ACORDA THERAPEUTICS INC
Form S-1/A
January 18, 2006

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As filed with the Securities and Exchange Commission on January 18, 2006

Registration No. 333-128827

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 3 TO

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ACORDA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**2836**	**13-3831168**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(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	**Danielle Carbone**
Covington & Burling	**Shearman & Sterling LLP**
1330 Avenue of the Americas	**599 Lexington Avenue**
New York, New York 10019	**New York, New York 10022**
(212) 841-1000	**(212) 848-4000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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

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 post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434 under the Securities Act, please check the following box. o

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

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

SUBJECT TO COMPLETION, DATED JANUARY 18, 2006

Prospectus

Shares

Common Stock

Acorda Therapeutics, Inc. is offering shares of common stock. This is our initial public offering, and no public market currently exists for our shares. We anticipate that the initial public offering price will be between $ and $ per share. After the offering, the market price for our shares may be outside this range.

We will apply to list our common stock on the Nasdaq National Market under the symbol "ACOR."

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 9.

	Per Share	Total
Offering price	$	$
Discounts and commissions to underwriters	$	$
Offering proceeds to Acorda Therapeutics, Inc., before expenses	$	$

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.

We have granted the underwriters the right to purchase up to additional shares of common stock to cover any over-allotments. The underwriters can exercise this right at any time within 30 days after the offering. The underwriters expect to deliver the shares on or about , 2006.

Banc of America Securities LLC

Lazard Capital Markets

Piper Jaffray

SG Cowen & Co.

, 2006

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

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SUMMARY

This summary highlights information contained elsewhere in this prospectus. You should read the entire prospectus carefully before making an investment decision.

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, is in a Phase 3 clinical trial for the improvement of walking ability in people with MS. Our preclinical programs also target MS and SCI, as well as 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.

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. We plan to accomplish this through our sales and marketing infrastructure, our extensive scientific and medical network, our partnerships and our clinical and management experience.

Our Product Pipeline

Zanaflex

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

In April 2005, we launched Zanaflex Capsules, a new capsule formulation of tizanidine. This product is protected by an issued U.S. patent. Zanaflex tablets lost compound patent protection in 2002 and both products now compete with 11 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 therapeutically 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, 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 our commercialization of Zanaflex Capsules, we have established a sales and marketing infrastructure consisting of our internal specialty sales force, a contract sales force and a pharmaceutical telesales group. Our internal specialty sales force currently consists of 14 sales professionals who call on neurologists and other prescribers specializing in treating patients with conditions that involve spasticity. Members of this sales force also call on managed care organizations, pharmacists and wholesale drug distribution customers. We plan to expand our specialty sales force to approximately 30 sales professionals in the first quarter of 2006. Our contract sales force is provided by Cardinal Health PTS, LLC, or Cardinal Health, and consists of approximately 160 sales representatives who market Zanaflex Capsules to primary care physicians, on a non-exclusive basis. We also have a contract with Access Worldwide Communications to provide a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care physicians, specialty physicians and pharmacists. Our current sales and marketing infrastructure enables us to reach virtually all high-volume prescribers of Zanaflex tablets and generic tizanidine. We believe that these prescribers are also potential high-volume prescribers for our lead product candidate, Fampridine-SR, if approved.

Fampridine-SR

Fampridine-SR is currently in a Phase 3 clinical trial for the improvement of walking ability in people with MS. The trial is being conducted pursuant to a Special Protocol Assessment, or SPA, with the FDA. The FDA has agreed that, if successful, this trial could qualify as one of the pivotal efficacy studies required for drug approval. Fampridine-SR is a small molecule drug contained in a sustained release oral tablet form. Laboratory studies have shown that fampridine, the active molecule 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.

More than 800 people have been treated with Fampridine-SR in over 25 clinical trials, including nine clinical trials in MS and 11 clinical trials in SCI. In six Phase 2 clinical trials, treatment with Fampridine-SR has been associated with a variety of neurological benefits in people with MS or SCI. In our most recently completed Phase 2 clinical trial, there was a trend toward improvement in the primary endpoint of walking speed and, when analyzed using the same methodology that the FDA has now agreed to in the SPA for our Phase 3 clinical trial, these results are statistically significant. We expect the recruitment period for the current Phase 3 clinical trial, which began in June 2005, to end in February 2006. The treatment period is 14 weeks and the subjects are involved in trial procedures for approximately five months. We expect to be able to evaluate data from this clinical trial in the third quarter of 2006.

We believe Fampridine-SR is the first potential therapy in late-stage clinical development for MS that seeks to improve the function of damaged nerve fibers, rather than only treating the symptoms of MS or slowing the progression of disease. To our knowledge, there are no current drug therapies that improve walking ability in people with MS. We plan to commercialize Fampridine-SR, if approved, ourselves in the United States, and possibly Canada, and with partners in various markets throughout the rest of the world.

Preclinical programs

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

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.

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.

Remyelinating antibodies. This program is based on research performed at Mayo Clinic. Studies have demonstrated the ability of this family of antibodies to stimulate remyelination in three different animal models of MS.

We believe that all of our preclinical therapies have the potential to address conditions for which no effective treatment currently exists. In addition to applicability in MS, SCI and various other CNS disorders, we believe that our preclinical programs also may have applicability in such fields as orthopedics, cardiology, oncology 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 and clinical 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:

maximize our revenue opportunity for Zanaflex Capsules;

complete the clinical development and obtain regulatory approval for Fampridine-SR in MS;

leverage the commercial presence of Zanaflex Capsules for the potential market launch of Fampridine-SR;

advance our pipeline of preclinical programs to clinical trials; and

pursue additional alliances for approved and development-stage products.

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

Risks Associated with our Business

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. We may be unable, for many reasons, including those that are beyond our control, to implement our current business strategy. Those reasons

could include failure to successfully promote Zanaflex Capsules and any other future marketed products; delays in obtaining, or a failure to obtain, regulatory approval for our product candidates; and failure to maintain and to protect our proprietary intellectual property assets, among others. The information about our preclinical and clinical trials may be useful to you in evaluating our company's current stage of development and our near-term and long-term prospects; however, you should note that of the large number of drugs in development only a small percentage successfully complete the FDA regulatory approval process and are commercialized.

We have a limited operating history and, as of September 30, 2005, had an accumulated deficit of approximately $198.5 million. We expect to incur losses for at least the next several years. We had net losses of $26.0 million and $44.7 million for the nine months ended September 30, 2005 and for the year ended December 31, 2004, respectively. We are unable to predict the extent of future losses or when we will become profitable, if at all. Even if we succeed in promoting Zanaflex Capsules and developing and commercializing one or more of our product candidates, we may never generate sufficient sales revenue to achieve and sustain profitability.

Corporate Information

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

"Acorda Therapeutics" is a registered trademark that we own and "Zanaflex" is a registered trademark that we exclusively license. We have pending U.S. trademark applications for our logo and "Zanaflex Capsules." Other trademarks, trade names and service marks used in this prospectus are the property of their respective owners.

THE OFFERING

Common stock offered	shares
Common stock outstanding after this offering	shares
Use of proceeds	We intend to use the net proceeds of this offering for sales and marketing activities, clinical and preclinical development programs and for general corporate purposes. See "Use of Proceeds."
Proposed Nasdaq National Market symbol	ACOR
Risk factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

The number of shares of common stock to be outstanding after this offering is based on the number of shares outstanding as of September 30, 2005 and excludes the following:

- 1,816,518 shares of common stock issuable, as of September 30, 2005, upon the exercise of outstanding options and warrants to purchase our common stock, at a weighted average exercise price of $5.13 per share;
- 756,620 shares of restricted stock outstanding as of September 30, 2005;
- 278,339 shares of common stock issuable, as of September 30, 2005, upon the conversion of outstanding convertible promissory notes; and
- 3,000,000 shares of common stock reserved for issuance under our stock option plans, including our 2006 Employee Incentive Plan adopted in January 2006.

Unless we specifically state otherwise, all information in this prospectus, including the number of shares of common stock to be outstanding after this offering:

- assumes the conversion of all outstanding shares of our convertible preferred stock and mandatorily redeemable convertible preferred stock into 13,338,279 shares of our common stock upon the closing of this offering;
- assumes no exercise by the underwriters of their over-allotment option to purchase up to additional shares; and
- gives effect to the 1-for-1.3 reverse stock split of our common stock on January 11, 2006.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following table presents a summary of our historical financial information. You should read this information in conjunction with our consolidated financial statements and related notes and the information under "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus. We changed our fiscal year end from June 30 to December 31, beginning with the six months ended December 31, 2003.

