ACORDA THERAPEUTICS INC
Form 10-K
March 26, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2006

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 000-50513

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3831168**
(State of incorporation)	(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)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes x No o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of June 30, 2006, the aggregate market value of the Registrant s voting stock held by non-affiliates was $71,336,207. For purposes of this calculation, shares of common stock held by directors, officers and stockholders whose ownership exceeds five percent of the common stock outstanding at June 30, 2006 were excluded. Exclusion of shares held by any person should not be construed to indicate that the person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant, or that the person is controlled by or under common control with the Registrant.

As of February 28, 2007, the registrant had 23,716,363 shares of common stock, par value $0.001 per share, outstanding. The registrant does not have any non-voting stock outstanding.

ACORDA THERAPEUTICS, INC.
2006 FORM 10-K ANNUAL REPORT

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This Annual Report on Form 10-K contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management s beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this report, particularly in the Risk Factors that May Affect Results section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not assume any obligation to update any forward-looking statements.

PART I

Item 1. Business.

Company Overview

Acorda Therapeutics is 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 drug, Zanaflex Capsules, is FDA-approved for the management of spasticity. Our lead product candidate, Fampridine-SR, has completed a positive Phase 3 clinical trial for the improvement of walking ability in people with MS and we expect to initiate a second Phase 3 clinical trial in the second quarter of 2007. Our preclinical programs also target other aspects of MS as well as SCI and other CNS disorders, including stroke and traumatic brain injury.

Approximately 650,000 people in the United States suffer from MS or SCI and the combined annual cost of treatment for these conditions exceeds $13 billion. In addition, it is estimated that a total of approximately 10 million people live with the long-term consequences of traumatic brain injury and stroke in the United States. Our goal is to continue to grow as a fully-integrated biopharmaceutical company by commercializing therapeutic products, developing our product candidates and advancing our preclinical programs for these large and underserved markets.

Company Highlights

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

Walking Scale, a self-rated assessment of walking disability. We expect to initiate a second Phase 3 trial in the second quarter of 2007 under an SPA, or Special Protocol Assessment, issued by the FDA. 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 and, if approved, could be complementary to existing drugs used to treat MS. To our knowledge, there are no current therapies indicated to improve walking ability in people with MS.

- Sales of Zanaflex Capsules, which we launched in April 2005, and Zanaflex tablets increased from $5.9 million for the year ended December 31, 2005 to $26.5 million for the year ended December 31, 2006. We acquired all marketing, sales and distribution rights in the United States to Zanaflex Capsules and Zanaflex tablets in 2005, based on the strategic fit of this product with our therapeutic focus and expertise. Both products are FDA-approved for the management of spasticity, a symptom of many CNS disorders, including MS and SCI. These products contain tizanidine, one of the two leading treatments for spasticity. Zanaflex Capsules are the only approved capsule formulation of tizanidine and are protected by a patent that expires in 2021. We believe that Zanaflex Capsules offer important pharmacokinetic benefits over Zanaflex tablets and generic equivalents of Zanaflex tablets. As a result, Zanaflex tablets and generic tizanidine tablets are not AB-rated with Zanaflex Capsules by the FDA, meaning that the FDA does not consider the tablet products to be therapeutically equivalent to Zanaflex Capsules. Therefore, under state laws, pharmacists may not properly substitute tablets when filling a prescription for our proprietary Zanaflex Capsules.

- To support and increase sales of Zanaflex Capsules, we have more than doubled the size of our internal specialty sales force since early 2006. As of January 8, 2007, our internal specialty sales force consists of 65 sales professionals who call on neurologists, other specialists, and primary care physicians who treat patients with conditions that involve spasticity. Members of this sales force also call on managed care organizations, pharmacists and wholesale drug distribution customers. We also engage a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care physicians, specialty physicians and pharmacists. We believe that our expanded sales and marketing infrastructure enables us to efficiently reach virtually all high-volume prescribers of Zanaflex tablets and generic tizanidine. We believe that many of these prescribers are also potential high-volume prescribers for our lead product candidate, Fampridine-SR, if approved.

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

- Our extensive scientific and medical network expands our reach and expertise in the core focus areas of MS and SCI. Our advisory team and network comprises 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.

Background and Market Opportunity

The Challenge of Nervous System Disorders

The spinal cord and brain together comprise the CNS. The billions of nerve cells that make up the CNS, in conjunction with the nerve bundles that run through all parts of the body, which make up the peripheral nervous system, transmit the electrical impulses necessary to sustain, regulate and monitor every aspect of human life. The spinal cord serves as the master link between the brain and the body and carries information that regulates movement, sensation and involuntary functions, such as breathing, blood pressure, temperature control, and bladder, bowel and sexual functions.

Nerve impulses travel within and between the brain and spinal cord via long, thin fibers, or axons, that transmit information to other nerve cells through microscopic junctions called synapses. When axons are damaged or lost, they do not normally regenerate, and there is only very limited adaptability, or plasticity, of the surviving axons that allow them to take over the role of damaged or lost axons. The myelin sheath that surrounds axons in the brain and spinal cord provides insulation that facilitates the transmission of nerve impulses. We refer to the axon and its surrounding myelin sheath as a nerve fiber. The myelin sheath is composed of multiple layers of tightly packed cell membrane and is vulnerable to damage in conditions like MS and SCI. Once damaged, it is often not effectively repaired. Although nerve fibers can survive in a demyelinated state, their ability to conduct nerve impulses may be completely lost or severely compromised.

Our Approach to the Market for CNS Disorders

We are focused on identifying, developing and commercializing novel pharmaceutical products that address large and underserved CNS markets. We view MS and SCI as the primary markets for our products as well as strategic points of access to a broad range of additional neurological conditions for the following reasons:

- Focusing on both MS and SCI provides insight into chronic and acute CNS conditions. MS is a chronic degeneration of the CNS, whereas SCI represents an acute CNS injury followed by a relatively stable chronic condition.

- Many of the mechanisms of secondary tissue damage and potential repair in MS and SCI are shared with other conditions, including stroke and traumatic brain injury.

- The functional deficits and symptoms suffered by MS and SCI patients, such as walking impairments, spasticity and loss of bladder and bowel function, are shared by other CNS disorders.

- A treatment that protects the spinal cord from the consequences of injury, regenerates neural connections, remyelinates or optimizes function of surviving structures in the spinal cord is also likely to be applicable to many conditions affecting the brain and the rest of the nervous system.

For people with MS, SCI and similar chronic neurological conditions, even relatively small and incremental improvements in CNS function can produce meaningful benefits in their quality of life.

Multiple Sclerosis

The National Multiple Sclerosis Society, or NMSS, currently estimates that 400,000 people in the United States have multiple sclerosis. The NMSS estimates that the medical costs associated with treating MS in the United States were approximately $6.2 billion in 2004. Medications accounted for approximately $3.5 billion of these costs. MS is more prevalent in Caucasians and women and is generally diagnosed between the ages of 20 and 50.

MS is a degenerative CNS disorder in which the immune system attacks and damages the insulating myelin sheath. This damage, which can occur at multiple sites in the CNS, blocks or diminishes conduction of electrical impulses. People with MS may suffer impairments in any number of neurological functions. These impairments vary from individual to individual and over the course of time, depending on which parts of the brain and spinal cord are affected, and often include difficulty walking, spasticity, fatigue, lack of stamina and loss or disturbance of vision. They may also include loss of sensation, loss of bowel and bladder control, sexual dysfunction, depression, neuropathic pain, muscle paralysis, dizziness, tremors and cognitive difficulties. Individuals vary in the severity of the impairments they suffer on a day-to-day basis, with impairments becoming better or worse depending on the activity of the disease on a given day.

MS is generally classified by how the disease progresses. The most common classification is relapsing-remitting MS, in which people go through periods during which their disease is relatively stable or in remission, only to experience a recurrence of their disease, known as a relapse, which creates additional damage and loss of function. Approximately 10% of MS cases in the United States are diagnosed as primary progressive MS, which does not involve distinct attacks but rather a steady worsening of symptoms. Secondary progressive MS involves an initial period of relapsing-remitting disease followed by a steady worsening that is punctuated by more severe flare-ups and partial remissions. Most people with relapsing-remitting disease will eventually convert to secondary progressive disease, though this may not occur for many years.

There are no current treatments indicated to address the weakness and loss of mobility that is a major aspect of the progressive disability experienced by people with MS.

Spinal Cord Injury

According to the National Spinal Cord Injury Statistical Center, approximately 250,000 people in the United States live with the long-term consequences of SCI and approximately 11,000 new spinal cord injuries occur each year, typically in young men. The majority of people with SCI are injured under the age of 30 and live with permanent disability and multiple related medical conditions for more than 40 years after their injury. The National Spinal Cord Injury Database at the University of Alabama estimates that the average lifetime costs directly attributable to SCI for an individual injured at age 25 varies from approximately $600,000 to $2.8 million depending on the severity of the injury.

The spinal cord can be injured by physical trauma that bends the neck or body violently, such as vehicular or diving accidents, or by objects that penetrate or impact the spinal cord, such as a bullet or a knife. The spinal cord can also be injured by tumor compression and loss of blood flow due to damage to major blood vessels or during surgical procedures. When an area of the spinal cord is damaged, motor and sensory function are partially or completely impaired throughout those parts of the body that are below the level of the injury.

Within the last two decades, researchers have shown that the spinal cord is not severed in most people with SCI. Rather, stretching or compression of the cord causes nerve fibers and blood vessels to tear and unleashes a secondary process of bleeding, loss of blood flow and inflammation that causes more tissue damage. The majority of people with spinal cord injury have some axons that survive within or around the site of injury. Because of these surviving axons, approximately 50% of people with SCI have some motor and/or sensory function remaining below the level of the injury and are said to have incomplete SCI. Those with no detectable function below the injury level are said to have complete SCI. Researchers have also shown that many axons that survive trauma are damaged and permanently lose part of their myelin sheath.

In addition to the impact of paralysis on mobility and independence, chronic SCI is often associated with several life-altering conditions that vary depending on the individual, location and the extent of injury. These include spasticity, as well as persistent pain, loss of control of bowel and

bladder functions, loss of sexual function, compromised breathing, loss of sensation, and unstable control of blood pressure, heart rate and body temperature. There is no cure for SCI and no approved treatment available that is capable of improving neurological function. Methylprednisolone, a high-dose steroid, is currently the standard of care in the United States. Methylprednisolone is a one-time treatment administered to the patient immediately following an injury to reduce secondary tissue damage. There are several treatments for the symptoms of SCI, many of which are the same treatments used to address the symptoms of MS. We believe that novel therapies that offer even an incremental improvement in these conditions would have a meaningful impact on the quality of life for people with SCI.

Spasticity

Spasticity refers to the often painful involuntary tensing, stiffening or contracting of muscles. Spasticity is not a disease but a symptom of other conditions, such as MS, SCI, stroke, traumatic brain injury and cerebral palsy, where portions of the nervous system that control voluntary movement have been damaged. This damage results in the nerve cells in the spinal cord becoming disconnected from controlling centers in the brain and, as a result, transmitting unregulated impulses to the muscles. People who have spasticity may experience it intermittently it may be triggered by a stimulus, such as pain, pressure sores, cold weather or a urinary tract infection. The majority of people with MS and SCI experience some form of spasticity, as do many people following stroke or brain injuries. We Move, a non-profit organization dedicated to movement disorders, estimates that spasticity affects approximately 500,000 people in the United States and over 12 million worldwide.

Current treatments for spasticity are focused on reducing spasm frequency, pain or irritating stimuli that can provoke spasticity. Treatment of spasticity often involves a combination of physical therapy and oral medications. Baclofen and tizanidine, the active ingredient in the Zanaflex products, are the two most frequently prescribed oral medications for spasticity. For more intractable spasticity, treatments sometimes include surgical or chemical destruction of nerve roots in the affected area.

Other Disorders of the Central Nervous System

Neurological injuries and degenerative diseases of the CNS, including stroke, traumatic brain injury, Parkinson s disease and Alzheimer s disease, are among the most devastating and costly of human ailments. These conditions are most often chronic and historically have been extremely difficult to treat. These disorders, like MS and SCI, involve damage to nerve cells and nerve fibers and would likely benefit from similar approaches to tissue protection and repair. For example, the inflammation process that occurs naturally after many types of tissue injury may damage both injured and healthy CNS cells. As with MS and SCI, these conditions could be treated with interventions that replace nerve cells, stimulate new nerve fiber growth, or increase the adaptability of connections within the nervous system.

Our Strategy

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

- *Complete the clinical development of and obtain regulatory approval for Fampridine-SR in MS.* One of our key objectives is to complete the clinical development of Fampridine-SR in MS and to seek and obtain regulatory approval for its commercial sale. In September 2006, we successfully completed a Phase 3 clinical trial of Fampridine-SR for the improvement of walking

ability in people with MS. We expect to initiate a second Phase 3 trial in the second quarter of 2007. We may also pursue subsequent approvals of Fampridine-SR in additional CNS disorders, including SCI.

