate ratably in all distributions, whether of dividends or assets in liquidation, dissolution or winding up, subject to any superior rights of holders of preferred stock outstanding at the time. See "Preferred Stock" below. There are no redemption or sinking fund provisions applicable to the common stock.

Registrar and Transfer Company is the transfer agent and registrar for our common stock. Their address is 10 Commerce Drive, Cranford, NJ 07016 and their telephone number is (800) 368-5948.

### Preferred Stock

We have the authority to issue 20,000,000 shares of preferred stock. As of June 30, 2008, no shares of our preferred stock were outstanding. The description of preferred stock provisions set forth below is only a summary and is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation and the certificate of designations relating to any series of preferred stock.

The board of directors has the right, without the consent of holders of common stock, to designate and issue one or more series of preferred stock, which may be convertible into common stock at a ratio determined by the board. A series of preferred stock may bear rights superior to common stock as to voting, dividends, redemption, distributions in liquidation, dissolution, or winding up, and other relative rights and preferences. The board may set the following terms of any series of preferred stock, and a prospectus supplement will specify these terms for any series offered:

the number of shares constituting the series and the distinctive designation of the series;

dividend rates, whether dividends are cumulative, and if so, from what date; and the relative rights of priority of payment of dividends;





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voting rights and the terms of the voting rights;

conversion privileges and the terms and condition of conversion, including provision for adjustment of the conversion rate;

redemption rights and the terms and conditions of redemption, including the date or dates upon or after which shares may be redeemable, and the amount per share payable in case of redemption, which may vary under different conditions and at different redemption dates;

sinking fund provisions for the redemption or purchase of shares;

rights in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights of priority of payment; and

any other relative powers, preferences, rights, privileges, qualifications, limitations and restrictions of the series.

The preferred stock will, if issued, be fully paid and nonassessable. The rights of the holders of preferred stock will be subordinate to those of our general creditors.

### **Debt Securities**

The following description, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provision of any 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, 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 may offer under a prospectus supplement may differ from the terms described below. For any debt securities that we may offer, an indenture, a form of which is filed as an exhibit to the registration statement that includes this prospectus, and any supplement to the indenture, which will be filed an exhibit to a current report on Form 8-K and incorporated by reference in this prospectus, will contain additional important terms and provisions.

With respect to any debt securities that we issue, we will issue such debt securities under an indenture, which we would enter into with the trustee named in the indenture. Any indenture would be qualified under the Trust Indenture Act of 1939.

With respect to any debt securities that we issue, 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, and if so, the terms and who the depository will be;

the maturity date;

the principal amount due at maturity;

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

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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 convertible into shares of common stock or preferred stock and, if so, the terms of such conversion;

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;

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

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

the date, if any, after which and the conditions upon 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 to pay dividends or will require us to maintain any asset ratios or reserves;

whether we will be restricted from incurring any additional indebtedness, issuing additional securities, or entering into a merger, consolidation or sale of our business;

a discussion of any material or special United States 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;

any provisions for payment of additional amounts for taxes;

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 of 1986, as amended;

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

events of default;

whether we and/or the debenture trustee may change an indenture without the consent of any holders;

the form of debt security and how it may be exchanged and transferred;

description of the debenture trustee and paying agent, and the method of payments; and

any other specified terms, preferences, rights or limitations of, or restrictions on, the debt securities and any terms that may be required by us or advisable under applicable laws or regulations.

## Warrants

The following description, together with the additional information we may include in any applicable prospectus supplement, summarizes the material terms and provisions of any 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 a prospectus supplement may differ from the terms described below. With respect to any warrants that we offer, specific warrant agreements will contain additional important terms and provisions and 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, incorporated by reference in this prospectus.

*General.* With respect to any warrants that we offer, 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 or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon exercise;

in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at which, and currently in which, this principal amount of debt securities may be purchased upon exercise;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement 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 agreement 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.

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Before exercising their warrants, the holders of such warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on, the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture; or

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in the case of warrants to purchase common stock or preferred stock, 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.* With respect to any warrants that we issue, 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. New York time on the expiration date 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 the warrants ("cashless exercise").

*Enforceability of Rights by Holders of Warrants.* With respect to any warrants that we issue, each 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.