Pro forma amounts in the following table reflect the conversion of our outstanding convertible and mandatorily redeemable convertible preferred stock into 13,338,279 shares of common stock on the closing of this offering, assuming that shares of our preferred stock were outstanding for the entire periods presented.

	Year Ended June 30,			Six Months Ended December 31,	Year Ended December 31,	Nine Months Ended September 30,	
						2004	2005
	2001	2002	2003	2003	2004	(unaudited)	
	(in thousands, except per share data)						
Statement of Operations Data:							
Gross sales Zanaflex	$	$	$	$	$	$	$ 3,239
Less: discounts and allowances					(4,417)	(144)	(992)
Net sales					(4,417)	(144)	2,247
Grant revenue	462	132	474	382	479	445	184
Total net revenue	462	132	474	382	(3,938)	(301)	2,431
Less: cost of sales					(885)	(363)	(2,274)
Gross profit	462	132	474	382	(4,823)	(62)	157
Operating expenses:							
Research and development	6,142	11,147	17,527	16,743	21,999	18,621	9,652
Research and development related party	2,223	4,687	2,265	3,343			
Sales and marketing					4,662	2,793	9,657
General and administrative	3,489	6,636	6,388	17,069	13,283	11,034	6,339
Total operating expenses	11,854	22,470	26,180	37,155	39,944	32,448	25,648
Operating loss	(11,392)	(22,338)	(25,706)	(36,773)	(44,767)	(32,510)	(25,491)
Other income (expense):							
Interest and amortization of debt discount expense			(78)	(38)	(385)	(297)	(824)
Interest and amortization of debt discount expense related party	(443)	(408)	(369)	(184)			
Interest income	1,824	984	393	276	409	329	347
Other income			26	7	2	2	1
Total other income (expense)	1,381	576	(28)	61	26	34	(476)
Minority interest related party	699	580					
							3

						Nine Months Ended September 30,	
Cumulative effect of change in accounting principle							
Net loss	(9,313)	(21,181)	(25,734)	(36,712)	(44,741	(32,476)	(25,964)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders	(36)	(55)	(24,320)	(11,985)	) (24,746)	(18,496)	(18,636)
Net loss allocable to common stockholders	$ (9,349)	$ (21,236)	$ (50,054)	$ (48,697)	$ (69,487)	$ (50,972)	$ (44,600)
Net loss per share allocable to common stockholders basic & diluted	$ (50.81)	$ (111.90)	$ (261.38)	$ (252.87)	$ (351.76)	$ (259.22)	$ (221.17)

	Year Ended June 30,			Six Months Ended December 31,	Year Ended December 31,	Nine Months Ended September 30,	
	2001	2002	2003	2003	2004	2004	2005
						(unaudited)	
Pro forma net loss per share allocable to common stockholders basic & diluted (unaudited)					$ (9.63)		$ (1.92)
Weighted average shares of common stock outstanding used in computing net loss per share allocable to common stockholders basic & diluted	184	190	191	193	198	197	202
Weighted average shares of common stock outstanding used in computing pro forma net loss per share allocable to common stockholders basic & diluted (unaudited)					13,536		13,547

The following table sets forth our cash, cash equivalents and short-term investments and capitalization as of September 30, 2005:

on an actual basis giving retroactive effect to the 1-for-1.3 reverse stock split on January 11, 2006;

on a pro forma basis to reflect:

our entry into a revenue interest assignment arrangement with an affiliate of Paul Royalty Fund, or PRF, on December 23, 2005, including (i) our receipt at signing of a payment in the amount of $15.0 million, (ii) our use of approximately $3.0 million of that payment to repay a portion of the amount we owe to GE Capital and approximately $700,000 of that payment to pay fees and expenses related to the transaction, including expenses incurred by PRF, (iii) our recognition of a revenue interest liability of approximately $14.6 million, (iv) our recognition of a put/call option liability of approximately $400,000, and (v) our capitalization of approximately $500,000 in fees and expenses related to the transaction; and

the automatic conversion of all of our outstanding convertible preferred stock and mandatorily redeemable convertible preferred stock into 13,338,279 shares of common stock on the closing of this offering; and

on a pro forma basis as adjusted to reflect our receipt of net proceeds from the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share (the midpoint of the estimated price range shown on the cover of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses.

	As of September 30, 2005		
	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma As Adjusted (unaudited)
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 3,581	$ 14,879	
Restricted cash	261	261	
Short-term investments	5,160	5,160	
Working capital	(12,203)	(14,207)	
Capitalized transaction costs PRF transaction		500	
Total assets	25,543	37,842	
Deferred product revenue Zanaflex Capsules	4,960	4,960	
Deferred product revenue Zanaflex tablets	10,686	10,686	
Current portion of notes payable	2,347	1,150	
Revenue interest liability PRF transaction		14,600	
Put/call option liability PRF transaction		400	
Long-term portion of notes payable	3,534	1,731	
Long-term convertible notes payable principal amount plus accrued interest, less unamortized debt discount related party	8,695	8,695	
Mandatorily redeemable preferred stock	85,000		
Total stockholders' (deficit)	(101,669)	(16,869)	

RISK FACTORS

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

Risks Related To Our Business

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

As of September 30, 2005, we had an accumulated deficit of approximately $198.5 million. We had net losses of $26.0 million and $44.7 million for the nine months ended September 30, 2005, and the year ended December 31, 2004, 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:

- market and sell Zanaflex Capsules;
- obtain FDA approval for and commercialize Fampridine-SR;
- continue to develop our preclinical product candidates and advance them into clinical trials; and
- enter into strategic partnerships and collaboration arrangements related to our drug discovery programs and product candidates.

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

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

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

If we are unable to successfully differentiate Zanaflex Capsules from both Zanaflex tablets and generic tizanidine tablets we may not be able to increase sales of Zanaflex Capsules.

There are currently 11 generic versions of tizanidine tablets on the market and they are significantly cheaper than either Zanaflex Capsules or Zanaflex tablets. In 2004, these generic versions of tizanidine tablets constituted 95% of tizanidine sales in the United States. Although Zanaflex Capsules have a different pharmacokinetic profile when taken with food and are available in a higher dose than Zanaflex tablets and their generic equivalents, we may be unsuccessful in convincing prescribers, patients and third-party payors that these differences justify the higher price of Zanaflex Capsules. Prescribers may prescribe generic tizanidine tablets instead of Zanaflex Capsules, and third-party payors may establish unfavorable reimbursement policies for Zanaflex Capsules or otherwise seek to encourage patients and prescribers to use generic tizanidine tablets instead of Zanaflex Capsules. In

addition, although the FDA has determined that neither Zanaflex tablets nor generic tizanidine tablets are therapeutically equivalent, or "AB-rated," to Zanaflex Capsules, it is possible that pharmacists may improperly fill prescriptions with generic tizanidine tablets or may seek to influence patients or physicians to change prescriptions from Zanaflex Capsules to generic tizanidine tablets. If we are unable to successfully differentiate Zanaflex Capsules from Zanaflex tablets and generic tizanidine tablets in the minds of prescribers, pharmacists, patients and third-party payors, our ability to generate meaningful revenue from this product will be adversely affected.

Our company has limited sales and marketing experience and we may not be successful in building an effective sales and marketing organization to market Zanaflex Capsules to specialty physicians.

As a company, we have limited sales and marketing experience, having only launched Zanaflex Capsules in April 2005. In order to successfully commercialize Zanaflex Capsules or any other products that we may bring to market, we will need to have adequate sales, marketing and distribution capabilities. Although we plan to expand our internal specialty sales force of 14 persons to approximately 30 persons in the first quarter of 2006, we may need to further expand that sales force in the future. We may not be able to attract and train skilled sales and marketing personnel, in a timely manner or at all, or integrate and manage a growing sales and marketing organization.

Returns of Zanaflex tablets may adversely affect our results of operations.