- *Maximize our revenue from Zanaflex Capsules.* We have targeted doubling Zanaflex Capsules gross sales in 2007. Our expanded sales force will enable us to call on a larger number of prescribers treating patients with conditions that involve spasticity. In addition, we are exploring the potential for new indications.

- *Leverage the commercial presence of Zanaflex Capsules for the potential launch of Fampridine-SR.* We expect that the sales and marketing organization that we have developed, and the expertise that we are gaining with Zanaflex Capsules will provide a strong foundation for the commercial launch of Fampridine-SR, if approved by the FDA. Target prescribers for both Zanaflex and Fampridine-SR are likely to overlap substantially. Through our acquisition of the Zanaflex products, we have been able to strengthen our long-standing relationships with the physician and patient communities for both MS and SCI.

- *Advance our pipeline of preclinical programs into clinical trials.* We have one preclinical program focused on cellular protection, one on remyelination and one on nerve fiber regeneration and enhanced CNS plasticity. In order to advance these programs we are using our in-house scientific expertise and animal modeling capabilities, supplemented by outside service providers and the development work of our partners. We are also seeking partnering and additional grant funding opportunities for these programs.

- *Explore alternatives to maximize shareholder value.* We continually explore opportunities to maximize shareholder value and review our strategic goals in light of available opportunities, including potential corporate and product transactions.

Our Product Pipeline

Name	Status	Marketing Rights
Zanaflex Capsules	FDA-approved	U.S.
Zanaflex (tablets)	FDA-approved	U.S.
Fampridine-SR	Phase 3	Worldwide
Neuregulin Program	Preclinical	Worldwide
Remyelinating Antibody Program	Preclinical	Worldwide
Chondroitinase Program	Preclinical	Worldwide

Zanaflex Products

Zanaflex Capsules and Zanaflex tablets are short-acting drugs approved by the FDA for the management of spasticity. We acquired all of Elan s U.S. sales, marketing and distribution rights to Zanaflex Capsules and Zanaflex tablets in July 2004. These products contain tizanidine, one of the two leading treatments for the management of spasticity. Zanaflex tablets were approved by the FDA in 1996 and lost compound patent protection in 2002. There are currently 12 generic versions of tizanidine tablets on the market. However, substantial brand loyalty remains in the prescriber community for the Zanaflex brand. Approximately 90% of all prescriptions for tizanidine tablets are written as Zanaflex, although most are switched automatically at the pharmacy for a generic tizanidine tablet. Zanaflex Capsules were approved by the FDA in 2002, but were never marketed by Elan. We began marketing Zanaflex Capsules in April 2005.

Clinical trials conducted by Elan demonstrated that Zanaflex Capsules, when taken with food, produce average peak levels of tizanidine in a person s blood that are lower and rise more gradually compared to the peak levels following a similar dose of the tablet form. The FDA recognizes these pharmacokinetic differences and therefore has determined that Zanaflex tablets and generic tizanidine tablets are not therapeutically equivalent, that is, are not AB-rated to Zanaflex Capsules. As a result, under state pharmacy laws, prescriptions written for Zanaflex Capsules may not be filled by the pharmacist with Zanaflex tablets or generic tizanidine tablets, although some substitution does take place in practice. Zanaflex Capsules are available in 2 mg, 4 mg and 6 mg doses, while tablet formulations are only available in 2 mg and 4 mg doses. Our goal is to convert sales of Zanaflex tablets and generic tizanidine tablets to sales of Zanaflex Capsules. We discontinued supply of the 2 mg dose of Zanaflex tablets in February 2006 due to a reduction in demand, and we do not intend to order additional supply of this product in the future. Demand for the 4 mg Zanaflex tablet is also declining, but supports continued supply. The 6 mg capsule gives patients and physicians an additional dosing choice and an opportunity to reduce the number of pills a patient must take daily. In addition, many patients may find capsules easier to swallow than tablets. Also, people who have difficulty swallowing may open the capsule and sprinkle it on food. The pharmacokinetic effect of sprinkling contents of the capsule on food, however, is different from when the intact capsule is taken with food.

In 2006, retail sales of Zanaflex capsules, Zanaflex tablets and generic equivalents of Zanaflex tablets (tizanidine) totaled approximately $290 million. For the same period, retail sales of Baclofen totaled approximately $181 million, for an approximate aggregate market of $471 million. The vast majority of these prescriptions were written by a relatively small group of prescribers. Specialists accounted for approximately 40% of tizanidine prescribing. High-volume specialist prescribers were responsible for approximately two or three-and-one-half times more prescriptions per physician than high-volume primary care prescribers. We believe that our internal specialty sales force including our tele-sales team, will be able to reach virtually all of these high-volume prescribers.

Sales and promotional support for Zanaflex Capsules

To support our commercialization of Zanaflex Capsules, we have established a sales and marketing infrastructure consisting of our internal specialty sales force and a pharmaceutical telesales group. As of January 8, 2007, our internal specialty sales force consists of 65 sales professionals who call on neurologists, other specialists and primary care physicians and prescribers treating patients with conditions that involve spasticity, who are high volume prescribers of tizanidine. Members of this sales force also call on managed care organizations, pharmacists and wholesale drug distribution customers. We also have a contract with TMS Professional Markets Group, LLC 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.

Concurrent with our launch of Zanaflex Capsules in April 2005, we initiated a sampling program as well as a number of educational, promotional and drug safety monitoring programs for prescribers and patients. In addition to our programs for prescribers and patients, we also have a number of programs in place to educate pharmacists about Zanaflex Capsules and the pharmacokinetic differences between tizanidine tablets, including generic tizanidine tablets and Zanaflex tablets, and Zanaflex Capsules.

Pharmacokinetic differences between Zanaflex Capsules and tizanidine tablets

Although tizanidine, the active ingredient in Zanaflex Capsules, Zanaflex tablets and generic tizanidine tablets, is the same, there are some important differences between the capsule and tablet formulations. To establish the differences between Zanaflex Capsules and Zanaflex tablets, Elan conducted a single dose clinical trial with 96 healthy volunteers. That trial demonstrated that Zanaflex Capsules, when taken with food, resulted, on average, in a more gradual rise in tizanidine levels in the blood and a lower peak concentration. By contrast, the trial demonstrated that Zanaflex Capsules taken without food resulted in essentially the same pharmacokinetic profile as the tablet formulation of tizanidine. The results of the trial are illustrated in Figure 1 below.

Figure 1. Average Blood Concentration Over Time

Average blood concentrations of tizanidine in subjects following a single dose of 4 mg Zanaflex tablet or a 4 mg dose of Zanaflex Capsules, taken either with or without food.

As a result of this difference in absorption rate and blood level when taken with food, the FDA has determined that neither Zanaflex tablets nor generic tizanidine tablets are therapeutically equivalent or AB-rated, to Zanaflex Capsules. Therefore, under state pharmacy laws, pharmacists cannot fill prescriptions written for Zanaflex Capsules with Zanaflex tablets or generic tizanidine tablets. The FDA-approved package insert for Zanaflex Capsules contains the following language regarding the differences between the products: Food has complex effects on tizanidine pharmacokinetics, which differ with different formulations. These pharmacokinetic differences may result in clinically significant differences when (1) switching administration of the tablet between the fed or fasted state, (2) switching administration of the capsule between the fed or fasted state, (3) switching between the tablet and capsule in the fed state, or (4) switching between the intact capsule and sprinkling the contents of the capsule on applesauce. These changes may result in increased adverse events or delayed/more rapid onset of activity, depending on the nature of the switch. For this reason, the prescriber should be thoroughly familiar with the changes in kinetics associated with these different conditions.

In July 2006, we received regulatory approval of a new package insert for Zanaflex which provides for updated safety information and enhanced differentiation between capsules and tablets. The new language adds that ZANAFLEX CAPSULES ARE NOT BIOEQUIVALENT TO ZANAFLEX®

TABLETS IN THE FED STATE. THE PRESCRIBER SHOULD BE THOROUGHLY FAMILIAR WITH THE COMPLEX EFFECTS OF FOOD ON TIZANIDINE PHARMACOKINETICS.

The most frequent adverse events associated with the use of tizanidine include dry mouth, drowsiness, fatigue and dizziness. These events are generally mild to moderate and are believed to be dose-related. In one single-dose study where patients were not titrated (that is, gradually increased in dose), two-thirds of patients experienced hypotension. Zanaflex Capsules have a short-acting effect, and patients are advised to take it at the times during the day when they most need relief from spasticity.

Fampridine-SR

Fampridine-SR is a small molecule drug contained in a sustained-release tablet form. Laboratory studies have shown that fampridine, the active ingredient in Fampridine-SR, improves impulse conduction in nerve fibers in which the myelin sheath has been damaged. Fampridine is not currently FDA-approved for use in MS or any other indications. Fampridine-SR is a sustained release formulation of fampridine that we believe produces blood levels that are maintained throughout the day, which cannot be easily accomplished with an immediate-release formulation. We believe that Fampridine-SR could represent a fundamental shift in the treatment of people with MS because it may improve neurological function rather than treating the symptoms or slowing the progression of disease, as current treatments do. We have obtained Orphan Drug designations from the FDA for Fampridine in both MS and incomplete SCI.

In MS, the myelin sheath is damaged by the body s own immune system, causing areas of myelin sheath loss, also known as demyelination. When a nerve fiber is demyelinated after injury, large numbers of the specialized potassium channels on the surface of the axon that are normally hidden or covered by the myelin sheath are exposed and leak potassium ions, causing the nerve fiber to short circuit its electrical impulses. Fampridine blocks these exposed channels, thereby simulating the insulation normally provided by the myelin sheath permitting the nerve fiber to transmit impulses again, even in a demyelinated state. Fampridine may also serve to amplify electrical signals at sites of contact or synapses between nerve cells by blocking the same channels in the tips of the nerve fiber, thereby improving the function of surviving tissue in the injured nervous system.

We have a worldwide, exclusive license from Elan for all of its rights to, among other things, develop, promote, distribute, use and sell Fampridine-SR in all human clinical indications, and to develop, promote, distribute, use and sell other patented sustained-release formulations of the drug. Elan also manufactures Fampridine-SR for us.

We believe there are compelling reasons to develop Fampridine-SR as a new therapy for improving walking ability in people with MS:

- According to a patient registry maintained by the North American Research Committee on Multiple Sclerosis, approximately 80% of people with MS experience some degree of walking impairment, which is one of the most limiting aspects of the disease.

- Our Phase 2 and Phase 3 clinical trials of Fampridine-SR in MS patients have consistently shown improvement in walking ability and leg strength.

- There are no current therapies indicated to improve walking ability or leg strength in people with MS.

Clinical Trials of Fampridine-SR

We have conducted a series of clinical trials to establish the safety, pharmacokinetics and optimal dosing of Fampridine-SR in MS and SCI, as well as to assess its efficacy. More than 1,300 people

have been treated with Fampridine-SR in over 25 clinical trials, including 13 clinical trials in MS and 11 clinical trials in SCI.

In September 2006, we announced positive results from our Phase 3 clinical trial of Fampridine-SR for the improvement of walking in patients with MS, which was performed under a Special Protocol Assessment, or SPA, from the FDA. Statistical significance was achieved on all three efficacy criteria defined in the SPA. The FDA agreed in the SPA that this trial, if successful, could qualify as one of the pivotal efficacy studies required for drug approval.

Based on a meeting with the FDA on December 7, 2006, we have designed and will conduct an additional Phase 3 trial of Fampridine-SR in people with MS, as well as a thorough QT safety cardiac study, consistent with the FDA s recently established standard requirements for all new compounds.

Clinical Trials in Multiple Sclerosis

Completed Phase 3 Trial. Our first MS Phase 3 clinical trial, MS-F203, was initiated in June 2005, pursuant to our SPA from the FDA. MS-F203 was a double-blind trial for which we enrolled a total of 304 patients at 33 MS clinical centers in the United States and Canada. Subjects completed a Timed 25-Foot Walking Test at each visit during the clinical trial, which included a 14 week treatment period. This test involves timing the subject s completion of a 25-foot walk as fast as he or she can do so safely. This test is widely used to measure walking function in patients with a range of diseases and conditions that affect mobility, and has been shown to relate closely to an individual s ability to walk longer distances. Neurologists employ this test as an indicator of the overall progression of MS, since many different pathways in the brain and spinal cord influence walking, including motor, sensory, position sense, balance and visual system pathways, as well as intrinsic locomotor pathways in the spinal cord.

In addition, subjects were asked to fill out a questionnaire known as the 12-item MS Walking Scale or MSWS-12. The MSWS-12 is a subjective measure of the degree to which walking disability impacts a person s activities of daily life.

