

ACORDA THERAPEUTICS INC

Form S-3/A

June 04, 2007

As filed with the Securities and Exchange Commission on June 4, 2007

Registration No. 333-143348

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Amendment No. 1 to

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:

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Ellen B. Corenswet

Covington & Burling LLP

1330 Avenue of the Americas

New York, New York 10019

(212) 841-1000

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective. o

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

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. x

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. o

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. o

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. o

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. o

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(2)	Amount of registration fee(2)
Common Stock, Preferred Stock, Debt Securities, Warrants, Units(3)	(4)	(4)	\$ 150,000,000(4)	\$ 4,605
Common Stock(5)	1,370,740	\$ 20.95(2)	\$ 28,713,203	\$ 882
Total			\$ 178,713,203	\$ 5,487

(1) In addition to the securities listed in the table, pursuant to Rule 416 under the Securities Act of 1933, this Registration Statement will cover any additional securities which become issuable from time to time as a result of a stock split, stock dividend or other similar transactions.

(2) With respect to the securities to be sold by us, the proposed maximum aggregate offering price has been estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933. With respect to the shares of our common stock to be sold by the selling stockholders, the proposed maximum aggregate offering price has been estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933 on the basis of the average of the high and low sale prices of our common stock as reported on the Nasdaq Global Market on May 25, 2007, which was approximately \$20.95 per share. With respect to the additional 3,040 shares of our common stock that are being registered under this Amendment No. 1 to the Registration Statement with respect to one of the selling stockholders, the proposed maximum aggregate offering price has been estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933 on the basis of the average of the high and low sale prices of common stock as reported on the Nasdaq Global Market June 1, 2007, which was approximately \$19.70 per share.

(3) Includes an indeterminate number of securities that may be issued in primary offerings or upon exercise, conversion or exchange of any securities registered hereunder that provide for exercise, conversion or exchange.

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

(5) Consists of an aggregate of up to 1,370,740 shares of common stock that the selling stockholders identified in the prospectus contained herein may sell, including (a) 67,476 shares of common stock issuable upon the conversion of outstanding convertible promissory notes and (b) an additional 3,040 shares of common stock that we are registering under this amendment No. 1 to the Registration Statement with respect to one of the selling stockholders.

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

SUBJECT TO COMPLETION, DATED JUNE 4, 2007

The information in this prospectus supplement is not complete and may change. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and they are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

**Prospectus Supplement
(To Prospectus dated June 4, 2007)**

3,500,000 Shares

Common Stock

We are offering 3,376,960 shares of our common stock, par value \$0.001 per share, and the selling stockholders identified in this prospectus supplement are offering 123,040 shares of our common stock. We will not receive any proceeds from the sale of shares being sold by the selling stockholders.

Our common stock is listed on the Nasdaq Global Market under the symbol ACOR. The last reported sale price of our common stock on the Nasdaq on June 1, 2007 was \$19.70 per share.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-8 of this prospectus supplement for the factors you should consider before buying shares of our common stock.

	Per share	Total
Offering price	\$	\$
Discounts and commissions to underwriters	\$	\$
Offering proceeds to Acorda Therapeutics, Inc., before expenses	\$	\$
Offering proceeds to the selling stockholders, before expenses	\$	\$

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

We have granted the underwriters the option to purchase from us up to 525,000 additional shares of common stock on the same terms and conditions as set forth above if the underwriters sell more than 3,500,000 shares in this offering. The underwriters can exercise this option at any time and from time to time, in whole or in part, within 30 days after the offering.

The underwriters expect to deliver the shares against payment on or about June , 2007.

Joint Book-Running Managers

Banc of America Securities LLC

Deutsche Bank Securities

Lazard Capital Markets

Piper Jaffray

Fortis Securities LLC

, 2007

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This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference. The second part is the accompanying prospectus, which gives more general information, some of which may not apply to this offering of common stock. To the extent the information contained in this prospectus supplement differs or varies from the information contained in the accompanying prospectus or any document incorporated by reference, the information in this prospectus supplement shall control.

You should rely only on the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and any free writing prospectus that we authorize to be distributed to you.

We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus before making your investment decision. You should also read and consider the information in the documents we have referred you to in the sections of this prospectus supplement entitled **Where You Can Find More Information and **Incorporation of Information by Reference**.**

PROSPECTUS SUPPLEMENT SUMMARY

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

Overview

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

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

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

Our Product Pipeline

Zanaflex

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

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

We believe that Zanaflex Capsules offer important benefits over Zanaflex tablets and generic tizanidine tablets. When taken with food, Zanaflex Capsules have a different blood absorption profile, referred to as pharmacokinetic profile, than Zanaflex tablets and generic tizanidine tablets, generally resulting in a lower level and more gradual rise of peak levels of tizanidine in a patient's blood. As a result of this different pharmacokinetic profile, Zanaflex tablets and generic tizanidine tablets are not equivalent, or AB-rated, with Zanaflex Capsules. Therefore, under state pharmacy laws, prescriptions written for Zanaflex Capsules may not properly be filled by the pharmacist with Zanaflex tablets or generic tizanidine tablets. Zanaflex Capsules are also available in a higher dose strength, which gives patients and prescribers

an additional choice in dosing and an opportunity to reduce the number of pills a person must take daily. In addition, people who have difficulty swallowing may find Zanaflex Capsules easier to take.

To support and increase sales of Zanaflex Capsules, we have more than doubled the size of our internal specialty sales force since early 2006. As of May 15, 2007, 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 expanded sales and marketing infrastructure enables us to efficiently reach virtually all high-volume prescribers of Zanaflex tablets and generic tizanidine. We believe that many of these prescribers are also potential high-volume prescribers for our lead product candidate, Fampridine-SR, if approved.