Prior to the launch of generic tizanidine tablets in June 2002, wholesalers established larger than normal inventories of Zanaflex tablets. These inventories had expiration dates that extended to June 2005. Our return policy is to accept returns for six months before and 12 months after the product's expiration date. According to our Zanaflex asset purchase agreement with Elan, we are responsible for all returns of Zanaflex tablets after January 17, 2005. Zanaflex tablets sold by Elan can be returned to us through June 2006. In the year ended December 31, 2004, we took a $4.1 million charge to establish a reserve for expected returns of Zanaflex tablets sold by Elan. This charge is an estimate. If returns for products not sold by us are higher than we have estimated, we will have to record additional charges, which will adversely affect our results of operations.

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

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

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

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

FDA approval of new drugs that are more effective than our product candidates;

change in the focus of our development efforts or a re-evaluation of our clinical development strategy; and

a change in our financial position.

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

If our Phase 3 clinical trials of Fampridine-SR are unsuccessful, or if we are unable to obtain regulatory approval for this product candidate or any approval is unduly limited in scope, our business prospects will be adversely affected.

In June 2005, we initiated a Phase 3 clinical trial for Fampridine-SR for the improvement of walking ability in patients with MS. In April 2004, we released results from a Phase 2 clinical trial designed to assess the relative safety and efficacy of varying doses of Fampridine-SR in MS. Our results did not reach statistical significance for the primary endpoint in this trial. Although we have designed the current Phase 3 clinical trial to address the difficulties we encountered in interpreting the patient data from the earlier trial, we cannot be sure that the results from our current clinical trial will be statistically significant.

To achieve the primary endpoint in our current Phase 3 clinical trial for MS, we need to show statistical improvement in the walking speed of the patients in the trial and that this improvement is both sustained and clinically meaningful to these patients. If we fail to achieve the primary endpoint in this clinical trial or the results are ambiguous, we will have to determine whether to re-design our MS trial and protocols and continue with additional testing, or cease development activities in this area. Redesigning the program could be extremely costly and time-consuming. Even if we are able to achieve the primary endpoint, we will need positive results from at least one other clinical trial to support the filing of a new drug application, or NDA, with the FDA. We cannot predict how long the second trial, or any additional trial that might be required by the FDA, will take or what the cost will be.

Our Phase 3 clinical trial for Fampridine-SR in MS is being conducted pursuant to a special protocol assessment, or SPA, with the FDA and the FDA has agreed that, if successful, this trial could qualify as one of the pivotal trials needed to support regulatory approval. This SPA may not be changed by either us or the FDA. However, if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of Fampridine-SR is identified after the trial began, the FDA may alter its conclusion on the adequacy of the protocol. In addition, even if the SPA remains in place and the trial meets its primary endpoint, 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. If the FDA denies approval of Fampridine-SR in MS, FDA approval is substantially delayed, approval is granted on a narrow basis or with restricted distribution or other burdensome post-approval requirements, or if the Fampridine-SR program is terminated, our business prospects will be adversely affected.

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

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 promising product candidates, complete preclinical development of these product candidates and advance them to clinical trials. These product candidates will require significant development, preclinical studies and clinical trials, regulatory clearances and substantial additional investment before they can be commercialized.

Our preclinical programs may not lead to commercially viable products for several reasons. For example, we may fail to identify promising product candidates, our product candidates may fail to be safe and effective in preclinical tests or clinical trials, or we may have inadequate financial or other resources to pursue discovery and development efforts for new product candidates. In addition, because we have limited resources, we are focusing on product candidates that we believe are the most promising. As a result, we may delay or forego pursuit of opportunities with other product candidates. From time to time, we may establish and announce certain development goals for our product candidates and programs; however, given the complex nature of the drug discovery and development process, it is difficult to predict accurately if and when we will achieve these goals. If we are unsuccessful in advancing our preclinical programs into clinical testing or in obtaining regulatory approval, our long-term business prospects will be harmed.

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

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

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

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

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

manufacturing practices may result in the termination of clinical studies, restrictions in the sale of, or withdrawal of the products from the market. Compliance by third parties with these standards and practices is outside of our direct control.

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

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

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

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

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

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

We may experience pressure to lower prices on our approved products due to new and/or proposed federal legislation.

Federal legislation enacted in December 2003 added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided primarily through private entities,

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

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

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Composition of matter patents on tizanidine, the active ingredient in Zanaflex Capsules and Zanaflex tablets, expired in 2002. There are currently 11 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 a meaningful amount of 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.

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 is 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.

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.

On September 30, 2005, on a pro forma as-adjusted basis after giving effect to this offering and our entry into our revenue interest assignment arrangement with PRF, we would have had approximately $ million in cash, cash equivalents and short-term investments. Although we anticipate this will be sufficient to fund our operations for approximately the next 24 months, 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 likely 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 fewer resources to marketing Zanaflex Capsules.

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

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

Under our arrangement with PRF, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events, transfer any of our interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfer all or substantially all of our assets, or breach certain of the covenants, representations or warranties under the revenue interests assignment agreement, PRF may (i) require us to repurchase the rights we assigned to it at the "put/call price" in effect on the date such right is exercised or (ii) foreclose on the Zanaflex assets that secure our obligations to PRF. Except in the case of certain bankruptcy events, if PRF exercises its right to cause us to repurchase the rights we assigned to it, PRF may not foreclose unless we fail to pay the put/call price as required. The put/call price on a given date is the greater of (i) 150% of all payments made by PRF to us as of such date, less all payments received by PRF from us as of such date, and (ii) an amount that would generate an internal rate of return to PRF of 25% on all payments made by PRF to us as of such date, taking into account the amount and timing of all payments received by PRF from us as of such date.

If PRF were to exercise its right to cause us to repurchase the right we assigned to it, we cannot assure you that we would have sufficient funds available to pay the put/call price in effect at that time. Even if we have sufficient funds available, we may have to use funds that we planned to use for other purposes and our results of operations and financial condition could be adversely affected. If PRF were to foreclose on the Zanaflex assets that secure our obligations to PRF, our results of operations and

financial condition could also be adversely affected. Because PRF's right to cause us to repurchase the rights we assigned to it is triggered by, among other things, a change in control, transfer of any of our interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement) or transfer of all or substantially all of our assets, the existence of that right could discourage us or a potential acquirer from entering into a business transaction that would result in the occurrence of any of those events.

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

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

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

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

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

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

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

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

We have an outstanding commitment with the FDA, inherited from Elan, to evaluate Zanaflex Capsules for pediatric use by February 2007, in accordance with the requirements of the Pediatric Research Equity Act, or PREA. The NDA for Zanaflex Capsules was approved with a plan to address the requirements of the PREA through a pediatric pharmacokinetic study. We have submitted a proposed design for this pharmacokinetic study to the FDA. Depending on the FDA's response to our submission or the outcome of this study, we may be required to conduct additional studies. These studies could be more extensive and more costly than the currently-planned study.

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 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. For example, the FDA recently completed an inspection relating to our adverse event and product complaint handling and reporting for Zanaflex. The FDA has informed us that there are several observations that they will be including in a Form 483, Inspectional Observations. We have completed or expect to complete shortly all necessary corrective actions. The cost of the corrective actions is not expected to be material.

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, Vermont, Maine, Minnesota, New Mexico and West Virginia, 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.

Vermont, Maine, Minnesota, New Mexico, and West Virginia have also enacted statutes of varying scope that impose reporting and disclosure requirements upon pharmaceutical companies pertaining to drug pricing and payments and costs associated with pharmaceutical marketing, advertising and promotional activities, as well as restrictions upon the types of gifts that may be provided to healthcare practitioners. Similar legislation is being considered in other states. Many of these 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 currently in the process of developing a 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 these 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, buprenophine, sodium pentobarbital, ether, acetonitrile, hexanes, chloroform, xylene, dehydrated alcohol, methanol, ethyl alcohol, isopropanol and formaldehyde. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. If we fail to comply with environmental regulations, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any substantial liability could exceed our resources. We currently maintain a general liability insurance policy that has a $2 million per claim limit and also caps aggregate claims at $2 million. In addition, we have an umbrella insurance policy that covers up to $9 million of liability in excess of the general liability policy's $2 million limit. This amount of insurance coverage may not be adequate to cover all liabilities or defense costs we might incur. In addition, the cost of compliance with environmental and health and safety regulations may be substantial.