Statistical significance was achieved on all three efficacy criteria defined in the SPA. A significantly greater proportion of people taking Fampridine-SR had a consistent improvement in walking speed, the study s primary outcome, compared to people taking a placebo. In addition, the effect was maintained throughout the 14-week treatment period, and there was a statistically significant improvement among responders compared to non-responders in the 12-Item MS Walking Scale.

Trial results were analyzed using our proprietary responder analysis which was accepted by the FDA in our SPA and for which we have applied for a patent. A subject was deemed to be a responder if his or her score on the 25-foot walk was better during the majority of his or her visits in the treatment phase of the trial, than the best visit during the non-treatment phase. The primary endpoint of the trial was the comparison of the percentage of responders in the Fampridine-SR group to the percentage of responders in the placebo group. To validate the clinical importance of improvements in the timed walk measurements, the MSWS-12 scores of the responders were compared against those of non-responders. This analysis was designed to ensure that being deemed a responder was clinically meaningful to the subject. In addition, the trial tested for significant improvement in walking ability in the Fampridine-SR-treated responder group at the last treatment visit versus the placebo group. This analysis was designed to ensure that the improvements seen by responders were maintained over the entire 14-week duration of the time on treatment. As a secondary outcome, the trial also measured lower extremity muscle strength, as assessed by the modified British Medical Research Council manual muscle testing procedures, referred to as the Lower Extremity Manual Muscle Test or LEMMT. Other secondary outcomes included a subject global and clinician global impression, each rated on a seven-point scale, and the Ashworth score, a measure of spasticity. We expect to disclose results of

these other secondary outcomes at our platform presentation at the annual meeting of the American Academy of Neurology, on May 2, 2007.

The design of the MS-F203 trial was closely modeled on the design of the preceding Phase 2 clinical trial, MS-F202, and built on our clinical trial experience in measuring improvements in neurological function against the variability in function that is inherent in people with MS. Individuals who suffer from MS vary in the severity of the impairments they experience on a day-to-day basis, depending on the activity of the disease on a given day. As a result, from one clinical trial visit to the next, a subject s walking ability can vary significantly. This variability makes it difficult to distinguish treatment-related changes in walking ability from disease-related changes in walking ability. Our review of data from our MS-F202 trial demonstrated that a responder form of analysis helps overcome the effect of the inherent variability of disease activity that people with MS experience.

Figure 2, below, summarizes the results of the MS-F203 trial for the three criteria defined in the SPA. Results are also presented for the same statistical analysis applied retrospectively to the MS-F202 study, which is discussed below in Phase 2 Clinical Trials. When applying this analysis, the results of the MS-F203 trial closely match the results obtained from the MS-F202 trial. For both studies, statistical significance was achieved on all three efficacy criteria defined in the SPA. A significantly greater proportion of people taking Fampridine-SR had a consistent improvement in walking speed measured by the Time 25-Foot Walk, compared to people taking placebo (*MS-F203*: 34.8% vs. 8.3%; *MS-F202*: 36.7% vs. 8.5%) ($p < 0.001$ for each study. A p-value is a statistical term that indicates the probability that a difference between treatment groups is random. The smaller the p-value, the lower the likelihood that the difference was random. Generally a p-value of less than 0.05 is considered to represent a statistically significant difference.). In addition, the effect was maintained in this study throughout the 14-week treatment period ($p < 0.001$ for each study) and there was a statistically significant reduction in walking disability as shown in the average change in the MSWS-12 for walking responders vs. non-responders (*MS-F203*: $p < 0.001$; *MS-F202*: $p = 0.020$).

Figure 2. Summary Study Results for the SPA Criteria (ITT Population)

MS-F202

MS-F203

Percentage of Responders

Change from Baseline in Walking Speed (ft/sec) at Double-Blind Endpoint

Average Change from Baseline in the MSWS-12 Score

ABBREVIATIONS: FNR=Fampridine-SR non-responders; FR=Fampridine-SR responders

*: p-value versus Fampridine-SR responder group.

Note: For MS-F202, some non-responders had no follow-up data for a particular variable; so the sample sizes (with respect to that variable) may be less than the actual number of ITT patients.

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Change in Walking Speed over Time

Figure 3, below, summarizes the changes from baseline in walking speed over time.

Figure 3. Percent Changes from Baseline in Walking Speed at each Double-Blind On-Treatment Visit (ITT Population)

MS-F202

MS-F203

ABBREVIATIONS: FR=Fampridine-SR Responders; FNR=Fampridine-SR Non-responders.

Note: For each patient, if a walking speed was missing at a given time point, then the average percent change among the available assessments was imputed in place of the missing value.

**: Significantly better than placebo and Fampridine-SR non-responders.

*: Significantly better than placebo (only)

^: Significantly better than Fampridine-SR non-responders (only)

#: The treatment sample sizes presented in the figure legend represent the number of ITT patients with at least one scheduled double-blind visit with an assessment of walking speed.

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The results of the MS-F203 study closely match the results obtained from the previous MS-F202 study. In particular, the Fampridine-SR responders exhibited a consistent pattern of improvement from visit to visit across both studies ranging from a mean of 24.2% to 28.9% across both studies. The placebo group showed a slightly larger mean improvement from visit to visit in MS-F203 (range of 2.1% to 7.4) compared to MS-F202 (1.7% to 3.7%). In both studies, at every double-blind on-treatment visit, the Fampridine-SR responders were statistically superior ($p<0.001$) to the placebo group.

Results for the Fampridine-SR non-responders are also illustrated and show that there was a relatively small, transient improvement in average walking speed at the earliest visit, two weeks after initiation of treatment in both trials, though this was statistically significant only in the MS-F203 study. Thereafter, there was no consistent difference between the non-responders and the placebo-treated groups. A small, but marginally significant decline in walking speed for the non-responders was seen at the last on-drug visit in MS-F202 but this was not repeated in MS-F203.

Leg strength. A statistically significant improvement in leg strength, as measured by the average change from baseline in the Lower Extremity Manual Muscle Test (LEMMT), was seen in Fampridine-SR responders compared to the placebo treated patients ($p < 0.001$). The Fampridine-SR non-responders were also statistically superior to the placebo group with respect to the average change from baseline in LEMMT during the double-blind period in both studies ($p < 0.046$). This suggests that improved leg strength may contribute to walking speed improvement in some patients, but does not account for the improvement in walking ability among responders as compared to non-responders. The data also suggest that patients treated with Fampridine-SR may achieve functional benefits, such as improved leg strength, even if they do not have consistent improvement in walking speed.

Phase 2 Clinical Trials.

The Phase 2 clinical trial of Fampridine-SR in MS, MS-F202, was designed to compare 10 mg, 15 mg and 20 mg doses of Fampridine-SR taken twice per day and to assess their relative safety and efficacy over a stable treatment period of 12 weeks. The pre-specified primary endpoint of the clinical trial was an improvement in average walking speed using the Timed 25-Foot Walk. The clinical trial was initiated in early 2003 and completed enrollment of 211 subjects in 24 major MS centers in August 2003. The clinical trial was designed to give us a clear indication of optimal dose and the number of subjects that we would need to establish efficacy in a subsequent Phase 3 trial.

The efficacy results, based on the prospective analysis plan of MS-F202, indicated a trend for improvement from baseline in walking ability (using the Timed 25-Foot Walk test) in the Fampridine-SR-treated subjects, relative to the placebo-treated subjects. Statistical significance was not reached on the primary efficacy analysis, which was defined as the percentage change from baseline in average walking speed during the 12 weeks of stable double-blind treatment (that is, the average for each group over the last three of the four treatment period visits). Statistical significance was obtained for the secondary outcome measure of lower extremity muscle strength, as assessed by LEMMT. All three Fampridine-SR dose groups showed greater mean increases from baseline in LEMMT scores relative to the placebo group and the differences were statistically significant for the 10 mg and 15 mg Fampridine-SR groups ($p< 0.05$).

Our analysis of the data led us to believe that part of the reason that statistical significance was not achieved on the primary endpoint was related to the disease-related variability of walking ability for a subject from visit to visit, together with the fact that not all subjects are expected to respond to the treatment. In order to try to reduce the effect of this variability, we developed an analysis designed to classify subjects as responders only if they demonstrated consistent improvement during the treatment period, when subjects were taking either Fampridine-SR or placebo. Subjects were deemed to be responders if their Timed 25-Foot Walk test results were better during at least three of the four treatment visits than their best score out of five visits during the non-treatment period. When examined using this form of analysis, all three of the groups receiving Fampridine-SR had a statistically

significant increase in the number of responders compared to placebo (10mg: p=0.006; 15 mg: p=0.004; 20 mg: p=0.002).

Since the differences in responder rates among the three doses examined were small, more detailed analyses were performed comparing the pooled Fampridine-SR-treated groups against the placebo-treated group. The difference in responder rate between the pooled Fampridine-SR-treated subjects and the placebo-treated subjects was also statistically significant (p-value<0.001).

In MS-F202, subjects were required to fill out the MSWS-12 questionnaire. When the results of this questionnaire were analyzed for all evaluable subjects, the average improvement, or reduction in score, during the treatment period was greater for responders than for non-responders, in each case including those subjects on placebo, and the difference was statistically significant. Similarly, a statistically significant difference was seen in the Subject Global Impression (SGI) scores between the responder and non-responder groups, indicating that the responder subjects as a group felt more positively about the effects of the medication they were taking. The SGI is a seven-point scale (from terrible to delighted) in which trial participants rated how they felt about the overall effect of the trial drug. We believe these results demonstrate that being a timed-walk responder is clinically meaningful to patients.

This analysis of the MS-F202 clinical trial served as the basis for the design of the Phase 3 MS-F203 clinical trial. The results of MS-F202 using this analysis showed that there was a statistically significant increase in the number of people being treated who experienced a consistent increase in walking ability over the full 14 weeks of treatment, compared to placebo, and that this improvement was sustained and clinically meaningful to patients. As previously noted, these results are similar whether the pooled Fampridine-SR-treated subjects (just those subjects receiving the current target dose of 10 mg twice a day), or subjects from the other two dose groups (15 and 20mg twice a day), are compared with the placebo-treated group. In addition, statistically significant improvements in LEMMT score were seen in MS-F202, as in MS-F203, in both the responder and non-responder groups.

In 2001, we completed a smaller double-blind Phase 2 clinical trial of Fampridine-SR, MS-F201, which was published in the online edition of the journal Multiple Sclerosis in February 2007, and will be available in the April 2007 print edition. This clinical trial was designed to determine the optimal dose range of Fampridine-SR and to evaluate possible ways in which to measure the effect of the drug on symptoms of the disease, including motor strength, timed walking and self-reported fatigue. The clinical trial involved a total of 36 MS subjects in four major academic MS research centers. A total of 25 subjects received Fampridine-SR in doses increasing from 10 mg to 40 mg twice per day during seven weeks of treatment and 11 subjects were given placebo during the same period. This treatment period was preceded by a series of baseline evaluations during the course of four weeks to allow the subjects to become adjusted to the clinic visits and allow the various measurements to stabilize. A one-week blinded treatment with placebo tablets preceded the first drug administration to look for potential placebo effects on the various outcome measures.

The clinical trial demonstrated that doses up to 25 mg twice a day were well tolerated and were associated with statistically significant improvements in walking ability and leg muscle strength. All the improvement in strength and walking ability was apparent within these first four weeks of the treatment, at doses from 10 mg to 25 mg twice a day. The placebo-treated subjects showed some tendency to improve or worsen in walking ability, mostly within 20% of their baseline average. However, the Fampridine-SR-treated group showed a marked tendency for improvement in walking speed, with 9 of 25 subjects improving more than 20% from baseline and two with greater than 50% improvement. These findings were consistent with the results of an earlier, small, crossover study sponsored by Elan, using doses of 17.5 mg twice a day for one week, which was published in the journal *Neurology* in 1997. Most of the benefit was seen in the first week of the study, a dose of 10mg

twice a day. The average improvement in walking speed for this week was approximately 70% of the maximum improvement measured across the first four weeks, up to 25mg twice a day.

We re-examined the data from the MS-F201 clinical trial using an equivalent responder analysis in which we defined a responder as a subject who showed walking ability on the 25-Foot Walk that was faster in a majority of treatment visits than the fastest speed recorded during the non-treatment period. In MS-F201, this meant that four or more of the seven treatment visits had to show faster walking than the visits during the non-treatment period. We found that the responder rates in this trial were 40% (10 of 25) for the Fampridine-SR-treated subjects and 9.1% (1 of 11) for the placebo-treated subjects. Hence, the response rate by this measurement was similar to that seen in the MS-F202 and MS-F203 clinical trials. We did not include the MSWS-12 measure in the MS-F201 trial.