**DELAWARE LAW AND CERTAIN CHARTER AND BYLAW PROVISIONS**

**Section 203 of the Delaware General Corporation Law**

We are subject to Section 203 of the Delaware General Corporation Law, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the time that such stockholder became an interested stockholder, unless:

prior to such time, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (a) by persons who are directors and also officers and (b) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

In general, Section 203 defines "business combination" to include the following

any merger or consolidation involving the corporation and the stockholder;

any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

subject to certain exception, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines "interested stockholder" as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

**Certificate of Incorporation and Bylaws**

Our amended and restated certificate of incorporation and amended and restated bylaws include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or our management. For example, our amended and restated certificate of incorporation authorizes the issuance of up to 20,000,000 shares of preferred stock, par value \$.001 per share. The board of directors has the authority, without approval of the stockholders, to issue and determine the rights and preferences of series of preferred stock. The ability to authorize and issue preferred stock with voting or other rights or preferences makes it possible for our board of directors to issue preferred stock with super voting, special approval, dividend or other rights or preferences on a discriminatory basis that could impede the success of any attempt to acquire us.



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Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our board of directors is divided into three classes, each serving staggered three-year terms ending at the annual meeting of our stockholders. All directors elected to our classified board of directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. Members of the board of directors may only be removed for cause and only by the affirmative vote of 75% of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of our board of directors.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that a meeting of stockholders may only be called by our board of directors, the chairman of our board of directors or our chief executive officer. Our amended and restated bylaws also specify requirements as to the form and content of a stockholder's notice. The provisions may delay or preclude stockholders from calling a meeting of stockholders, bringing matters before a meeting of stockholders or from making nominations for directors at a stockholders' meeting, which could delay or deter takeover attempts or changes in management. Our amended and restated certificate of incorporation also does not provide for cumulative voting. The absence of cumulative voting may make it more difficult for stockholders owning less than a majority of our stock to elect any directors to our board of directors.

**PLAN OF DISTRIBUTION**

We may sell securities under this prospectus in public offerings:

through one or more underwriters or dealers

through other agents; or

directly to purchasers.

The securities that we may sell under this prospectus may be priced:

at a fixed public offering price or prices, which may be changed from time to time;

at market prices prevailing at the times of sale;

at prices calculated by a formula based on prevailing market prices;

at negotiated prices; or

in a combination of any of the above pricing methods.

If we use underwriters for an offering, they will acquire securities for their own account and may resell them from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all the securities offered by the prospectus supplement. The public offering price and any discounts or concessions allowed or reallocated or paid to dealers may change from time to time. Only underwriters named in a prospectus supplement are underwriters of the securities offered by that prospectus supplement.

We may also sell securities directly or through agents. We will name any agent involved in an offering and we will describe any commissions we will pay the agent in the applicable prospectus supplement. Unless the prospectus supplement states otherwise, our agents will act on a best-efforts basis.

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 of these contracts and the commissions we must pay for solicitation of these contracts in the applicable prospectus supplement.

We may provide agents and underwriters with indemnification against certain civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to such liabilities. Underwriters or agents may engage in transactions with us, or perform services for us, in the ordinary course of business. We may also use underwriters or agents with whom we have a material relationship. We will describe the nature of any such relationship in the applicable prospectus supplement.

An underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934. Overallotment 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 securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriter to reclaim a selling concession from a dealer when the securities originally sold by the dealer are



purchased in a covering transaction to cover short positions. These activities may cause the price of our securities to be higher than it would otherwise be on the open market. The underwriter may discontinue any of these activities at any time.

All securities we offer, other than common stock, will be new issues of securities, with no established trading market. Underwriters may make a market in these securities, but will not be obligated to do so and may discontinue market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

In compliance with guidelines of the Financial Industry Regulatory Authority, Inc. or the FINRA, the maximum commission or discount to be received by any FINRA member or independent broker-dealer may not exceed 8% of the aggregate amount of the securities offered by this prospectus; however, it is anticipated that the maximum commission or discount to be received in any particular offering of securities will be significantly less than this amount.

**RATIO OF EARNINGS TO FIXED CHARGES AND TO COMBINED FIXED CHARGES AND PREFERRED STOCK DIVIDENDS**

**Ratio of Earnings to Fixed Charges**

The ratio of earnings to fixed charges is computed by dividing earnings by fixed charges. Earnings consist of income before income taxes plus fixed charges. Fixed charges consist of interest expense, including amortized discounts, premiums and capitalized expenses related to indebtedness.

The following table sets forth our ratios of earnings to fixed charges for the periods indicated (deficiencies in thousands):

|                                    | Six Months Ended | Year Ended December 31, |            |            |            | Six Months Ended  | Year Ended    |
|------------------------------------|------------------|-------------------------|------------|------------|------------|-------------------|---------------|
|                                    | June 30, 2008    | 2007                    | 2006       | 2005       | 2004       | December 31, 2003 | June 30, 2003 |
| Ratio of earnings to fixed charges | *                | *                       | *          | *          | *          | *                 | *             |
| Deficiency                         | \$(35,253)       | \$(37,975)              | \$(60,631) | \$(65,721) | \$(74,675) | \$(50,908)        | \$(50,684)    |

\*  
Less than one-to-one coverage.