Risks Related to Our Dependence on Third Parties

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

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

We rely on a single manufacturer, Elan, for the supply of Zanaflex Capsules. Zanaflex Capsules are manufactured using Elan's proprietary SODAS (spheroidal oral drug absorption system) multiparticulate drug delivery technology. Elan is obligated, in the event of a failure to supply Zanaflex Capsules, to use commercially reasonable efforts to assist us in either producing Zanaflex Capsules ourselves or in transferring production of Zanaflex Capsules to a third-party manufacturer, provided that such third-party manufacturer is not a technological competitor of Elan. In the event production is transferred to a third party, the FDA may require us to demonstrate through bioequivalence studies and laboratory testing that the product made by the new supplier is equivalent to the current Zanaflex Capsules before we could distribute products from that supplier. The process of transferring the technology and qualifying the new supplier could take a year or more.

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

The Elan facility located in Gainesville, Georgia, which is responsible for bottling Zanaflex Capsules, has been operating under a court-ordered consent decree and injunction since 2001, which were imposed following adverse FDA inspections and FDA allegations that the facility was failing to comply with current good manufacturing requirements. These prior issues were not related to the manufacture of our products. If, however, Elan fails to comply with the requirements of the consent decree and injunction, it could be held in contempt and the facility could be shut down and the manufacturing of our products halted or interrupted.

We currently rely on Novartis for our supply of Zanaflex tablets and tizanidine, the active pharmaceutical ingredient, or API, in both Zanaflex Capsules and Zanaflex tablets. Under a supply agreement we assumed from Elan, Novartis is responsible for manufacturing Zanaflex tablets and

tizanidine for us through February 2007. This includes the tizanidine that Elan uses to manufacture Zanaflex Capsules for us. Novartis currently produces tizanidine, but has arranged with another party to formulate Zanaflex tablets. We have arranged for another company, Sharp Corporation, to package and bottle Zanaflex tablets. Novartis has informed us that it intends to discontinue production of tizanidine by the end of the first quarter of 2006. It is our understanding that Novartis is currently in the process of transferring the methods of manufacturing tizanidine to Rohner, a manufacturer in Pratteln, Switzerland. We have also identified an alternate source for tizanidine in collaboration with Elan but do not have an agreement with that alternative source or any other alternate manufacturer. By the expiration of our contract with Novartis in 2007, we will need to have established a direct relationship with an alternative supplier of tizanidine for Zanaflex tablets if we want them to continue to be manufactured.

We also rely exclusively on Elan to supply us with our requirements for Fampridine-SR. Elan relies on a third-party manufacturer to supply fampridine, the API 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, Inc., a mutually agreed-upon and qualified second manufacturing source, without 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 or 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 otherwise adversely affect on our preclinical testing or clinical trials and ultimately on the timely advancement of our development programs.

We rely on a third party to provide the sales representatives to market Zanaflex Capsules to primary care physicians.

We recently entered into a contract with Cardinal Health pursuant to which it provides us with approximately 160 sales representatives who market Zanaflex Capsules to primary care physicians. These sales representatives are not our employees and we do not have control over their performance or compliance with applicable laws. Their failure to increase prescriptions for Zanaflex Capsules from the targeted primary care physicians would negatively impact our sales growth, and their failure to comply with applicable laws could subject us to liability.

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 more than 25 U.S. patents, more than 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. 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.

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 The Offering

There is no existing market for our common stock. An active trading market may not develop and you may not be able to resell your shares at or above the initial offering price.

Prior to this offering, there has been no public market for our common stock. We cannot predict the extent to which trading will lead to the development of an active and liquid trading market in our common stock. The initial public offering price of our common stock was determined by negotiations between the representatives of the underwriters and us and may not be indicative of future market

prices. The market price for our common stock may decline below the initial offering price. Our stock price could fluctuate significantly due to a number of factors, including:

- publicity regarding actual or potential clinical trial results relating to products under development by us or our competitors;
- 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;
- changes in securities analysts' estimates of our performance or our failure to meet analysts' expectations;
- sales of substantial amounts of our stock;
- variations in product revenue and profitability; and
- variations in our anticipated or actual operating results.

Many of these factors are beyond our control. In addition, the stock markets in general, and the Nasdaq National 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.

As a new investor, you will experience immediate and substantial dilution in the net tangible book value of your investment and may experience further dilution in the future.

The initial public offering price for this offering is substantially higher than the pro forma net tangible book value per share of our outstanding common stock. Investors purchasing shares of our common stock in this offering will pay more for their shares than the amount paid by existing stockholders who acquired shares prior to this offering. Accordingly, if you purchase common stock in this offering, you will incur immediate dilution in pro forma net tangible book value of approximately $ per share. If the holders of outstanding options or warrants exercise these options or warrants, you will incur further dilution. Investors purchasing shares of our common stock in this offering will contribute approximately % of the total amount we have raised since our inception, but will own only approximately % of our total common stock immediately following the completion of this offering.

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

Sales of substantial amounts of our common stock in the public market after this offering, or the possibility of those sales or other distributions, could put downward pressure on the market price of our common stock. After the consummation of this offering, our current stockholders will be subject to a 180-day lock up on the sale of their shares. After the lock-up expires, based on the number of shares outstanding as of December 31, 2005, 19,698,104 shares of common stock will be eligible for sale subject to Rule 144, Rule 144(k) or Rule 701. The remaining 913,155 shares held by existing stockholders will be eligible for sale from time to time in the future under Rule 144, Rule 144(k) or Rule 701 and holders of 13,338,279 shares of our common stock will have rights to cause us to file a registration statement on their behalf and to include their shares in registration statements that we may file on our behalf or on behalf of other stockholders. By exercising their registration rights and selling a large number of shares, these holders could cause the price of our common stock to decline.

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

After this offering, our officers, directors and holders of 5% or more of our outstanding common stock will beneficially own approximately % of our common stock. Moreover, a majority of our directors are principals or representatives of entities that own substantial amounts 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 by-laws 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.

Following this offering, our certificate of incorporation and by-laws will 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 certificate of incorporation provides for the board of directors to be 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.

Our certificate of incorporation requires the vote of the holders of 75% of the outstanding shares of our common stock 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 after the offering or even maintain the price at which you purchased your shares.

FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," contains forward-looking statements. 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:

inability to successfully market and sell any approved product;

unfavorable results of our preclinical or clinical testing;

delays in obtaining, or failure to obtain FDA approvals;

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 Securities Litigation Reform Act of 1995 protects companies from liability for their forward looking statements if they comply with the requirements of the Act. The Act does not provide this protection for initial public offerings.

USE OF PROCEEDS

We estimate that we will receive approximately $ million in net proceeds from the sale of our common stock in this offering, or approximately $ million if the underwriters exercise their over-allotment option in full, based on an assumed initial public offering price of $ per share (the midpoint of the estimated price range shown on the cover of this prospectus) after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the proceeds of this offering as follows:

- approximately $10.0 million for sales and marketing activities and market development for Zanaflex Capsules and Fampridine-SR, if approved by the FDA;

- approximately $25.0 million principally to complete our current Fampridine-SR clinical trial and to conduct other activities related to the filing of an NDA for Fampridine-SR, as well as for research and development, including for Zanaflex and our preclinical studies related to our Chondroitinase, Neuregulin and Remyelinating Antibodies programs; and

- the remainder for general corporate purposes, which may include the payment of one or more sales-based milestones to Elan for Zanaflex Capsules, the funding of working capital, capital expenditures and the potential acquisition or licensing of pharmaceutical products or product candidates that are complementary to our own.

Under our revenue interest assignment arrangement with PRF, if this offering results in our having a total market capitalization in excess of $150.0 million, we will have the option, for 180 days, to repurchase PRF's rights at the "put/call price" in effect on the date such right is exercised. The put/call price on a given date is the greater of (i) 150% of the payments made by PRF to us as of such date, less all payments received by PRF from us as of such date, and (ii) an amount that would generate an internal rate of return to PRF of 25% of 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. We do not currently intend to exercise this option if it becomes exercisable, but we may reevaluate whether we would exercise the option during the 180-day period. If we do exercise any such option, we would use a portion of the proceeds from this offering to make the repayment. Unless earlier terminated, the revenue interest assignment arrangement will expire on December 31, 2015. We entered into our revenue interest assignment arrangement with PRF in order to provide additional immediate funding to support the commercialization of Zanaflex Capsules. All funds from the PRF transaction must be used for the commercialization and other activities and obligations related specifically to our Zanaflex operations. We currently intend to use $3 million of the PRF proceeds to pay a Zanaflex Capsules sales-based milestone due to Elan on March 31, 2006.