Measurement of Walking Disability in MS. Our clinical trials have concentrated on walking because gradual loss of walking ability is a key physical problem for patients, a clear indicator of progression of MS, and widely used by neurologists to measure the neurological status of their patients. We have used the Timed 25 Foot Walk because it is the most standardized, objective measure that can be readily implemented in large, multi-center studies. A number of published studies have shown that walking ability measured with this test correlates well with other measures, such as the Six Minute Walk, that involve more extensive walking efforts. Changes in the Timed Walk, that are usually measured in seconds, are therefore representative of more substantial changes in the patient s daily activities, A number of studies have shown that changes of 20% in the Timed Walk correlate significantly with changes in broader measures of neurological status and disability.

Our two most recent trials have shown that approximately 35% of people with MS treated with Fampridine-SR have a consistent improvement in walking speed, measured with the Timed 25 Foot Walk. The average improvement in walking speed among Fampridine-SR responders was approximately 25%. Consistent with previous data on the clinical impact of changes in the Timed Walk, our trials showed that responders as a group reported significantly greater improvement in their self-assessed walking disability, as measured by the 12-Item MS Walking Scale. The MSWS-12 is a questionnaire that was developed specifically to provide a reliable and valid patient-based measure of the impact of MS on daily activities that depend on walking.

Fampridine-SR responders were distributed across the full range of baseline disability, defined by our inclusion criteria of average walking times for the 25 Foot Timed Walk from eight to 45 seconds. Response to Fampridine-SR also appears to be independent of the type or duration of MS, as well as of concomitant treatment with other drugs or physical therapy.

Clinical Trials in Spinal Cord Injury

Recent clinical research using imaging and post-mortem studies has shown that the majority of people with SCI do not have severed spinal cords and maintain some nerve fibers that cross the site of injury. However, these surviving nerve fibers are often damaged and lose their myelin sheath. A series of preclinical studies and clinical trials have indicated that fampridine can potentially improve conduction in nerve fibers injured by spinal cord injury and improve function in people with spinal cord injury.

Phase 3 Clinical Trials. In March 2004, we released results from two Phase 3 double-blind clinical trials of Fampridine-SR in people with SCI. The trials did not reach statistical significance in their primary endpoints, which were reduction of spasticity, as measured by the Ashworth scale, and improvement of patients Subject Global Impression, or SGI. The Ashworth scale is a validated, 5-point clinician assessment of an individual s spasticity. The SGI is a seven-point scale in which trial participants rate how they feel about the overall effect of the trial drug. In one of the SCI trials, the data showed a positive trend (p=0.069) toward improvement on the Ashworth scale when analyzed across all observations during the double-blind trial treatment period, which was the trial s pre-specified plan of analysis. When analyzed based on the subjects last observation carried forward, a commonly used

method of analysis, the improvement in, or reduction of, Ashworth score in that trial was statistically significant (p=0.006). The drug groups in both trials showed a progressive mean improvement on the Ashworth score during the double-blind treatment period. However, the placebo group in one of the trials showed a more pronounced reduction in Ashworth score than expected.

The design of these Phase 3 clinical trials was based on a series of earlier Phase 2 clinical trials in which the most consistent finding was a greater reduction in spasticity in Fampridine-SR-treated subjects relative to placebo-treated subjects, as measured by the Ashworth score. Other benefits observed in the Phase 2 trials were improved motor, bowel, bladder and sexual function. Unlike the design of our Phase 3 clinical trials, our Phase 2 clinical trials did not require a minimum spasticity level for enrollment and the treatment period was from one to four weeks rather than 14 weeks. These changes were made in the Phase 3 trials because the FDA required minimum twelve week duration of treatment for approval of a long-term therapy of this kind and because adequate measurement of benefit required a certain degree of spasticity at baseline.

Based on the entire body of data in clinical trials of fampridine in people with SCI and the new approaches to evaluating response to the drug that we have learned in MS trials, we may resume development of Fampridine-SR for SCI after we have completed further development of the drug for MS.

Safety Profile of Fampridine-SR

Fampridine-SR has been taken by over 1,300 subjects in clinical studies. In addition to our placebo-controlled clinical studies, as part of our continuing evaluation of safety, we have established extension studies that allow subjects in completed clinical trials to receive Fampridine-SR on an unblinded, or open-label basis, with their progress followed at regular clinical visits. These studies are intended primarily to gain sufficient subject experience to satisfy the regulatory guidelines for long-term and overall safety assessments, though some additional uncontrolled efficacy data is also assessed.

As of March 16, 2007, 177 subjects from MS-F202 had been enrolled in an extension trial and 122, or approximately 69 percent, remained active in the trial, with duration of treatment ranging from two and a half to three years. As of the same date, 268 patients from MS-F203 had been enrolled in a new extension study and 232 of these, or approximately 87 percent, remained active, with duration of treatment ranging from five to 15 months. These extension studies have included treatment of 406 people for more than six months and 223 people treated for more than one year. The total exposure to Fampridine-SR in our MS studies to date, including both double-blind and open label studies, is over 700 patient-years, while exposure to placebo is approximately 35 patient-years.

The adverse events most commonly experienced in the MS-F202 and MS-F 203 studies were falls, urinary tract infection, insomnia, dizziness, asthenia, headache, fatigue, nausea and balance disorder. The majority of these events were mild to moderate in intensity. Among these types of event, only insomnia, asthenia, nausea, and balance disorder were seen more than 50% more frequently in the Fampridine-SR-treated than the placebo-treated patients.

Seizures have been reported in a small number of subjects over the course of the development program and have also been reported in cases of overdose with fampridine outside the program. The incidence of seizures appears to be dose-related. Overall, the incidence of seizure at the current dose of 10 mg twice a day cannot be distinguished from rates that would be expected from previous long-term controlled studies of other drugs in MS patients, either in placebo-treated or investigational-drug-treated groups. These rates typically have been in the range of one percent to two percent over two to three years of study.

We are carefully monitoring the potential for seizure as a side effect, including the possibility of interaction with other drugs that are known to lower the threshold for seizure in susceptible subjects.

We have excluded from our studies subjects known to be at risk for seizures because they have had seizures previously or because they have an abnormal electroencephalogram indicative of such risk.

Fampridine is known to block a wide range of potassium ion channels in cell membranes, which are potentially important not only in the nervous system but also in the heart. We have completed studies to examine the specific effects of the drug on the cardiac potassium channels of principal interest from the point of view of cardiac safety, the human ether-a-go-go related gene or hERG channel. These are standardized tests of the potential for a drug to affect the QT interval, a measure of heart function. Prolongation of the QT interval is believed to be a risk factor for triggering potentially fatal cardiac arrhythmias. These laboratory studies showed that fampridine blocks the hERG channel by 50% at a concentration which is approximately ten thousand times the average peak concentration expected in the blood of patients taking 10 mg doses of Fampridine-SR. Based on these observations, fampridine would not be expected to affect the hERG channel at clinically relevant concentrations. In another standard test, we have also performed studies on isolated dog cardiac Purkinje fibers. These showed no effect on the electrical behavior of these heart cells in the range of concentrations relevant to clinical experience, including concentrations 100 times higher than the expected average peak levels in the blood of patients. Additional studies of cardiac safety in dogs showed no notable changes in cardiac electrical behavior or function, up to maximum tolerated doses.

Most of the clinical trials in the Fampridine-SR development program have included electrocardiogram recordings, at baseline and during treatment, to examine the potential for cardiac effects of fampridine. Although this monitoring has not demonstrated an effect on heart function, these kinds of measurements are not sufficient to satisfy the current regulatory requirements for a thorough study of potential effects on QT interval. Therefore, in accordance with recently developed regulatory guidelines, we are conducting a Thorough QT Study . This study in normal healthy subjects will examine the effects of the planned therapeutic dose, a higher dose, and a positive control drug against placebo. The positive control, which is known to prolong QT interval, will assure that, if any prolongation is present, it would be measurable in the study. This kind of study is now a standard requirement for the approval of any new drug.

Other Research and Development Programs

Remyelination Programs

Our remyelination programs include two distinct therapeutic approaches to stimulate repair of the damaged myelin sheath in MS, Glial Growth Factor 2, or GGF-2, and remyelinating antibodies. These two approaches address remyelination by different and potentially complementary routes. Both programs require finalizing production of clinical-grade material and completion of preclinical toxicology tests before moving into clinical development. We believe a therapy that could permanently repair myelin sheaths has the potential to restore substantial neurological function to those affected by demyelinating conditions.

Neuregulins/GGF-2

The neuregulins form a family of growth factors related to epidermal growth factor. These molecules bind to erbB receptors, which translate the growth factor signal to the cell and cause changes in cell growth, protein production and gene expression. Neuregulins have been shown in published studies to have a range of effects in protection and repair of cells both in the nervous system and in the heart. In 2002, we obtained from CeNeS Pharmaceuticals plc., or CeNeS, an exclusive worldwide license to its neuregulin patents and related technology, including GGF-2, our lead molecule for the neuregulin family.

Neuregulins covered in the portfolio from CeNeS have a number of potential applications. Neuregulins and their erbB receptors are essential for cardiac development and have been shown to protect cardiac muscle cells from stressors that can lead to congestive heart failure and myocardial infarction. Additionally, neuregulins have been shown to protect the heart and brain from the toxicity of

commonly used chemotherapeutic agents, such as anthracyclines. Studies in mouse, rat and dog models of congestive heart failure have shown that neuregulins significantly improve cardiac function and survival. Neuregulins have been shown to stimulate remyelination in animal models of MS and to protect the brain in an animal model of stroke. Therefore, the neuregulins offer us the potential for multiple CNS and cardiac indications, including MS and congestive heart failure as well as protection from chemotherapy-induced damage.

Remyelinating Antibodies Program

Our remyelinating antibodies program is based on research performed at Mayo Foundation for Medical Education and Research, or Mayo Clinic. Under a license agreement entered into with Mayo Clinic in September 2000, we have exclusive worldwide rights to patents and other intellectual property for these antibodies related to use and treatment of CNS disorders. Studies have demonstrated the ability of this family of antibodies to stimulate repair of the myelin sheath in three different animal models of MS. In particular, these antibodies were found to react with molecules on the surface of the cells that make the myelin sheath and stimulate them in a number of ways, leading to increased remyelination activity. First identified in mice, similar antibodies were subsequently identified in human blood samples by the Mayo team and we have been able to produce a recombinant human antibody that may be suitable for clinical development.

We have also supported preclinical studies at Mayo Clinic to learn more about the ways the antibodies act to stimulate the myelin sheath-forming cells. In 2004, Mayo Clinic received a $2 million grant to develop and manufacture clinical-grade material and progress the program towards clinical development. A pre-IND meeting with the FDA was held during which the details of a preclinical development program were discussed. Manufacturing has proceeded and a program of toxicology studies required for an IND is planned. The manufacturing of material to support preclinical toxicology and potential phase 1 human studies is underway. meeting and to support an IND filing. Manufacturing has proceeded and a program of toxicology studies required for an IND is planned. Manufacturing and toxicology program have been designed to meet the requirements established by the pre-IND Agreements with commercial laboratories to perform toxicology studies have been established.

Chondroitinase Program

We have developed a program 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. A similar matrix exists even in uninjured parts of the CNS tissue and restricts plasticity, the ability to modify or re-establish nerve connections. One or both forms of matrix may also inhibit repair of the myelin sheath by restricting the movements of the myelinating cells into the area of damage.

A major component of these two forms of matrix are chondroitin sulfate proteoglycans, or CSPGs. Cell culture studies and a number of animal studies have shown that these CSPGs inhibit the growth of nerve fibers and are likely to be key factors in the failure of the spinal cord or brain to regenerate and repair. Studies also have shown that bacterial enzymes called chondroitinases break down the CSPG molecules, thereby reducing their inhibitory activity.

Six independent laboratories have published animal studies showing that application of chondroitinase results in recovery of function following injuries to various areas of the brain or spinal cord. These functions have included walking, forelimb grasping, sensation, and visual and bladder function. We have successfully tested the ability of one of these molecules, Chondroitinase ABC-I, to improve function in an animal model of spinal cord injury. These studies were published in the Journal of Neurotrauma in February 2005. In these studies, rats that sustained a spinal cord injury were treated with either chondroitinase or an ineffective enzyme control and evaluated over 10 weeks of recovery. Animals treated with chondroitinase showed significant improvements both in motor function of the limbs and in bladder function, compared to those treated with the control enzyme. We

have also produced and successfully tested in animal models a recombinant version of naturally-occurring Chondroitinase ABC-I.

We are conducting a research program, which has been funded in part by federal and state grants, to develop second generation approaches to overcoming the proteoglycan matrix. These include novel enzyme molecules and alternative approaches to blocking matrix formation. We are now exploring the possibility of obtaining additional research grants from the NIH as well as potential partnerships with other companies to support completion of our preclinical program in chondroitinase. In 2003, we obtained an exclusive worldwide license to certain patents and technology from Cambridge University Technical Services Limited and King s College London related to our chondroitinase program. We are also building our intellectual property position with respect to this technology with patent applications around uses of the known compound and new chemical structures.