**Ratio of Earnings to Combined Fixed Charges and Preferred Stock Dividends**

The ratio of earnings to combined fixed charges and preferred stock dividends is computed by dividing earnings by the sum of fixed charges and preferred stock dividends. Earnings consist of income before income taxes plus fixed charges. Fixed charges consist of interest expense, including amortized discounts, premiums and capitalized expenses related to indebtedness.

We have not included a ratio of earnings to combined fixed charges and preferred stock dividends because we have not paid any preferred stock dividends during the five fiscal years ended December 31, 2007 nor for the six-month period ended June 30, 2008.

## LEGAL MATTERS

Unless otherwise specified in any applicable prospectus supplement, the validity of the securities covered by this prospectus will be passed upon for us by Covington & Burling LLP, New York, New York.

## EXPERTS

The consolidated financial statements of Acorda Therapeutics, Inc. as of December 31, 2007 and 2006 and each of the years in the three year period ended December 31, 2007, and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2007, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2007 consolidated financial statements contains an explanatory paragraph that refers to Acorda Therapeutics, Inc.'s adoption of Statement of Financial Accounting Standards No. 123R "Share-based Payments", as of January 1, 2006.

## WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement on Form S-3ASR that we filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules of the SEC. We are a public company and file proxy statements and annual, quarterly and special reports and other information with the SEC. The registration statement, such reports and other information can be inspected and copied at the Public Reference Room of the SEC located at 100 F Street, N.E., Washington D.C. 20549. Copies of such materials, including copies of all or any portion of the registration statement, can be obtained from the Public Reference Room of the SEC at prescribed rates. You can call the SEC at 1-800-SEC-0330 to obtain information on the operation of the Public Reference Room. Such materials may also be accessed electronically by means of the SEC's home page on the Internet ([www.sec.gov](http://www.sec.gov)).



**INCORPORATION OF INFORMATION BY REFERENCE**

We incorporate into this prospectus information contained in documents which we file with the Securities and Exchange Commission. We are disclosing important information to you by referring you to those documents. The information which we incorporate by reference is an important part of this prospectus, and certain information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below, and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934:

annual report on Form 10-K for the year ended December 31, 2007, filed on March 14, 2008;

quarterly reports on Form 10-Q for the quarters ended March 31, 2008, filed on May 9, 2008, and for the quarter ended June 30, 2008, filed on August 5, 2008;

current reports on Form 8-K, filed on January 28, 2008, February 4, 2008, February 6, 2008, February 11, 2008, February 14, 2008, March 19, 2008, April 4, 2008, June 2, 2008 and July 30, 2008;

the description of our common stock in our Registration Statement on Form S-1/A (File No. 333-128827) filed on February 9, 2006, including any amendment or reports filed for the purpose of updating this description.

You may access our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to any of these reports, free of charge on the SEC's website. Information contained on, or that can be accessed through, our website is not part of this prospectus.

In addition, we will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, other than exhibits to those documents. You should direct any requests for documents to Corporate Secretary, Acorda Therapeutics, Inc., 15 Skyline Drive, Hawthorne, New York 10532, or call (914) 347-4300.

**Common Stock**  
**Preferred Stock**  
**Debt Securities**  
**Warrants**  
**Units**

**Acorda Therapeutics, Inc.**

The date of this prospectus is August 6, 2008

**PROSPECTUS**

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**PART II. INFORMATION NOT REQUIRED IN PROSPECTUS****ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

We will bear all expenses, estimated at \$281,395, incurred in connection with the registration of the securities offered in this registration statement under the Securities Act of 1933 and qualification or exemption of the registered securities under state securities laws.

|                                  |                   |
|----------------------------------|-------------------|
| SEC registration fees            | \$ 5,895          |
| Costs of printing and engraving* | 25,000            |
| Legal fees and expenses*         | 150,000           |
| FINRA Fee                        | 15,500            |
| Accountants fees and expenses*   | 75,000            |
| Miscellaneous*                   | 10,000            |
| <b>TOTAL*</b>                    | <b>\$ 281,395</b> |

\*

Estimated.

**ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

The Registrant is a Delaware corporation. Section 145 of the Delaware General Corporation Law, or the DGCL, grants each corporation organized thereunder the power to "indemnify any person who is or was a director, officer, employee or agent of a corporation or enterprise, against expenses, attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of being or having been in any such capacity if he acted in good faith in a manner reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful."

Section 102(b)(7) of the DGCL enables a corporation in its certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director to the corporation or its stockholders for monetary damages for violations of the directors' fiduciary duty of care, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL (providing for liability of directors for unlawful payment of dividends or unlawful stock purchases or redemptions) or (iv) for any transaction from which a director derived an improper personal benefit.