Fampridine-SR

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

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

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

Preclinical programs

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

- *Neuregulins.* This program is based on using GGF-2, a neuregulin growth factor to stimulate remyelination, or repair of the myelin sheath. In published studies, GGF-2 has been shown to stimulate remyelination in animal models of MS and to have other effects in neural protection and repair. In addition, the neuregulins have been shown to have potential cardiovascular applications, promoting the growth of heart muscle cell and reversing signs and symptoms in animal models of cardiac damage, such as congestive heart failure.
- *Remyelinating antibodies.* This program is based on research performed at the Mayo Clinic. Studies have demonstrated the ability of this family of antibodies to stimulate remyelination in three different animal models of MS. Currently, there is no available therapy indicated to repair myelin that has been destroyed in MS or other demyelinating diseases.

- *Chondroitinase*. This program is based on the concept of breaking down the matrix of scar tissue that develops as a result of an injury to the CNS. Published research has demonstrated that this scar matrix is partly responsible for limiting the regeneration of nerve fibers in the CNS and restricting their ability to modify existing neural connections. Independent academic laboratories have also published animal studies showing that application of chondroitinase results in recovery of function following injuries to various areas of the brain or spinal cord.

We believe all of our preclinical programs 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:

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

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

Risks Associated with our Business

Our business is subject to numerous risks, as described in the section entitled "Risk Factors" in this prospectus supplement, and in documents incorporated by reference herein. 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; 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 March 31, 2007, had an accumulated deficit of approximately \$239.6 million. We expect to incur losses for at least the next several years. We had net losses of \$7.5 million, \$60.0 million and \$60.4 million for the three-month period ended March 31, 2007, and the years ended December 31, 2006 and 2005, respectively. We are unable to predict the extent of future losses or when we will become profitable, if at all. Even if we succeed in promoting Zanaflex Capsules and developing and commercializing one or more of our product candidates, we may never generate sufficient sales revenue to achieve and sustain profitability.

Corporate Information

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 15 Skyline Drive, Hawthorne, New York 10532. Our telephone number is (914) 347-4300. Our website is www.acorda.com. Please note that all references to www.acorda.com in this prospectus supplement and the accompanying 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 and Zanaflex are registered trademarks that we own. Zanaflex Capsules is a trademark that we own. Other trademarks, trade names and service marks used in this prospectus supplement and the accompanying prospectus are the property of their respective owners.

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The Offering

For a description of our common stock, see **Description of Securities Common Stock** in the accompanying prospectus.

Common stock offered by us	3,376,960 shares
Common stock offered by the selling stockholders	123,040 shares
Common stock outstanding after this offering	27,503,932 shares
Use of proceeds	We intend to use the net proceeds of this offering to complete our second Phase 3 Fampridine-SR clinical trial in MS and to conduct other activities related to the filing of a new drug application, or NDA, for Fampridine-SR, for research and development and for general corporate purposes. See Use of Proceeds .
Dividend Policy	We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business.
Nasdaq Global Market symbol	ACOR
Risk Factors	See Risk Factors beginning on page S-8 and other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

The number of shares of our common stock to be outstanding after this offering is based upon the number of voting shares outstanding as of May 15, 2007 and excludes:

- 3,394,575 shares of common stock issuable, as of May 15, 2007, upon the exercise of outstanding options to purchase our common stock, at a weighted average exercise price of \$9.71 per share;
- 67,476 shares of common stock issuable upon the conversion of an outstanding convertible promissory note; and
- 1,085,009 shares of common stock reserved for issuance under our stock option plans, including our 2006 Employee Incentive Plan.

Unless otherwise stated, information herein assumes that the underwriters will not exercise their option to purchase additional shares.

Summary Consolidated Financial Data

The following summary consolidated financial data should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes appearing in our Annual Report on Form 10-K/A for the year ended December 31, 2006 (2006 Annual Report), and our unaudited financial statements and related notes appearing in our Form 10-Q for the period ended March 31, 2007. These historical results are not necessarily indicative of results to be expected in any future period.

	Three Months Ended March 31, 2007 (unaudited)	Three Months Ended March 31, 2006	Year Ended December 31,		Six Months Ended December 31, 2003	Year Ended June 30, 2003 2002	
	(in thousands, except per share data)						
Statement of Operations Data:							
Gross sales Zanaflex	\$ 8,805	\$ 3,874	\$ 26,548	\$ 5,923	\$	\$	\$
Less: discounts and allowances	(494)	(196)	396	(1,114)	(4,417)		
Net sales	8,311	3,677	26,944	4,809	(4,417)		
Grant revenue	6	122	407	336	479	382	474 132
Total net revenue	8,316	3,799	27,351	5,145	(3,938)	382	474 132
Less: cost of sales	(1,554)	(1,041)	(7,123)	(5,132)	(885)		
Gross profit	6,762	2,759	20,228	13	(4,823)	382	474 132
Operating expenses:							
Research and development	3,244	3,277	12,055	12,890	21,999	16,743	17,527 11,147
Research and development related party						3,343	2,265 4,687
Sales and marketing	6,969	4,562	19,079	13,099	4,662		
General and administrative	4,354	2,278	12,561	8,435	13,283	17,069	6,388 6,636
Total operating expenses	14,567	10,117	43,695	34,424	39,944	37,155	26,180 22,470
Operating loss	(7,805)	(7,358)	(23,467)	(34,411)	(44,767)	(36,773)	(25,706) (22,338)
Other income (expense):							