Sales and Marketing

We have established two sales channels for marketing Zanaflex Capsules: an internal specialty sales force and an external telemarketing group.

- *Internal Specialty Sales Force.* We employ a team of highly experienced sales professionals to call on 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 wholesale drug distribution customers. Our sales professionals have had an average of 13 years of sales experience prior to joining us. From May 2006 to January 2007, we expanded our specialty sales force from 32 to 65 sales professionals in order to extend our reach among neurologists, other specialists, and primary care prescribers treating patients with conditions that involve spasticity, and who are high volume prescribers of tizanidine.

- *Contract Pharmaceutical Telesales Organization.* We have retained TMS Professional Markets Group, LLC (which purchased various telesales assets from Access Worldwide Communications, Inc., with whom we had previously contracted) to provide a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care physicians and specialty physicians to determine their interest in receiving samples of Zanaflex Capsules or a visit from one of our sales representatives. TMS Professional Markets Group also contacts pharmacies to assist us in educating pharmacists that Zanaflex Capsules are not interchangeable with Zanaflex or tizanidine tablets.

We believe that, in general, people with MS and SCI are knowledgeable about their conditions, actively seek new treatments, and directly influence their prescriber s evaluation of treatment options. We have existing relationships with the major advocacy groups that focus on MS and SCI. We provide regular updates regarding our development programs and we sponsor or support several educational initiatives. We have implemented a comprehensive series of educational and promotional programs to support Zanaflex Capsules. These include educational materials, a peer-to-peer speakers program, samples, medical information and drug safety monitoring services, as well as a patient assistance program. At the request of the FDA, we have also implemented an educational program to inform pharmacists, prescribers and patients that Zanaflex tablets or generic tizanidine tablets are not therapeutically equivalent to Zanaflex Capsules and that, as a result, a prescription for Zanaflex Capsules should not be substituted with any tablet formulations at the pharmacy.

We believe that the expertise we are developing through commercializing Zanaflex Capsules will provide a strong foundation for our marketing of Fampridine-SR, if approved, as well as for additional potential treatments in CNS conditions. As a result, we plan to market Fampridine-SR ourselves in the United States and possibly in Canada, if it is approved in both countries. We expect that the sales force for Zanaflex Capsules would also promote Fampridine-SR in the United States since both products would have many of the same prescribers. We are exploring various alternatives for commercializing Fampridine-SR internationally.

Similar to other pharmaceutical companies, our principal customers are wholesale pharmaceutical distributors. We currently depend on three key customers. For the year ended December 31, 2006, Cardinal Health, McKesson Corporation and AmerisourceBergen Corporation accounted for approximately 40.1%, 43.8% and 11.2% of our shipments, respectively.

Scientific and Medical Network

We have an established 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. Some members of our advisory team are highlighted below.

Name	**Affiliation**
Michael S. Beattie, Ph.D.	Professor Emeritus, Department of Neuroscience, University of California.
Jacqueline C. Breshnahan, Ph.D.	Professor Emeritus, Department of Neuroscience, University of California.
Mary B. Bunge, Ph.D.	Professor of Cell Biology and Anatomy, Neurological Surgery and Neurology, University of Miami School of Medicine.
Carl W. Cotman, Ph.D.	Professor of Psychobiology and Neurology, University of California, Irvine.
James W. Fawcett, Ph.D.	Merck Company Professor of Experimental Neurology, Cambridge University, and Chairman of the MRC Cambridge Centre for Brain Repair.
Martin Grumet, Ph.D.	Professor of Cell Biology and Neuroscience, Rutgers University Director, W. M. Keck Center for Collaborative Neuroscience.
Eugene Johnson, Jr., Ph.D.	Norman J. Stupp Professor of Neurology, and Professor of Molecular Biology and Pharmacology at Washington University School of Medicine, St. Louis.
Mark D. Noble, Ph.D.	Professor of Genetics at the Center for Cancer Biology, University of Rochester Medical Center.
Melitta Schachner, Ph.D.	Professor and Director of the Institute for Synthesis of Neural Structures, University of Hamburg, Germany.
Jerry Silver, Ph.D.	Professor of Neurosciences, Case Western Reserve University.
Patrick A. Tresco, Ph.D.	Professor of Bioengineering, Director Keck Center for Bioengineering, University of Utah.
Mark H. Tuszynski, M.D., Ph.D.	Professor of Neurosciences, Director of the Center for Neural Repair, and Attending Neurologist at the University of California, San Diego.
Stephen G. Waxman, M.D., Ph.D.	Chairman of the Department of Neurology, Yale University School of Medicine.
Wise Young, Ph.D., M.D.	Professor II and Founding Director of the W. M. Keck Center for Collaborative Neuroscience, Rutgers University.

In addition, we have recruited approximately 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.

Collaborations, Alliances and License Agreements

Elan Corporation plc

Fampridine-SR

In January 1997, we licensed from Elan exclusive worldwide rights to Elan s sustained release formulation of fampridine, Fampridine-SR, for the treatment of SCI. In April 1998, we formed MS Research & Development Corporation, or MSRD, with Elan s subsidiary, Elan International Services, Ltd., or EIS, to develop Fampridine-SR for treatment of MS. At that time, MSRD licensed from Elan exclusive worldwide rights to Fampridine-SR for the treatment of MS.

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 the assets and assumed liabilities of MSRD. MSRD distributed the purchase price to its shareholders according to their equity ownership interest. We received a distribution of approximately $9.5 million. We also purchased EIS s shares at par value, and own approximately 88% of MSRD, which now has no assets or liabilities and is inactive.

In September 2003, we entered into an amended and restated license with Elan, which replaced the two prior licenses for Fampridine-SR in oral sustained release dosage form. Under this agreement, Elan granted us exclusive worldwide rights to Fampridine-SR for all indications, including SCI, MS and all other indications. We agreed to pay Elan milestone payments of up to $15.0 million and royalties based on net sales of the product, if approved. We have not made any payments under this agreement through December 31, 2006.

Elan is responsible for completing the chemistry, manufacturing and controls section of our New Drug Application, or NDA for Fampridine-SR and equivalent regulatory applications outside the United States. Elan is also supplying us with product for our clinical trials under this agreement.

Elan may terminate our license 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 the license agreement if we fail to launch a product in such countries within 180 days of NDA or equivalent approval or if we fail to fulfill our payment obligations under the license agreement. If Elan terminates our license in any applicable country, Elan is entitled to license from us our patent rights and know-how relating to the product and to market the product in the applicable country, subject to royalty payments to us.

We have the right to terminate the Elan license at any time by written notice. In addition, the Elan license may be immediately terminated by either party following an incurable breach of any term or provision by the other party. The Elan license may also be terminated by either party following notice and a cure period with respect to an uncured breach by either party.

Subject to the early termination provisions, the Elan license terminates on a country by country basis on the last to occur of fifteen years from the date of the agreement, the expiration of the last to expire Elan patent or the existence of competition in that country.

Zanaflex

In July 2004, we entered into an Asset Purchase Agreement with Elan pursuant to which we acquired all of Elan s research, development, distribution, sales and marketing rights to Zanaflex

Capsules and Zanaflex tablets in the United States. The assets acquired include the products FDA registrations and FDA dossiers, proprietary product know-how, a patent and two related patent applications, certain inventory of Zanaflex tablets and certain product books and records. Elan also granted us a license allowing us to use the Zanaflex trademarks in the United States, with the right to buy the Zanaflex trademark for a nominal sum once specified milestone and royalty payments were made. Those payments have been made, and we purchased and now own the trademarks. Elan also granted us an exclusive, perpetual and royalty-free license to certain intellectual property relating to technology contained in Zanaflex Capsules and Zanaflex tablets or used in the manufacture of Zanaflex Capsules, for use in connection with the sale and marketing of Zanaflex Capsules and Zanaflex tablets in the United States. We also acquired the right to develop new indications, formulations, dosage forms, delivery systems and process improvements of Zanaflex. Under the agreement, Elan agreed not to directly or indirectly market, distribute or sell any products containing tizanidine as an active pharmaceutical ingredient in the United States until the later of the end of our obligation to pay royalties to Elan or valid termination of our supply agreement with Elan. In addition, we agreed not to directly or indirectly market, distribute or sell any products containing tizanidine as its active pharmaceutical ingredient in the United Kingdom or Ireland until July 2007.

Our agreement with Elan obligates us to pay a combination of sales-based milestone payments of up to $19.5 million and royalties on future sales of Zanaflex Capsules and Zanaflex tablets. We have made or accrued an aggregate of $9.5 million in payments under this agreement through December 31, 2006. Our obligation to pay royalties to Elan for Zanaflex tablets and Zanaflex Capsules ends on the later of July 2014 or when the last patent included in the acquisition expires. We also agreed to use commercially reasonable efforts to commercialize Zanaflex Capsules.

As part of the acquisition, we assumed certain of Elan s rights and obligations relating to Zanaflex under a license agreement with Novartis, to the extent that these rights and obligations arise subsequent to our acquisition of Zanaflex. Under this agreement we obtained certain rights to market and sell tizanidine products and rights to product improvements developed by Novartis.

Elan manufactures Zanaflex Capsules for us and we plan to contract with Patheon Inc. for the manufacture of Zanaflex tablets. See Manufacturing. In December 2005, we entered into a financing arrangement with Paul Royalty Fund, or PRF, pursuant to which we assigned PRF the right to receive a portion of our net revenues from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. This agreement was amended in November 2006 potentially to increase the total amount of royalty payments to which PRF is entitled and to provide for additional lump-sum payments both from us to PRF and from PRF to us. The arrangement covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the arrangement is terminated earlier. See Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Financing Activities.

Rush-Presbyterian St. Luke s Medical Center

In 1990, Elan licensed from Rush-Presbyterian St. Luke s Medical Center, or Rush, know-how relating to fampridine for the treatment of MS. We subsequently licensed this know-how from Elan. In September 2003, we entered into an agreement with Rush and Elan terminating the Rush license to Elan and providing for mutual releases. We also entered into a license agreement with Rush in which Rush granted us an exclusive worldwide license to its know-how relating to fampridine for the treatment of MS. Rush has also assigned to us its Orphan Drug Designation for fampridine for the relief of symptoms of MS.

We agreed to pay Rush a license fee, milestone payments of up to $1.15 million and royalties based on net sales of the product for neurological indications. We have made an aggregate of $300,000 in payments under this agreement through December 31, 2006.

The Rush license may be terminated by either party following an uncured material breach by the other party and notice. The Rush license may also be terminated upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other party. We also entered into an agreement with Elan relating to the allocation of payments between us and Elan of certain payments to Rush under the Rush license. Subject to the early termination provisions, the Rush license terminates upon expiration of the royalty obligations, which expire fifteen years from the date of the agreement.

Canadian Spinal Research Organization

In August 2003, we entered into an Amended and Restated License Agreement with the Canadian Spinal Research Organization, CSRO. Under this agreement we were granted an exclusive and worldwide license under certain patent assets and know-how of CSRO relating to the use of fampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject.

We are required to pay to CSRO royalties based on a percentage of net sales of any product incorporating the licensed rights, including royalties on the sale of Fampridine-SR for any indication. No royalty payments have been made to date.

We have the right to terminate the CSRO agreement at any time by written notice. In addition, the CSRO agreement may be terminated by either party following an uncured material breach by the other party. The CSRO agreement may also be terminated by either party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of assets, by the other party. Subject to the early termination provisions, the CSRO agreement will expire upon the termination of all royalty or other payment obligations on a country-by-country basis, which will be no longer than the earlier of the expiration of the last to expire licensed patent in such country or ten years from the date of the first commercial sale of the product in such country.

Cornell Research Foundation, Inc.

In February 2003, we entered into a license agreement with Cornell Research Foundation, Inc., or Cornell, pursuant to which we were granted an exclusive license under a patent for the use of fampridine in the treatment of anterior horn cell diseases. In consideration for the license, we paid Cornell an upfront license fee and are required to make payments of up to $150,000 to Cornell upon the achievement of certain milestones relating to the successful reissuance or reexamination of the patents licensed to us and, the completion of a clinical trial testing the use of Fampridine-SR in amyotrophic lateral sclerosis. We have made an aggregate of $50,000 in payments under this agreement through December 31, 2006. We are also obligated to pay Cornell an annual royalty on net sales of Fampridine-SR in any and all indications, subject to a minimum annual royalty requirement of $25,000.

Under the Cornell agreement, Cornell is responsible for all patent prosecution and maintenance activities relating to the licensed patent, and we are responsible for paying all fees incurred by Cornell in connection therewith. We have the right under this agreement to enforce any patent rights within the licensed patents against infringement by third parties at our own expense.

We have the right to terminate the Cornell agreement at any time by written notice. In addition, the Cornell agreement may be terminated by either party following an uncured material breach by the other party. Subject to the early termination provisions, the term of the Cornell agreement will continue until the expiration of the last to expire valid claim under the licensed patent.