Article Seven of the Registrant's Amended and Restated Certificate of Incorporation (filed as Exhibit 3.3) provides that except as otherwise provided by the DGCL, no director of the Registrant shall be personally liable to the Registrant or its stockholders for monetary damages for breach of fiduciary duty as a director.

Article Eight of the Registrant's Amended and Restated Certificate of Incorporation provides that, to the fullest extent permitted by the DGCL, the Registrant shall indemnify any current or former director or officer of the Registrant and may, at the discretion of the Board of Directors, indemnify any current or former employee or agent of the Registrant against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was a director or officer of the Registrant, or is or was serving as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise.

**ITEM 16. EXHIBITS**

The exhibits listed on the Index of Exhibits to this registration statement are filed herewith or are incorporated herein by reference to other filings.

**ITEM 17. UNDERTAKINGS**

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;
  - (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 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 a 20% 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;  
*Provided, however, that:* Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of 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.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
  - (i) If the registrant is relying on Rule 430B:
    - (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
    - (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the



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information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii)

If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(iii)

That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(1)

Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(2)

Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(3)

The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(4)

Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

The undersigned registrant hereby undertakes 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

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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.

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 foregoing 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, 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.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

The undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act of 1939 ("Act") in accordance with the rules and regulations prescribed by the Commission under section 305(b)(2) of the Act.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3ASR and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on August 6, 2008.

ACORDA THERAPEUTICS, INC.

By: */s/* RON COHEN, M.D.

---

Ron Cohen, M.D.

*President and Chief Executive Officer*

II-5

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**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Ron Cohen as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for the undersigned and in his name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this Registration Statement and to sign any Registration Statement that is to be effective on filing pursuant to Rule 462(b) promulgated under the Securities Act of 1933, and all post-effective amendments thereto, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, and each of them, full power of 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 he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, each acting alone, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

| <b>Signature</b>  | <b>Title</b>   | <b>Date</b>    |
|---|--|----------------|
| <u>/s/ RON COHEN, M.D.</u><br>Ron Cohen, M.D.                           | President, Chief Executive Officer<br>and Director (Principal Executive<br>Officer)          | August 6, 2008 |
| <u>/s/ DAVID LAWRENCE, M.B.A.</u><br>David Lawrence, M.B.A.             | Chief Financial Officer (Principal<br>Financial Officer and Principal<br>Accounting Officer) | August 6, 2008 |
| <u>/s/ BARRY GREENE</u><br>Barry Greene                                 | Director   | August 6, 2008 |
| <u>/s/ SANDRA PANEM, PH.D.</u><br>Sandra Panem, Ph.D.                   | Director   | August 6, 2008 |
| <u>Barclay A. Phillips</u>  | Director   | August 6, 2008 |
| <u>/s/ LORIN J. RANDALL</u><br>Lorin J. Randall                         | Director   | August 6, 2008 |
| <u>/s/ STEVEN M. RAUSCHER,<br/>M.B.A.</u><br>Steven M. Rauscher, M.B.A. | Director   | August 6, 2008 |
| <u>Ian Smith</u>  | Director   | August 6, 2008 |
| <u>Wise Young, Ph.D., M.D.</u>  |  | August 6, 2008 |

**Exhibit Index**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 1.1*               | Underwriting Agreement   |
| 3.3                | Amended and Restated Certificate of Incorporation of the Registrant. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, No. 333-138842, filed on November 20, 2006. |
| 3.4                | Amended and Restated Bylaws of the Registrant. Incorporated herein by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on March 21, 2007.   |
| 4.1                | Specimen Stock Certificate evidencing shares of common stock. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.          |
| 4.2*               | Form of Securities Purchase Agreement  |
| 4.3*               | Certificate of Designation of Preferred Stock and Form of Preferred Stock Certificate  |
| 4.4                | Form of Indenture  |
| 4.5                | Form of Note (included in Exhibit 4.4)   |
| 4.6*               | Form of Warrant Certificate  |
| 5.1                | Opinion of Covington & Burling LLP   |
| 12.1               | Calculation of Ratio of Earnings to Fixed Charges and Preferred Stock Dividends  |
| 23.1               | Consent of KPMG LLP, Independent Registered Public Accounting Firm   |
| 23.2               | Consent of Covington & Burling LLP (included in Exhibit 5.1)   |
| 24.1               | Power of Attorney (included on the signature pages hereto)   |
| 25.1               | Statement of Eligibility of Trustee on Form T-1  |

\*

To be filed by amendment, or as an exhibit to a current report on Form 8-K and incorporated by reference, or incorporated by reference from a subsequent filing in accordance with Section 305(b)(2) of the Trust Indenture Act of 1939, as applicable.

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