We expect that the proceeds of this offering will allow us to complete our current Fampridine-SR Phase 3 clinical trial. The amount and timing of our actual expenditures on sales and marketing and our research and development programs will depend on numerous factors, including the progress of our research and development activities, the progress of our clinical trials and regulatory approval process, the number and breadth of our product development programs, our success in marketing Zanaflex Capsules, and any in-licensing and acquisition activities. Our research programs are in an early stage of development and it is difficult to predict what advances, if any, we will make in our research activities using the proceeds of this offering. Accordingly, we will retain broad discretion in the allocation and use of the proceeds of this offering. Currently we have no specific plans or commitments related to any acquisitions or licenses.

Pending application of the net proceeds, we intend to invest them in short-term, investment-grade, interest-bearing instruments.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends for the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in current or future financing instruments and other factors our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and capitalization as of September 30, 2005:

- on an actual basis giving retroactive effect to the 1-for-1.3 reverse stock split on January 11, 2006;
- on a pro forma basis to reflect:
  - our entry into a revenue interest assignment arrangement with PRF on December 23, 2005, including (i) our receipt at signing of a payment in the amount of $15.0 million, (ii) our use of approximately $3.0 million of that payment to repay a portion of the amount we owe to GE Capital and approximately $700,000 of that payment to pay fees and expenses related to the transaction, including expenses incurred by PRF, (iii) our recognition of a revenue interest liability of approximately $14.6 million, (iv) our recognition of a put/call option liability of approximately $400,000, and (v) our capitalization of approximately $500,000 in fees and expenses related to the transaction; and
  - the automatic conversion of all of our outstanding convertible preferred stock and mandatorily redeemable convertible preferred stock into 13,338,279 shares of common stock on the closing of this offering; and
- on a pro forma basis as adjusted to reflect our receipt of net proceeds from the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share (the midpoint of the estimated price range shown on the cover of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses.

	As of September 30, 2005		
	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma As Adjusted (unaudited)
		(in thousands)	
Cash, cash equivalents and short-term investments	$ 8,741	$ 20,039	$
Current portion of notes payable	2,347	1,150	
Revenue interest liability PRF transaction		14,600	
Put/call option liability PRF transaction		400	
Long-term portion of notes payable	3,534	1,731	
Long-term convertible notes payable principal amount plus accrued interest, less unamortized debt discount Related party	8,695	8,695	
Mandatorily Redeemable Convertible Preferred Stock, $.001 par value:	85,000		

	As of September 30, 2005		
7,472,612 shares of Series E convertible preferred stock authorized, issued and outstanding at September 30, 2005; 10,204,047 shares of Series I convertible preferred stock authorized, issued and outstanding at September 30, 2005; 112,790,246 shares of Series J convertible preferred stock authorized, 112,790,233 shares issued and outstanding at September 30, 2005; 1,573,330 shares of Series K convertible preferred stock authorized, 1,533,327 shares issued and outstanding at September 30, 2005; 0 shares issued and outstanding on a pro forma and pro forma as adjusted basis			

Stockholders' equity (deficit):			
Non-redeemable Convertible Preferred Stock, $.001 par value: 1,306,068 shares of Series A convertible preferred stock; 900,000 shares of Series B convertible preferred stock; 333,333 shares of Series C convertible preferred stock; 0 shares of Series D preferred stock; 2,300,000 shares of Series F convertible preferred stock; 0 shares of Series G preferred stock; 1,575,229 shares of Series H convertible preferred stock; 0 shares issued and outstanding on a pro forma and pro forma as adjusted basis	6		
Common stock, $.001 par value; 200,000,000 shares authorized at September 30, 2005 and 80,000,000 shares authorized on a pro forma and on a pro forma as adjusted basis; 208,766 shares issued and outstanding at September 30, 2005, issued and outstanding on a pro forma basis and on a pro forma as adjusted basis, respectively		13	
Additional paid-in capital	96,806	181,801	
Accumulated deficit	(198,475)	(198,677)	
Other comprehensive loss	(6)	(6)	
Total stockholders' (deficit)	(101,669)	(16,869)	
Total capitalization	$ (2,093)	$ 9,707	$

The table above excludes, as of September 30, 2005:

1,816,518 shares of common stock issuable, as of September 30, 2005, upon the exercise of outstanding options and warrants to purchase our common stock, at a weighted average exercise price of $5.13 per share;

756,620 shares of restricted stock outstanding as of September 30, 2005;

278,339 shares of common stock issuable, as of September 30, 2005, upon the conversion of outstanding convertible promissory notes; and

3,000,000 shares of common stock reserved for issuance under our stock option plans, including our 2006 Employee Incentive Plan adopted in January 2006.

DILUTION

Our net tangible book value as of September 30, 2005 was approximately $(123.0) million, or approximately $ per share based on shares of common stock outstanding as of September 30, 2005, after giving effect to:

- the 1-for 1.3 reverse stock split on January 11, 2006;
- the automatic conversion of our outstanding convertible preferred stock and mandatorily redeemable convertible preferred stock into 13,338,279 shares of common stock upon the closing of this offering; and
- our entry into a revenue interest assignment arrangement with PRF on December 23, 2005, including (i) our receipt at signing of a payment in the amount of $15.0 million, (ii) our use of approximately $3.0 million of that payment to repay a portion of the amount we owe to GE Capital and approximately $700,000 of that payment to pay fees and expenses related to the transaction, including expenses incurred by PRF, (iii) our recognition of a revenue interest liability of approximately $14.6 million, (iv) our recognition of a put/call option liability of approximately $400,000, and (v) our capitalization of approximately $500,000 in fees and expenses related to the transaction.

Net tangible book value per share represents our total tangible assets reduced by our total liabilities, mandatorily redeemable convertible preferred stock, deferred offering costs and the liquidation value of our convertible preferred stock and divided by the number of shares of common stock outstanding. Dilution per share to new investors represents the difference between the amount per share that you pay for our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our pro forma as adjusted net tangible book value as of September 30, 2005, would have been approximately $ million, or approximately $ per share, after giving further effect to our sale of shares in this offering, assuming an initial public offering price of $ per share (the midpoint of the estimated price range shown on the cover of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses. This represents an immediate increase in net tangible book value of $ per share to existing stockholders and an immediate decrease in net tangible book value per share of $ to you. The following table illustrates the dilution.

Assumed initial public offering price per share		$
Pro forma net tangible book value per share as of September 30, 2005	$	
Pro forma as adjusted increase in net tangible book value per share attributable to this offering	$	
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors		$

If the underwriters exercise their over-allotment option in full, the pro forma net tangible book value per share after the offering would be $ per share, the increase in net tangible book value per share to existing stockholders would be $ per share and the dilution to new investors would be $ per share.

The following table sets forth, as of September 30, 2005, on a pro forma as adjusted basis, (i) the total number of shares of common stock purchased from us, after giving effect to this offering and the reverse stock split and automatic conversion of our outstanding preferred stock described above,

(ii) the total consideration paid to us, and (iii) the average price per share paid by the existing stockholders and by new investors purchasing shares in this offering.

	Shares Purchased		Total Consideration		
	Number	%	Amount	%	Average Price Per Share
Existing stockholders	13,547,022	%	$	%	$
New investors(1)					
Total		100.0%	$	100.0%	

(1) Before the underwriters' commissions and our expenses.

The table above assumes no exercise of stock options or warrants outstanding as of September 30, 2005. At September 30, 2005, there were 1,816,518 shares of common stock issuable upon exercise of outstanding stock options and warrants at a weighted average exercise price of $5.13 per share. To the extent that outstanding options or warrants are exercised in the future, there will be further dilution to new investors. To the extent all of such outstanding options and warrants had been exercised as of September 30, 2005, pro forma as adjusted net tangible book value per share after this offering would be $ and total dilution per share to new investors would be $.

The issuance of additional common stock will result in further dilution to new investors.

If the underwriters' over-allotment option is exercised in full, the number of shares of our common stock held by existing stockholders will be reduced to % of the aggregate number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors will be increased to or % of the aggregate number of shares of common stock outstanding after this offering.

SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated statement of operations data for the fiscal years ended June 30, 2001, 2002 and 2003, six month period ended December 31, 2003, and the year ended December 31, 2004 and the selected consolidated balance sheet data presented below as of June 30, 2001, 2002 and 2003, and December 31, 2003 and 2004, set forth below are derived from, and are qualified by reference to, our consolidated financial statements other than the pro forma financial information, which have been audited by KPMG LLP, our Independent Registered Public Accounting Firm, and that are included elsewhere in this prospectus for the years ended June 30, 2002 and 2003, six months ended December 31, 2003 and year ended 2004.

We changed our fiscal year end from June 30 to December 31, effective for the six months ended December 31, 2003. The selected consolidated statement of operations data presented below for the nine months ended September 30, 2004 and 2005, and selected consolidated balance sheet data presented below as of September 30, 2005, have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial information include, in the opinion of management, all adjustments, consisting of normal and recurring adjustments, that management considers necessary for a fair presentation, in all material respects, of its consolidated results for those periods. Our historical results are not necessarily indicative of the results to be expected in the future periods and the results for the nine months ended September 30, 2005, should not be considered indicative of results expected for the full year.

This data should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our Consolidated Financial Statements and the related notes included elsewhere in this prospectus.

Pro forma per share amounts in the following table reflect the conversion of our outstanding convertible and mandatorily redeemable convertible preferred stock into 13,338,279 shares of common stock on the closing of this offering, assuming that shares of our preferred stock were outstanding for the entire periods presented. Pro forma balance sheet data amounts in the following table reflect the conversion of our outstanding convertible and mandatorily redeemable convertible preferred stock, as well as our entry into a revenue interest assignment arrangement with PRF on December 23, 2005, including (i) our receipt at signing of a payment in the amount of $15.0 million, (ii) our use of approximately $3.0 million of that payment to repay a portion of the amount we owe to GE Capital and approximately $700,000 of that payment to pay fees and expenses related to the transaction, including expenses incurred by PRF, (iii) our recognition of a revenue interest liability of approximately $14.6 million, (iv) our recognition of a put/call option liability of approximately $400,000, and (v) our capitalization of approximately $500,000 in fees and expenses related to the transaction.

	Year Ended June 30,			Six Months Ended December 31,	Year Ended December 31,	Nine Months Ended September 30,	
						2004	2005
	2001	2002	2003	2003	2004	(unaudited)	
	(in thousands, except per share data)						
Statement of Operations Data:							
Gross sales Zanaflex	$	$	$	$	$	$	$ 3,239
Less: discounts and allowances					(4,417)	(144)	(992)
Net sales					(4,417)	(144)	2,247
Grant revenue	462	132	474	382	479	445	184
Total net revenue	462	132	474	382	(3,938)	(301)	2,431
Less: cost of sales					(885)	(363)	(2,274)
Gross profit	462	132	474	382	(4,823)	(62)	157
Operating expenses:							
Research and development	6,142	11,147	17,527	16,743	21,999	18,621	9,652
Research and development related party	2,223	4,687	2,265	3,343			
Sales and marketing					4,662	2,793	9,657
General and administrative	3,489	6,636	6,388	17,069	13,283	11,034	6,339
Total operating expenses	11,854	22,470	26,180	37,155	39,944	32,448	25,648
Operating loss	(11,392)	(22,338)	(25,706)	(36,773)	(44,767)	(32,510)	(25,491)
Other income (expense):							
Interest and amortization of debt discount expense			(78)	(38)	(385)	(297)	(824)
Interest and amortization of debt discount expense related party	(443)	(408)	(369)	(184)			
Interest income	1,824	984	393	276	409	329	347
Other income			26	7	2	2	1
Total other income (expense)	1,381	576	(28)	61	26	34	(476)
Minority interest related party	699	580					
Cumulative effect of change in accounting principle							3
Net loss	(9,313)	(21,181)	(25,734)	(36,712)	(44,741)	(32,476)	(25,964)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred	(36)	(55)	(24,320)	(11,985)	(24,746)	(18,496)	(18,636)

stockholders						**Nine Months Ended September 30,**	
Net loss allocable to common stockholders	$ (9,349)	$ (21,236)	$ (50,054)	$ (48,697)	$ (69,487	(50,972)	$ (44,600)
Net loss per share allocable to common stockholders basic & diluted	$ (50.81)	$ (111.90)	$ (261.38)	$ (252.87)	$ (351.76)	) $ (259.22)	$ (221.17)

	Year Ended June 30,			Six Months Ended December 31,	Year Ended December 31,	Nine Months Ended September 30,	
	2001	2002	2003	2003	2004	2004	2005
						(unaudited)	
Pro forma net loss per share allocable to common stockholders basic & diluted (unaudited)(1)					$ (9.63)		$ (1.92)
Weighted average shares of common stock outstanding used in computing net loss per share allocable to common stockholders basic & diluted	184	190	191	193	198	197	202
Weighted average shares of common stock outstanding used in computing pro forma net loss per share allocable to common stockholders basic & diluted (unaudited)(1)(2)					13,536		13,547

(1) The pro forma net loss per share and weighted average shares of common stock used in computing pro forma net loss per share allocable to common stockholders for the year ended December 31, 2004 and the nine months ended September 30, 2005 are calculated as if all our convertible preferred stock and mandatorily redeemable convertible preferred stock were converted into common stock as of the beginning of the year ended December 31, 2004 or from their respective dates of issuance, if issued after the beginning of the year ended December 31, 2004. The pro forma net loss per share allocable to common stockholders for the year ended December 31, 2004 has been computed assuming the offering was completed at the beginning of the fiscal year presented and has been adjusted to give effect to the following: (a) recognition of the unamortized portion of a beneficial conversion charge of $67.9 million; (b) recognition of the unamortized portion of issuance costs relating to Series E, Series I, Series J and Series K preferred stock of $379,000; and (c) reversal of accrued preferred dividends on Series J and Series K preferred stock of $7.4 million (see Note 8 to the consolidated financial statements). The pro forma net loss per share allocable to common stockholders for the nine month period ended September 30, 2005 reflects the reversal of the accrued preferred dividend of $4.0 million, amortized beneficial conversion charge of $14.5 million and amortized issuance cost of $81,000 assuming that the automatic conversion occurred as of the beginning of the fiscal year ended December 31, 2004.

(2) The weighted average shares of our common stock outstanding used in computing the pro forma net loss per share allocable to common stockholders is calculated based on (a) Series A through Series J equivalent shares of common stock from the beginning of the fiscal year; and (b) Series K equivalent shares of common stock issuable from the date of issuance of the Series K preferred stock.

	As of June 30,			As of December 31,		As of September 30,	Pro Forma As of September 30,
	2001	2002	2003	2003	2004	2005	2005
	(in thousands)					(unaudited)	
Consolidated Balance Sheet Data:							
Cash and cash equivalents	$ 48,083	$ 27,012	$ 48,319	$ 8,965	$ 11,729	$ 3,581	$ 14,879
Restricted cash	243	250	253	254	257	261	261
Short-term investments		2,836	12,250	32,250	9,397	5,160	5,160
Capitalized transaction costs PRF transaction							500

	As of June 30,			As of December 31,		As of September 30,	Pro Forma As of September 30,
Working capital	46,115	27,097	58,975	35,375	9,067	(12,203)	(14,207)
Total assets	50,349	33,597	64,807	45,960	30,982	25,543	37,842
Deferred grant revenue			95	48			
Deferred product revenue Zanaflex Capsules						4,960	4,960
Deferred product revenue Zanaflex tablets					6,668	10,686	10,686
Current portion of notes payable			310	324	302	2,347	1,150
Non-current portion of notes payable			612	447	145	3,534	1,731
Revenue interest liability PRF transaction							14,600
Put/call option liability PRF transaction							400
Long-term convertible notes payable related party	7,131	7,538	7,907	8,091	8,422	8,695	8,695
Mandatorily redeemable preferred stock	59,604	59,659	18,187	30,171	66,364	85,000	
Total stockholders' (deficit)	(19,041)	(36,910)	35,328	(130)	(60,571)	(101,669)	(16,869)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and related notes included in this prospectus. This discussion and analysis contains forward-looking statements that are subject to risks, uncertainties and other factors, including, but not limited to, those discussed under "Risk Factors" and elsewhere in this prospectus, that could cause our actual results, performance, prospects or opportunities to differ materially from those expressed in, or implied by, these forward-looking statements. See "Forward-Looking Statements."