Cambridge University Technical Services Limited and King s College London

In December 2003, we entered into a license agreement with Cambridge University Technical Services Limited and King s College London, pursuant to which we were granted an exclusive worldwide license, including the right to sublicense, under a U.S. patent application and its foreign counterpart to develop and commercialize products related to enzymatic methods, including chondroitinase, of treating CNS disorders. We were also granted a non-exclusive worldwide license, including the right to sublicense, under the same U.S. and foreign patent applications to develop and commercialize products related to small molecule inhibitors for use in treating CNS disorders.

In consideration for these licenses, we paid an upfront license fee and are required to make payments of up to $2.15 million upon the achievement of certain milestones. We have made an aggregate of $45,000 in payments under this agreement through December 31, 2006. We are also obligated to pay royalties on net sales and on any sublicense royalties that we receive.

The King s College license may be terminated by any party following an uncured material breach by any other party. The King s College license may also be terminated by any party if any other party ceases to carry on business, is declared by a court of competent jurisdiction to be bankrupt or upon the appointment of a liquidator of that party. Subject to the early termination provisions, the King s College license agreement will continue until the expiration of the last to expire valid claim under the licensed patent applications, at which time the licenses granted under the license agreement will automatically become non-exclusive, worldwide, fully paid-up and irrevocable.

Mayo Foundation for Medical Education and Research

In September 2000, we entered into a license agreement with Mayo Foundation for Education and Research, pursuant to which we were granted an exclusive worldwide license to its patents and other intellectual property on remyelinating antibodies. Under this agreement, we have the right to develop, make, use and sell the remyelinating antibody products for the prevention, mitigation and treatment of CNS disorders. We have worked closely with one of Mayo Clinic s research groups on developing and patenting this emerging technology in connection with the therapeutic use of these antibodies, specifically myelination and remyelination in MS and SCI. Mayo Clinic has the right to continue researching the antibodies and, in the event it develops other applications related to the licensed patent, which are outside of the scope of our current license, but are for the treatment of CNS disorders. Mayo Clinic is required to offer rights in these new applications to us before it offers such rights to a third party.

Under the Mayo Clinic agreement, we are obligated to make milestone payments of up to $1.875 million. We also pay royalties based on net sales. We have not made any milestone or royalty payments under this agreement through December 31, 2006. The Mayo Clinic agreement may be terminated by either party following an uncured material breach by the other party. We may terminate the Mayo Clinic agreement at will upon prior written notice to Mayo. In addition, either party also has the right to terminate upon the insolvency of the other party, the filing of bankruptcy by or against the other party, or the assignment of assets to the benefit of creditors by the other party. Unless otherwise terminated, this license agreement will terminate upon the expiration of the last licensed patent in any such licensed product.

We have also supported preclinical studies at Mayo Clinic to learn more about the ways the antibodies act to stimulate the myelin sheath-forming cells. In 2004, Mayo Clinic received a $2 million grant to develop and manufacture clinical-grade material and progress the program towards clinical development. A subsequent letter agreement between Mayo Clinic and us acknowledges that the work under this grant is being performed subject to and pursuant to the Mayo Clinic agreement.

CeNeS Pharmaceuticals plc

In November 2002, we entered into two license agreements with CeNeS Pharmaceuticals plc. The first agreement relates to an exclusive worldwide sublicense under certain patents, patent applications and know-how to make, have made, use, import, offer for sale and sell protein products composed of GGF-2 and non-protein products developed through the use of material covered by a valid claim in the patents. The license to these patents and the right to sub-license these patents were granted to CeNeS by the Ludwig Institute for Cancer Research.

Our payment obligations to CeNeS include payment of an upfront license fee, royalties based on annual net sales of the product, if any, as well as payments of up to $8.5 million upon achieving certain milestones in connection with the development, testing and regulatory approval of any protein products. We have not made any payments under this agreement through December 31, 2006. We are obligated to make minimum royalty payments commencing on the third calendar year following the first commercial sale of any licensed product. If we fail to pay any minimum royalty, CeNeS will have the option to convert our license or any sublicense to a non-exclusive license. This agreement with CeNeS is effective until the later of November 12, 2017 or the expiration of the last-to-expire valid claim in the licensed patents. We may terminate this agreement at will upon prior written notice to CeNeS. In addition, this first agreement may be terminated by either party following an uncured material breach by the other party and if this agreement is terminated under that provision, we may retain the exclusive worldwide sublicense granted to us under this agreement, provided that we continue to pay royalties.

The second agreement relates to an exclusive worldwide sublicense to us under certain patents, patent applications and know-how to make and have made, use and have used, sell, offer for sale, have sold and import protein products composed of one or more proteins encoded by the growth factor gene nrg-2 and non-protein products developed through the use of material covered by a valid claim of the patents. The license to this patent and the right to sub-license this patent was granted to CeNeS by the President and Fellows of Harvard College.

We have agreed to a timeline to achieve certain milestones relating to the research and development and the clinical testing and filing of regulatory approvals for the products. We are also required to make milestone payments of up to $5.93 million. If we are unable to meet a milestone, CeNeS has agreed to negotiate in good faith with us to agree for a reasonable extension of the time to achieve the milestone up to one year. We are obligated to pay CeNeS a license fee and royalties based on a percentage of net sales of protein products and non-protein products covered under the agreement. We have made payments of $25,000 in connection with this agreement through December 31, 2006.

This second agreement may be terminated by either party following an unremedied default of a material obligation by the other party. CeNeS may terminate this agreement upon our failure to cure a default in our obligations relating to maintenance of insurance liability or our failure meet certain milestones. Harvard may terminate the underlying Harvard license if CeNeS becomes insolvent, makes an assignment of assets for the benefit of creditors, or has a petition bankruptcy filed for or against it. In that case, Harvard is required, upon our written request, to enter into a direct license with us under the same terms as those set forth in the agreement. We have the right to terminate this agreement upon written notice to CeNeS. The license granted to us pursuant to this agreement continues after the expiration of this agreement and may continue after the termination of this agreement, depending upon the circumstances under which this agreement is terminated.

Subject to early termination provisions, this agreement remains effective until the last patent, patent application or claim included in the licensed patents has expired, been abandoned or been held finally rejected or invalid.

Manufacturing

Fampridine-SR

In September 2003, we entered into an agreement with Elan for the supply of Fampridine-SR. Under that agreement, we are required to purchase at least 75% of our annual requirements of Fampridine-SR from Elan unless Elan is unable or unwilling to meet our requirements. In addition, the agreement also obligates us to make compensatory payments if we do not purchase 100% of our requirements from Elan.

As permitted by our agreement with Elan, we have designated Patheon, Inc. as a qualified second manufacturing source of Fampridine-SR. In connection with that designation, Elan assisted us in transferring manufacturing technology to Patheon. We and Elan have agreed that we may purchase up to 25% of our annual requirements from Patheon if we make compensatory payments to Elan. In addition, Patheon may supply us with Fampridine-SR if Elan is unable or unwilling to meet our requirements.

Zanaflex

We currently rely on Elan and other third parties to supply us with Zanaflex Capsules and Zanaflex tablets. Zanaflex Capsules are manufactured using Elan s proprietary SODAS (spheroidal oral drug absorption system) multiparticulate drug delivery technology. 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 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 products in excess of our forecast requirements, but will use commercially reasonable efforts to fulfill any such orders. The initial term of the agreement expires in 2009, with two automatic two-year renewal terms. Either party may terminate the agreement by notifying the other party at least 12 months prior to the expiration of the initial term or any renewal term. In addition, either party may terminate the agreement if the other party commits a material breach that remains uncured. If a failure to supply occurs under the agreement, other than a force majeure event, or if we terminate the supply agreement for cause, Elan must use commercially reasonable efforts to assist us in transferring production of Zanaflex Capsules to us or a third-party manufacturer, provided that such third party is not a technological competitor of Elan. If we need to transfer production, Elan has agreed to grant us a royalty-free, fully paid-up license of its manufacturing know-how and other information and rights related to the production of Zanaflex Capsules, including a license to use its SODAS technology for specified purposes. We have the right to sublicense this know-how to a third party manufacturer, provided that this third party is not a technological competitor of Elan. In the event of termination of the supply agreement due to a force majeure event that continues for more than three months, Elan has agreed to enter into negotiations with us to preserve the continuity of supply of products, including the possibility of transferring manufacturing of Zanaflex Capsules to us or a third party manufacturer.

Prior to March 2007, Novartis manufactured and supplied us with tizanidine, the active pharmaceutical ingredient, or API, in Zanaflex Capsules and Zanaflex tablets. Under our supply agreement, Novartis also managed the supply relationship with Patheon Inc., or Patheon, the manufacturer of Zanaflex tablets. Our agreement with Novartis expired in February 2007 and Novartis, the only FDA-approved supplier of tizanidine for use in Zanaflex Capsules and Zanaflex tablets, has discontinued tizanidine production. We are currently in contract negotiations with Patheon regarding the manufacture of Zanaflex tablets, and Patheon has agreed to continue to manufacture Zanaflex tablets for us prior to a contract being executed.

Elan is responsible for sourcing all tizanidine that is used in the manufacture of Zanaflex Capsules, while we are responsible for obtaining tizanidine to be used in the manufacture of Zanaflex

tablets. In collaboration with Elan, we have identified two tizanidine manufacturers, and we are working to have both approved by the FDA as tizanidine suppliers for Zanaflex Capsules and Zanaflex tablets. Elan has agreed to supply us with tizanidine for the manufacture of Zanaflex tablets until a new tizanidine supplier is approved and, based on our current sales forecasts, we believe that Elan has sufficient Novartis-manufactured tizanidine to meet Zanaflex Capsules and Zanaflex tablets manufacturing requirements through the second quarter of 2009. Because we have 12 months of Zanaflex Capsule and Zanaflex tablet inventory, the combination of Elan s tizanidine inventory and our Zanaflex inventory is expected to meet sales requirements through the second quarter of 2010. If we and Elan do not gain FDA approval for either tizanidine supplier prior to the depletion of Elan s tizanidine inventory and our Zanaflex inventory, we could experience an interruption in our Zanaflex supply.

We do not anticipate an interruption in Zanaflex Capsule or Zanaflex tablet API supply given the current Zanaflex sales forecast, the quantity of Elan tizanidine inventory and tizanidine s long-term stability profile.

Preclinical Products

We have established the internal capability to manufacture research quantities of antibody and protein product candidates and in the past also have contracted for testing and manufacturing development activities for GGF-2 to be performed by an outside contractor.

Intellectual Property

We have in-licensed, or are the assignee of, over 25 U.S. patents, over 60 foreign patents and over 65 patent applications pending in the United States or abroad. There are five major families of patents in our portfolio. Our logo, Acorda Therapeutics, Zanaflex and Zanaflex Capsules are registered trademarks that we own.

Fampridine-SR

We hold an exclusive, worldwide license from CSRO for a U.S. patent and its foreign counterparts for the use of fampridine in the treatment of spasticity and neuropathic pain in chronic SCI. The U.S. patent expires in 2013.

We hold an exclusive, worldwide license from Elan to three U.S. patents, with corresponding issued patents and pending applications in a number of foreign countries, relating to timed delivery formulations of a family of aminopyridine compounds, including fampridine, which also claim methods of administration and treatment for relevant neurological conditions. One of the three U.S. patents expires in 2011 and the other two U.S. patents expire in 2013.

We hold an exclusive license from Cornell University for an issued patent that relates to the use of aminopyridine compositions, including fampridine, for the treatment of diseases of anterior horn cells, including amyotrophic lateral sclerosis, which is also known as Lou Gehrig s disease. This patent expires in 2016.

We also have a pending U.S. patent application and its foreign equivalent directed to methods of using aminopyridines and a pending U.S. patent directed to aminopyridine formulations.

Zanaflex

As part of our purchase from Elan of the Zanaflex assets, we acquired one issued U.S. patent and two pending U.S. patent applications. Our issued patent is generally directed to certain methods of reducing somnolence and reducing peak plasma concentrations in patients receiving tizanidine therapy. This issued patent expires in 2021. Our two pending U.S. patent applications are directed to multiparticulate formulations of tizanidine and certain other methods of using tizanidine. The process

of seeking patent protection can be time consuming and we cannot assure you that patents will be issued from these pending applications or that, if patents are issued, they will be of sufficient scope to provide meaningful protection of our products.

In addition, we entered into a Supply Agreement with Elan as part of the acquisition, whereby Zanaflex Capsules are manufactured for us by Elan using Elan s proprietary SODAS technology and proprietary information. This proprietary technology is owned by Elan and, in the event Elan ceases to manufacture Zanaflex Capsules, Elan has agreed to grant us a royalty-free, fully paid-up license of its manufacturing know-how and other information and rights related to the production of Zanaflex Capsules, including a license to use its SODAS technology for specified purposes. We have the right to sublicense this know-how to a third party manufacturer, so long as this third party is not a technological competitor of Elan.

We have purchased the Zanaflex trademarks in the United States from Elan.

Neuregulins

We are the exclusive licensee under a license agreement with CeNeS Pharmaceuticals, plc, of a worldwide portfolio of patents, patent applications and IP rights related to products of neuregulin genes, including GGF-2. These patents claim the use of particular neuregulins to treat various pathophysiological conditions, particularly stimulating myelinating cells in order to treat demyelinating conditions of the central and peripheral nervous system. These patents also claim a number of additional potential applications of neuregulins, including stimulation of growth in mammalian muscle cells and treating cardiac failure, peripheral neuropathy and nerve injury.

Remyelinating Antibodies

We are the exclusive licensee of a portfolio of patents and patent applications related to a series of remyelinating antibodies discovered in the laboratory of Dr. Moses Rodriguez at the Mayo Clinic in Rochester, Minnesota for the treatment of CNS disorders. One U.S. patent has been issued and foreign counterparts of this patent have also issued in Australia, Mexico, New Zealand and South Korea, as well as in Europe, where patents have been validated in Germany, Spain, France, Great Britain and Italy. Applications are pending elsewhere, including Canada and Japan.

Chondroitinase

We have a license to a U.S. application and its foreign counterpart from King s College and University of Cambridge directed to treatment of CNS damage. We have recently filed a number of U.S. patent applications and their foreign counterparts directed to chondroitinase enzymes and methods of use and preparation. In particular, we have filed eight U.S. applications, with foreign equivalents to five of them, and an additional international application directed to fusion proteins of chondroitinase, chimeric proteins including chondroitinase, deletion mutants, and certain methods relating to chondroitinase.

Competition

The market for developing and marketing pharmaceutical products is highly competitive. We are aware of many biotechnology and pharmaceutical companies that are engaged in development and/or marketing of therapeutics for a broad range of CNS conditions. Many of our competitors have substantially greater financial, research and development, human and other resources than we do. Furthermore, many of these companies have significantly more experience than we do in preclinical testing, human clinical trials, regulatory approval procedures and sales and marketing.

MS and SCI

Current disease management approaches to MS are classified either as relapse management or disease course management approaches. For relapse management, the majority of neurologists treat sudden and severe relapses with a four-day course of intravenous high-dose corticosteroids. Many of these corticosteroids are available generically. For disease course management, there are a number of FDA-approved MS therapies that seek to modify the immune system. These treatments attempt to reduce the frequency and severity of exacerbations or slow the accumulation of physical disability for people with certain types of MS, though their precise mechanisms of action are not known. These products include Avonex from Biogen-IDEC, Betaseron from Schering AG, Copaxone from Teva Pharmaceutical Industries, Ltd., Rebif from Serono, and Tysabri from Biogen-IDEC and Elan.

Several 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 that Aventis is developing a sodium/potassium channel blocker, HP 184, with a potential indication in SCI, MS and other conditions. We believe that HP 184 is in clinical trials for SCI and any resulting product could compete with Fampridine-SR. Neurorecovery Inc. has publicly disclosed that it has an immediate release form of fampridine for peripheral nervous system conditions in Phase 2 trials and any resulting product might compete with Fampridine-SR. 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. Although we expect this use to decrease substantially if Fampridine-SR is approved, it is possible that some people will continue to use this formulation of fampridine. 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 with Fampridine-SR or our preclinical candidates in the future.

Our lead product candidate, Fampridine-SR, is the first product to our knowledge that acts to improve neurological function in subjects with MS. We are not aware of other companies in clinical development with products that specifically address walking ability in subjects with MS. As a result of its focus on improving function, we believe that Fampridine-SR may be complementary to both the relapse management and disease course management therapies that are commercially available. Nonetheless, Fampridine-SR may compete for market acceptance with these current treatments because they have been accepted and regularly prescribed to people with MS by physicians.

Spasticity

Tizanidine, the active pharmaceutical ingredient in Zanaflex Capsules, Zanaflex tablets and generic tizanidine tablets, is one of the two leading FDA-approved treatments for spasticity, a symptom suffered by both MS and SCI patients. Zanaflex tablets were approved by the FDA in 1996 and lost compound patent protection in 2002. Twelve generic manufacturers of tizanidine are distributing their own tablet formulations. In addition, NovaDel Pharma has announced that it is developing an oral tizanidine spray for potential treatment of spasticity. Baclofen, which is also available generically, is the other leading drug for the treatment of spasticity. The mechanism of action and associated effects of baclofen are different from those of tizanidine. Due to the different pharmacokinetic profile of Zanaflex Capsules, Zanaflex tablets and generic tizanidine tablets are not AB-rated with Zanaflex Capsules.

Government Regulation

FDA Regulation and Product Approval

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the preclinical testing, clinical development,

manufacture, distribution and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising, sale, promotion, import and export of our products and product candidates.

In the United States, Zanaflex tablets, Zanaflex Capsules, and some of our product candidates are regulated by the FDA as drugs. Other of our product candidates are potentially regulated both as drugs and as biological products. Drugs are subject to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations of the FDA, as well as to other federal, state, and local statutes and regulations. Biologics are also regulated under the Public Health Service Act, as amended. Violations of regulatory requirements at any stage may result in various adverse consequences, including FDA s and other health authorities delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions, including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions and/or civil or criminal penalties.

The process required by the FDA under these laws before our product candidates may be marketed in the United States generally involves the following:

- preclinical laboratory and animal tests;
- submission to the FDA of an IND, an application which must become effective before clinical trials may begin;
- completion of two adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use(s);
- FDA review of whether the facility in which the product is manufactured, processed, packed or held meets standards designed to assure the product s continued quality; and
- submission to the FDA of an NDA in the case of a drug, or a Biologics License Application, or BLA, in the case of a biologic, that must be approved containing preclinical and clinical data, proposed labeling and information to demonstrate that the product will be manufactured to appropriate standards of identity, purity and quality.

The research, development and approval process requires substantial time, effort, and financial resources and we cannot be certain that any approval will be granted on a timely or commercially viable basis, if at all.

Preclinical studies include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess its safety and potential efficacy. We then submit the results of the preclinical studies, together with manufacturing information, analytical data and any available clinical data or literature to the FDA as part of an IND application, which must become effective before we may begin human clinical trials. The IND becomes effective 30 days after the FDA filing, unless the FDA, within the 30-day time period, raises concerns or questions about the preclinical studies or the safety of the proposed clinical trial as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Further, an independent Institutional Review Board charged with protecting the welfare of human subjects involved in research at each medical center proposing to conduct the clinical trials must review and approve any clinical trial and study subjects must provide informed consent before their participation in the research study.

Human clinical trials are typically conducted in three sequential phases, which may overlap:

- *Phase 1.* The drug is initially administered into healthy human subjects or subjects with the target condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

- *Phase 2.* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase 3.* When Phase 2 evaluations demonstrate that a dosage range of the drug is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken to confirm the clinical efficacy from Phase 2 and to further test for safety in an expanded population at geographically dispersed clinical trial sites.

In the case of product candidates for severe or life-threatening diseases such as MS, the initial human testing is often conducted in affected patients rather than in healthy volunteers. Since these patients already have the target condition, these clinical trials may provide initial evidence of efficacy traditionally obtained in Phase 2 clinical trials and thus these clinical trials are frequently referred to as Phase 1b clinical trials.

Before proceeding with a study, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as an SPA. Three types of studies are eligible for SPAs: (1) animal carcinogenicity studies, (2) final product stability studies, and (3) clinical studies for pivotal Phase 3 studies whose data will form the primary basis to establish a product s efficacy. Where the FDA agrees to an SPA, the agreement may not be changed by either the sponsor or the FDA except if the sponsor and the FDA agree to a change, or an appropriately senior FDA official determines that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the testing began. SPAs thus help establish up front agreement with the FDA about the adequacy of the design of a clinical trial to support a regulatory approval, but the agreement is not binding if new circumstances arise. In addition, even if an SPA remains in place and the trial meets its endpoints with statistical significance, the FDA could determine that the overall balance of risks and benefits for the product candidate is not adequate to support approval, or only justifies approval for a narrow set of clinical uses or approval with restricted distribution or other burdensome post-approval requirements or limitations. There is thus no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

U.S. law requires that studies conducted to support approval for product marketing be adequate and well controlled. In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice, or GCP, requirements.

We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or the Institutional Review Boards or the sponsor may prevent clinical trials from beginning or may place clinical trials on hold or terminate them at any point in this process if, among other reasons, they conclude that study subjects or patients are being exposed to an unacceptable health risk.

In the U.S., the results of product development, preclinical studies and clinical trials must be submitted to the FDA for review and approval prior to marketing and commercial shipment of the product candidate. If the product candidate is regulated as a drug, an NDA must be submitted and approved before commercial marketing may begin. If the product candidate, such as an antibody, is regulated as a biologic, a Biologic License Application, or BLA must be submitted and approved before commercial marketing may begin. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness (and, in the case of a biologic, purity and potency) of the compound from laboratory, animal and clinical testing, as well as data and information on manufacturing, product stability, and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA or BLA and must be registered with the FDA. The application will generally not be approved until the FDA conducts a manufacturing inspection,

approves the applicable manufacturing process for the drug or biological product, and determines that the facility is in compliance with current good manufacturing practice, or cGMP, requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing a BLA or NDA and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. The NDA or BLA review fee alone can exceed $800,000, although certain limited deferrals, waivers and reductions may be available.

Under applicable laws and FDA regulations, each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will file the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable. If the FDA refuses to file an application, the FDA will retain 25% of the user fee as a penalty. The FDA has established performance goals for the review of NDAs and BLAs six months for priority applications and 10 months for regular applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an action letter that describes additional work that must be done before the application can be approved. The FDA s review of an application may involve review and recommendations by an independent FDA advisory committee.

The FDA may deny an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. If the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that contraindications, warning statements or precautions be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval or post-approval, or limit labeling. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of the above FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years or more and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product candidate. Government regulation may delay or prevent marketing of potential products for a considerable period of time or permanently and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for any of our product candidates on a timely basis, or on a commercially viable basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive or applicable to humans and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific indications. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business. Marketing our product candidates abroad will require similar regulatory

approvals and is subject to similar risks. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug, other reporting, advertising and promotion restrictions. The FDA s rules for advertising and promotion require in particular that we not promote our products for unapproved uses, and that our promotion be fairly balanced and adequately substantiated by clinical studies. We must also submit appropriate new and supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current Good Manufacturing Practices, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the current Good Manufacturing Practices and other FDA regulatory requirements. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In addition to inspections related to manufacturing, we are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements that apply to marketed drugs manufactured or distributed by us. For example, the FDA may conduct periodic inspections regarding our reporting of adverse events, and the FDA has indicated to the industry that it may be conducting increased inspections related to compliance with the requirements of the PDMA concerning the handling of drug samples. When the FDA conducts an inspection, it will identify any deficiencies it believes exist in the form of a notice of inspectional observations, or Form FDA 483. The observations may be more or less significant. If we receive a notice of inspectional observations, we likely will be required to respond in writing, and may be required to undertake corrective and preventive actions in order to address the FDA s concerns.

We and our product candidates are also subject to a variety of state laws and regulations in those states or localities where they are or will be marketed. Any applicable state or local regulations may hinder our ability to market our product candidates in those states or localities.

The FDA s policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations which could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation which might arise from future legislative or administrative action, either in the United States or abroad.

Orphan Drugs

Under the Orphan Drug Act, special incentives exist for sponsors to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the U.S. Sponsors may request that FDA grant a drug orphan designation prior to approval. We have received Orphan Drug designation for Fampridine-SR for the treatment of both MS and incomplete SCI.

Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications, and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity prevents FDA approval of applications by others for the same drug and the designated orphan disease or condition. FDA may approve a

subsequent application from another person if FDA determines that the application is for a different drug or different use, or if FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public s need. In addition, even when a drug has orphan exclusivity, the FDA may approve a competing drug for the same orphan use. The FDA may also approve someone else s application for the same drug that has orphan exclusivity, but for a different use, in which case the competing drug could be prescribed by physicians outside its FDA approval for the orphan use, notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another person from receiving approval for the same or a similar drug for the same or other uses.

Generic Drugs, AB Ratings and Pharmacy Substitution

Generic drugs are approved through an abbreviated process, which differs in important ways from the process followed for innovative products. Generally an abbreviated new drug application, or ANDA, is filed with the FDA. The ANDA must seek approval of a product candidate that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as a so-called reference listed drug approved under an NDA with full supporting data to establish safety and effectiveness. Only limited exceptions exist to this ANDA sameness requirement, including certain limited variations approved by the FDA through a special suitability petition process. The ANDA also generally contains clinical data to demonstrate that the product covered by the ANDA is absorbed in the body at the same rate and to the same extent as the reference listed drug. This is known as bioequivalence. In addition, the ANDA must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the reference listed drug.