Background

Since we commenced operations in 1995, we have devoted substantially all of our resources to the identification, development and commercialization of novel therapies that improve neurological function in people with MS, SCI and other disorders of the CNS. Our marketed drug, Zanaflex Capsules, is FDA-approved for the management of spasticity. Our lead product candidate, Fampridine-SR, is in a Phase 3 clinical trial for the improvement of walking ability in people with MS. Our preclinical programs also target MS and SCI, as well as other CNS disorders, including stroke and traumatic brain injury.

From 1995 until mid-2004, we were engaged almost exclusively in the in-licensing of compounds and the preclinical and clinical development of these compounds. We licensed the rights to Fampridine-SR from Elan for the treatment of SCI in 1997. In 1998, we formed a joint venture, MS Research & Development Corporation, or MSRD, with Elan International Services, Ltd., or EIS, a subsidiary of Elan, to develop Fampridine-SR for the treatment of MS under an exclusive worldwide license from Elan.

In September 2003, we entered into a termination and assignment agreement with Elan, EIS and MSRD, pursuant to which MSRD assigned to us its assets, including the license from Elan for Fampridine-SR for MS. We paid MSRD approximately $11.5 million for all of the assets and assumed all of the liabilities of MSRD, and MSRD distributed to us approximately $9.5 million as our pro rata portion of the purchase price. From the time of establishment of MSRD until the sale of MSRD's assets to us, Elan was considered to be a related party under generally accepted accounting principles. In conjunction with the termination and assignment, we entered into an amended license agreement with Elan that granted us exclusive worldwide rights to Fampridine-SR in return for the payment of royalties and milestones. In addition, we entered into a supply agreement under which Elan provides Fampridine-SR based upon an agreed upon price schedule.

In September 2003, we entered into a collaboration agreement with Teva Pharmaceutical Industries Ltd., or Teva, to jointly develop and promote in the United States products containing valrocemide, pursuant to which we made an initial payment to Teva of $2.1 million. We and Teva amicably terminated this collaboration agreement in June 2005 and in connection with the termination we paid Teva approximately $3.1 million. We and Teva have no further obligations to each other under this collaboration agreement.

We have expended a significant portion of our funds on a number of clinical trials for Fampridine-SR, our most advanced product candidate, including two Phase 3 clinical trials of Fampridine-SR in SCI and a Phase 2 clinical trial in MS, the results of which were announced in March 2004. An earlier Phase 2 clinical trial in MS was completed in 2001. In mid-2004, we decided to put our clinical trials of Fampridine-SR in SCI on hold, and refocused our efforts on our ongoing Fampridine-SR in MS program, leading to our current Phase 3 clinical trial of Fampridine-SR for improvement of walking ability in people with MS. We may resume our clinical development of Fampridine-SR for SCI following completion of our MS clinical program, or sooner.

In July 2004, we acquired all of Elan's research, development, distribution, sales and marketing rights to Zanaflex Capsules and Zanaflex tablets in the United States. These products are FDA-approved for the management of spasticity. We made an upfront payment to Elan of $2.0 million and are obligated to pay royalties on sales and to make milestone payments upon achievement of specified sales levels. To date, we have achieved two milestones, the first triggering a payment of $1.5 million, 50% of which was paid in the first quarter of 2005 and 50% of which is due in the first quarter of 2006. The second milestone of $3.0 million is due on March 31, 2006. As part of our Zanaflex acquisition, we entered into a long-term supply agreement with Elan under which Elan provides us with Zanaflex Capsules. Elan also assigned us its rights under an agreement with Novartis for the supply of tizanidine and Zanaflex tablets.

Our marketing efforts are focused on Zanaflex Capsules, which we launched in April 2005. Zanaflex tablets lost compound patent protection in 2002 and both Zanaflex Capsules and Zanaflex tablets compete with 11 generic tizanidine products. Although we currently distribute Zanaflex tablets, 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 as many sales of Zanaflex tablets and generic tizanidine tablets to sales of Zanaflex Capsules as possible. We believe that sales of Zanaflex Capsules will constitute a significant portion of our total revenue for the foreseeable future.

In late 2004, we began establishing our own specialty sales force in the United States, which consisted of 14 sales professionals as of September 30, 2005. This sales force targets neurologists and other prescribers who specialize in treating people with conditions that involve spasticity. Members of this sales force also call on managed care organizations, pharmacists and distribution customers. We plan to expand our specialty sales force to approximately 30 sales professionals in the first quarter of 2006. We have also entered into an agreement with Cardinal Health, under which, since August 2005, they have provided approximately 160 sales representatives to market Zanaflex Capsules, on a non-exclusive basis, to primary care physicians in the United States. We have retained Access Worldwide Communications to provide a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care, specialty physicians and pharmacists. We expect to expand this sales and marketing infrastructure in the future, as appropriate.

In February 2004, we changed our fiscal year end from June 30 to December 31, effective for the six months ended December 31, 2003.

In December 2005, we entered into a revenue interests assignment agreement with PRF pursuant to which we assigned PRF the right to receive a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement is terminated earlier. In consideration for the assignment, PRF paid us $15.0 million at signing. We used approximately $3.0 million of that payment to repay a portion of the amount we owe to GE Capital, $200,000 of that payment for expenses associated with such repayment and $500,000 of that payment to reimburse PRF for expenses it incurred in the transaction. Under our agreement with PRF, we are required to use the remainder of the amount we received at signing and any other amounts we receive under the agreement to support commercialization, sales, marketing, clinical and regulatory activities and other financial obligations related specifically and solely to our Zanaflex operations. At our election, PRF is also required to pay us (i) an additional $5.0 million if our Zanaflex net revenues in 2005 equal or exceed $11.0 million and our Zanaflex net revenues in the first six months of 2006 equal or exceed $16.0 million, and (ii) an additional $5.0 million if our Zanaflex net revenues in 2006 equal or exceed $33.5 million. If we meet these milestones and decide to borrow these additional funds, we would be required to pay PRF $5.0 million on December 1, 2009 in the case of the first additional payment and $5.0 million on December 1, 2010 in the case of the second additional payment. For more information regarding our agreement with PRF, see " Liquidity and Capital Resources Financing Arrangements."

Product Revenue and Returns

Ongoing Zanaflex Capsule and Tablet Sales

Product revenue consists of sales of Zanaflex Capsules and Zanaflex tablets. Under SFAS 48, *Revenue Recognition When the Right of Return Exists,* we are not permitted to recognize revenue until we can reasonably estimate the likely return rate for our products. Since we have only limited sales history with Zanaflex Capsules and due to generic competition and customer conversion from Zanaflex tablets to Zanaflex Capsules, we cannot reasonably determine a return rate. As a result, we account for sales of these products using a deferred revenue recognition model. At a future point in time, which could be in a number of years, when we are able to reasonably estimate product returns we will begin to recognize revenue based on shipments of product to our wholesale drug distributors.

Under our deferred revenue model, we do not recognize revenue upon shipment of product to our wholesale drug distributors. Instead, we record deferred revenue at gross invoice sales price, and classify the cost basis of the inventory held by the wholesaler as a component of inventory. We recognize revenue when prescriptions are filled to end-users because once prescriptions are filled the product cannot be returned. We use monthly prescription data that we purchase from NDC Health, a leading provider of healthcare data, to determine the amount of revenue to be recognized. When we receive the prescription data, we use the number of units of product prescribed to record gross sales. We then reduce deferred revenue and record cost of goods sold. We began receiving end-user prescription data in March 2005 which enabled us to begin recognizing revenue from Zanaflex tablet sales. We began marketing Zanaflex Capsules in April 2005 and began receiving prescription data and recognizing revenue in the same month. Through September 30, 2005, we have recognized $2.1 million in revenue from Zanaflex tablets and $1.1 million from Zanaflex Capsules.

Under our revenue interests assignment agreement with PRF, PRF is entitled to a portion of our net revenues from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. Under the agreement, PRF is entitled to the following portion of Zanaflex net revenues:

with respect to Zanaflex net revenues up to and including $30.0 million for each fiscal year during the term of the agreement, 15% of such net revenues;

with respect to Zanaflex net revenues in excess of $30.0 million but less than and including $60.0 million for each fiscal year during the term of the agreement, 6% of such net revenues; and

with respect to Zanaflex net revenues in excess of $60.0 million for each fiscal year during the term of the agreement, 1% of such net revenues.

Notwithstanding the foregoing, once PRF has received and retained payments under the agreement that are at least twice the aggregate amount PRF has paid us under the agreement, PRF will only be entitled to 1% of Zanaflex net revenues.

We accept returns of products for six months prior to and 12 months after their expiration date. Returns of products sold by us are charged directly against deferred revenue, reducing the amount of deferred revenue that we may recognize.

Sale of Zanaflex Tablet Inventory Acquired From Elan

When we acquired Zanaflex from Elan, we also acquired Elan's inventory of Zanaflex tablets. This inventory included partial lots with expiration dating of less than 12 months and full lots with expiration dating greater than 12 months. We have deferred recognition of any revenue from sales of the partial lot inventory until the return period for the product expires in June 2006, and will recognize revenue

then only to the extent that deferred revenues exceed returns. We cannot use prescription data to recognize revenue associated with the partial lot inventory acquired from Elan because we cannot determine whether the prescription was filled with product that Elan sold prior to our acquisition of Zanaflex or with product we sold.

All Zanaflex tablet partial lot inventory that we acquired from Elan has either been sold or is no longer being sold by us. As a result, after the return period expires in June 2006, there will no longer be deferred revenue associated with the Zanaflex tablet partial lot inventory acquired from Elan.

In July 2005 we began to recognize revenue from the full lots based on prescriptions filled for Zanaflex tablets. All of the Zanaflex tablet inventory sold by Elan prior to our acquisition reached expiration in June 2005, therefore any prescriptions filled for Zanaflex tablets subsequent to June 2005 must be from the full inventory lots acquired by and sold by us.

We are uncertain about the amount of returns that we may receive on these products, for a number of reasons including our limited historical returns experience. Returns of Zanaflex tablet inventory acquired from Elan and sold by us are charged against deferred revenue, reducing the amount of deferred revenue that we may recognize.

Returns of Zanaflex Tablets sold by Elan

As part of the acquisition of Zanaflex, we agreed to accept returns of Zanaflex tablets that were returned subsequent to January 17, 2005, including returns of product that was originally sold by Elan. Product returns prior to January 17, 2005, were the responsibility of Elan. We have recorded a charge of $4.1 million in the year ended December 31, 2004, for the estimated returns of Zanaflex tablets sold by Elan. To the extent that returns exceed the estimated charge, we will be required to record further charges. The return period for Zanaflex tablets sold by Elan ends in June 2006, after which time we do not anticipate any further charges resulting from Zanaflex tablets sold by Elan.

Discounts and Allowances

Discounts and allowances consist of estimated reserves for cash discounts, rebates and chargebacks. At the time product is shipped to wholesalers an allowance is recorded for these discounts and allowances. Allowances are established on a product-by-product basis. These allowances are established by management as its best estimate based on each product's historical experience adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates and discounts are established based on the contractual terms with customers, analysis of historical levels of discounts, chargebacks and rebates, communications with customers and the levels of inventory remaining in the distribution channel as well as expectations about the market for each product and anticipated introduction of competitive products.

Grant Revenue

Grant revenue is recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied. To the extent expended, grant revenue related to purchase of equipment is deferred and amortized over the shorter of its useful life or the life of the related contract.

Cost of Sales

Cost of sales consists of cost of inventory, royalty expense and milestone amortization of intangible assets associated with the Zanaflex acquisition, packaging costs, freight and required inventory stability testing costs. Our inventory costs, royalty obligations and milestone obligations are set forth in the agreements entered into in connection with our Zanaflex acquisition. The Company does not expect

any payments it makes to PRF in connection with the revenue interests assignment transaction entered into in December 2005 to constitute royalty expense or otherwise affect the Company's cost of sales or other operating expenses. See " Liquidity and Capital Resources Financing Arrangements."

Research and Development Expenses

Research and development expenses consist primarily of salaries and related expenses for personnel, fees paid to professional service providers in conjunction with independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop our products, costs of facilities and the legal costs of pursuing patent protection of our intellectual property. We expense research and development costs as incurred. We expect our research and development expenses to increase as we continue to develop our product candidates and preclinical programs.

The following table summarizes our research and development expenses for the fiscal years ended June 30, 2001, 2002, 2003, the six months ended December 31, 2003, the year ended December 31, 2004 and the nine months ended September 30, 2005. Included in this table are our external research and development costs, consisting largely of clinical trial and research services provided by outside laboratories and vendors recognized in connection with each product candidate currently in clinical development and all preclinical programs as a group. Many of our internal research and development costs, including personnel costs, related benefits and stock-based compensation, are not attributable to any individual project because we use these resources across several development projects. Compensation expense for option grants is classified between clinical development and preclinical research and development based on employee job function.

	Year Ended June 30,			Six Months Ended December 31,	Year Ended December 31,	Nine Months Ended September 30,	
	2001	2002	2003	2003	2004	2004	2005
						(unaudited)	
				(in thousands)			
Clinical development:							
Contract expense SCI	$ 1,557	$ 3,359	$ 5,777	$ 4,266	$ 5,853	$ 5,630	$ 30
Contract expense MS	649	908	1,613	2,116	2,850	2,205	2,296
Other contract expense			1,015	1,388	4,945	4,292	3,729
Operating expense	695	1,518	2,356	1,789	2,652	2,108	951
Licensing expense Teva				2,000			
Total clinical development	2,901	5,785	10,761	11,559	16,300	14,235	7,006
Preclinical research & development:							
Research contracts	586	617	271	412	628	469	68
Contract expense		213	1,441	216	113	47	62
Operating expense	2,655	4,531	5,054	4,556	4,958	3,870	2,516
Total preclinical research & development	3,241	5,361	6,766	5,184	5,699	4,386	2,646
Total research & development	6,142	11,146	17,527	16,743	21,999	18,621	9,652
Research & development related party expense	2,223	4,687	2,265	3,343			
Total	$ 8,365	$ 15,833	$ 19,792	$ 20,086	$ 21,999	$ 18,621	$ 9,652

					Nine Months Ended September 30,

Research and Development Related Party

In cooperation with Elan, we have conducted a series of clinical trials during the past eight years evaluating Fampridine-SR. Elan was considered to be a related party during the period from April, 1998 when MSRD, our jointly-owned venture with Elan to develop Fampridine-SR in MS, was formed until September 2003, when Elan's interest in MSRD was sold to us (see Note 11 to our consolidated financial statements included in this prospectus). Related party research and development or sales and marketing expenses have been included as a separate line item in our financial statements for this period and in the table above. These expenses consisted of the contracted development and supply of our lead product candidate, Fampridine-SR, license fees and expenses associated with our acquisition of Elan's interest in MSRD.

Sales and Marketing Expenses

Sales and marketing expenses includes the costs of salaries for our sales and marketing personnel and the cost of our advertising, promotion and education programs. Sales and marketing expenses include the cost of our contract sales force provided by Cardinal Health and our contract pharmaceutical telesales services provided by Access Worldwide.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, business development, legal, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development or sales and marketing expense and professional fees for legal and accounting services. We expect that our general and administrative expenses will increase as we add personnel and become subject to the reporting obligations applicable to public companies.

Stock-Based Compensation

We have accounted for options and restricted stock granted to employees and directors in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, and related interpretations. As such, compensation expense is recorded on stock option and restricted stock grants based on the fair value of the restricted stock and options granted, which is estimated on the date of grant using an option-pricing model and it is recognized on a straight-line basis over the vesting period. Compensation expense for options and restricted stock granted to employees amounted to $643,000, $1.3 million, $1.6 million, $13.2 million, $9.0 million, and $3.5 million for the years ended June 30, 2001, 2002 and 2003, the six months ended December 31, 2003, the year ended December 31, 2004 and the nine months ended September 30, 2005. Compensation expense for options and restricted stock granted to employees are classified between research and development and general and administrative expense based on employee job function.

We have accounted for stock options granted to non-employees on a fair-value basis in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, Emerging Issues Task Force ("EITF") Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and FASB Interpretations No. 28, *Accounting for Stock Appreciation Rights and Other Var*