Every state has a law permitting or requiring pharmacists to substitute generic equivalents for brand-name prescriptions unless the physician has prohibited substitution. Managed care organizations often urge physicians to prescribe drugs with generic equivalents, and to authorize substitution, as a means of controlling costs of prescriptions. They also may require lower copayments as an incentive to patients to ask for and accept generics.

While the question of substitutability is one of state law, most states look to the FDA to determine whether a generic is substitutable. FDA lists therapeutic equivalence ratings in a publication often referred to as the Orange Book. In general, a generic drug that is listed in the Orange Book as therapeutically equivalent to the branded product will be substitutable under state law and, conversely, a generic drug that is not so listed will not be substitutable. To be considered therapeutically equivalent, a generic drug must first be a pharmaceutical equivalent of the branded drug. This means that the generic has the same active ingredient, dosage form, strength or concentration and route of administration as the brand-name drug. Tablets and capsules are presently considered different dosage forms that are pharmaceutical alternatives and not substitutable pharmaceutical equivalents.

In addition to being pharmaceutical equivalents, therapeutic equivalents must be bioequivalent to their branded counterparts. Bioequivalence for this purpose is defined in the same manner as for ANDA approvals, and usually requires a showing of comparable rate and extent of absorption in a small human study.

Solid oral dosage form drug products generally are rated AB in the Orange Book if they are considered therapeutic equivalents. If bioequivalence has been adequately demonstrated, the products will be rated AB.

Foreign Regulation and Product Approval

Outside the United States, our ability to market a product candidate is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product in more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA clearance discussed above.

Other Regulations

In the U.S., 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 (formerly the Health Care Financing Administration), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), 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, also as amended, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, 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 are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Reimbursement and Pricing Controls

In many of the markets where we or our collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms.

In the United States, there has been an increased focus on drug pricing in recent years. Although there are currently no direct government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under certain public health care programs such as Medicaid. Various states have adopted further mechanisms under Medicaid and otherwise that seek to control drug prices, including by disfavoring certain higher priced drugs and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. Federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs covered by Medicare are reimbursed. Under the new reimbursement methodology, physicians are reimbursed based on a product s average sales price, or ASP. This new reimbursement methodology has generally led to lower reimbursement levels. The new federal legislation also has 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.

Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, or OBRA 93, with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supported by one or more citations in the American Hospital Formulary Service Drug Information, the American Medical Association Drug Evaluations, or the U.S. Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Clinical Excellence in the UK which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

EMPLOYEES

As of March 23, 2007, we had 126 employees. Of the 126 employees, 24 perform research and development activities, including both preclinical programs and clinical trials, 81 work in sales, marketing, business development, manufacturing and communications and 21 perform general and administrative tasks.

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*.

ADDITIONAL INFORMATION AND WHERE TO FIND IT

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available on our website (*http://www.acorda.com* under the SEC Filings caption) as soon as reasonably practicable after we electronically file such material with, or furnish them to, the Securities and Exchange Commission (SEC).

RISK FACTORS

An investment in our common stock involves a high degree of risk. Additional risks that are not currently known or foreseeable to us may materialize at a future date. The trading price of our common stock could decline if any of these risks or uncertainties occur and you might lose all or part of your investment.

Risks Related To Our Business

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

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

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

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

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

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

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

Notwithstanding the results of our clinical trials, the FDA could determine that the overall balance of risks and benefits for Fampridine-SR is not adequate to support approval, or only justifies approval for a narrow set of uses or approval with restricted distribution or other burdensome post-approval requirements and limitations. Subjects taking Fampridine-SR have experienced adverse events, including falls, urinary tract infection, insomnia, dizziness, asthenia, headache, fatigue, nausea and balance disorder. A small number of subjects have also experienced seizures while taking

Fampridine-SR, and there is a possibility that additional seizures will occur even at low doses of the drug. If the FDA denies approval of Fampridine-SR in MS, if FDA approval is substantially delayed, if approval is granted on a narrow basis or with restricted distribution or other burdensome post-approval requirements, or if the Fampridine-SR program is terminated, our business prospects will be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Clinical trials are subject to oversight by institutional review boards and the FDA to ensure compliance with the FDA s good clinical practice requirements, as well as other requirements for the protection of clinical trial participants. We depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices required by regulators. If any such standards are not complied with in our clinical trials, the resulting data from the clinical trial may not be usable or we, an institutional review board or the FDA may suspend or terminate such trial, which would severely delay our development and possibly end the development of such product candidate. We also depend upon third party manufacturers of our products to qualify for FDA approval and to comply with good manufacturing practices required by regulators. We cannot be certain that our present or future manufacturers and suppliers will comply with current good manufacturing practices. The failure to comply with good manufacturing practices may result in the termination of clinical studies, restrictions in the sale of, or withdrawal of the products from the market. Compliance by third parties with these standards and practices is outside of our direct control. For example, we and other pharmaceutical companies recently received notification from the FDA regarding the FDA s concerns with the reliability of certain study analyses conducted by MDS Pharma Services, or MDS Pharma, at its St. Laurent (Montreal) and Blainville (Quebec) Canada sites from 2000 through 2004. MDS Pharma helped conduct the studies submitted to FDA for the approval of Zanaflex Capsules. The MDS Pharma facility involved was in Ireland, not Canada, and MDS Pharma s role in the studies did not include performing the types of analyses that the FDA identified in its recent notice as being of concern. Nonetheless, if the FDA s concerns extend to other MDS Pharma facilities or activities, the reliability of the studies that MDS Pharma assisted on for Zanaflex Capsules could be called into question, and we might have to confirm or repeat the studies.

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

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

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

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

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

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

Federal legislation enacted in December 2003 added an outpatient prescription drug benefit to Medicare. The benefit is provided primarily through private entities, which attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations increase pressure to lower prescription drug prices. While the new law specifically prohibits the U.S. government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the U.S. government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating de facto price controls on prescription drugs. In addition, the new law contains triggers for Congressional

consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include limitations on prescription drug prices. This Medicare prescription drug coverage legislation, as well as additional healthcare legislation that may be enacted at a future date, could reduce our sales and adversely affect our results of operations.

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

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

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

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

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

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

As of December 31, 2006, we had approximately $53.8 million in cash, cash equivalents and short-term investments. Although we anticipate this will be sufficient to fund our operations and meet our financial obligations through the first quarter of 2008 based on our current projected revenue and spending levels, we have several product candidates in various stages of development, and all will require significant further investment to develop, test and obtain regulatory approval prior to commercialization. We will need to seek additional equity or debt financing or strategic collaborations

to continue our product development activities, and could require substantial funding to commercialize any products that we successfully develop. We may seek additional financing in the near future to ensure the completion of Fampridine-SR s clinical development. We may not be able to raise additional capital on favorable terms or at all. To the extent that we are able to raise additional capital through the sale of equity securities, the issuance of those securities would result in dilution to our stockholders. Holders of such new equity securities may also have rights, preference or privileges that are senior to yours. If additional capital is raised through the incurrence of indebtedness, we may become subject to various restrictions and covenants that could limit our ability to respond to market conditions, provide for unanticipated capital investments or take advantage of business opportunities. To the extent funding is raised through collaborations or intellectual property-based financings, we may be required to give up some or all of the rights and related intellectual property to one or more of our products, product candidates or preclinical programs. If we are unable to obtain sufficient financing on favorable terms when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs or devote fewer resources to marketing Zanaflex Capsules.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, the research, manufacturing, distribution, sale and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, as amended, the False Claims Act, as amended, the privacy provisions of the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

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

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

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

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

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

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

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials and chemicals that are subject to federal, state and local laws and regulations governing their use, storage, handling and disposal. These materials include ketamine, 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 and other third party suppliers to manufacture Zanaflex Capsules, Zanaflex tablets and Fampridine-SR.

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

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

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

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

We are currently in contract negotiations with Patheon regarding the manufacture of Zanaflex tablets, and Patheon has agreed to provide us with Zanaflex tablets prior to the contract being executed. If either Elan or Patheon experiences any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or we locate an alternate source of supply. We may not be able to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements. We could experience substantial delays before we are able to qualify any new supplier and transfer the required manufacturing technology to that supplier.

Elan s inventory of tizanidine will reach its retest date by April 2007. Thereafter, the chemical stability of Elan s tizanidine must be retested within 30 days of each manufacturing run. If Elan s tizanidine inventory fails its retest prior to FDA approval of a new tizanidine supplier, a delay or interruption in our supply of our Zanaflex products could result. We depend on another company, Sharp Corporation, to package and bottle Zanaflex tablets.

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, a mutually agreed-upon and qualified second manufacturing source, with compensatory payment.

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

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

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We rely and will continue to rely on clinical investigators, third-party contract research organizations and consultants to perform some or all of the functions associated with preclinical testing and clinical trials. The failure of any of these vendors to perform in an acceptable and timely

manner in the future, including in accordance with any applicable regulatory requirements, such as good clinical and laboratory practices, or preclinical testing or clinical trial protocols, could cause a delay or otherwise adversely affect on our preclinical testing or clinical trials and ultimately on the timely advancement of our development programs.

Risks Related to Our Intellectual Property

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

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

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

We may initiate actions to protect our intellectual property and in any litigation in which our patents or our licensors patents are asserted, a court may determine that the patents are invalid or unenforceable. Even if the validity or enforceability of these patents is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by the patent claims. In addition, effective intellectual property enforcement may be unavailable or limited in some foreign countries. 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 Our Common Stock

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

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

- publicity regarding actual or potential clinical trial results or updates 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;
- announcement of new corporate partnerships, alliances, financings or other transactions;
- 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 Global Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations recently. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

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

If our existing stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. Sales of substantial amounts of shares of our common stock in the public market by our executive officers, directors, 5% or greater shareholders or other shareholders, or the prospect of such sales, could adversely affect the market price of our common stock. As of December 31, 2006 we have outstanding 23,657,755 shares of common stock. We have registered 5,481,334 shares of common stock that are authorized for issuance under our equity compensation plans, including outstanding options to acquire 2,534,663 shares of common stock outstanding as of December 31, 2006, exercisable at an average exercise price of $6.23 per share. As of December 31, 2006, there were warrants to acquire 16,869 shares of common stock outstanding, exercisable at an exercise price of $11.856 per share. These warrants were exercised in January 2007. To the extent that option holders exercise outstanding options, there may be further dilution and the sales of shares issued upon such exercises could cause our stock price to drop further.

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

Our officers, directors and holders of 5% or more of our outstanding common stock beneficially own approximately 65.4% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval or mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

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

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

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

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

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

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

We have not paid cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. The success of your

investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares.

Risk Relating to our 2006 Private Placement

If we do not maintain effectiveness of the registration statements covering the resale of the shares issued in the October 2006 private placement, we will be required to pay certain liquidated damages, which could be material in amount.

The terms of the securities purchase agreement in connection with the private placement would require us to pay certain liquidated damages to the purchasers in the private placement in the event that the registration statement does not remain effective until 2 years after the closing or until the shares may be sold under Rule 144(k). The only exception is our right, without incurring liquidated damages, to suspend the use of the registration statement during two periods of no more than 60 days in any 12-month period. Subject to this exception, for each 30-day period or portion thereof when the registration statement is not effective, we are obligated to pay to each purchaser an amount in cash equal to 1.0% of that purchaser s aggregate purchase price, up to a maximum of 10% of the aggregate purchase price paid by that Purchaser. These amounts could be material. If we are unable to maintain the effectiveness of the registration statement (or effectiveness is suspended other than as provided in the securities purchase agreement), the amounts we are required to pay could materially adversely affect our financial condition.

Unresolved Staff Comments

None.

Item 2. Properties.

Our principal executive offices are located in an approximately 38,200 square foot facility in Hawthorne, NY, which houses offices and laboratory space. The current annual rent for this facility is $789,600. We believe that our facility is currently adequate for our purposes and that it will continue to be so for the foreseeable future. The lease for this facility expires in December 2009.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders.

No matter was submitted to a vote of security holders during the fourth quarter of 2006.

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been quoted on the Nasdaq Global Market under the symbol ACOR since our initial public offering on February 9, 2006. Prior to that date, there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low bid prices per share of our common stock as reported on the Nasdaq Global Market.

	High	Low
Year Ended December 31, 2006:		
Fourth Quarter	$ 20.60	$ 8.27
Third Quarter	$ 11.90	$ 2.20
Second Quarter	$ 5.50	$ 3.30
First Quarter (beginning February 9, 2006)	$ 7.48	$ 5.10

As of March 12, 2007 we had approximately 2,202 holders of record of our common stock.

Stock Price Performance Graph

The graph below matches the cumulative 10-month total return of holders of Acorda Therapeutics, Inc. s common stock with the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology index. The graph assumes that the value of the investment in the company s common stock and in each of the indexes (including reinvestment of dividends) was $100 on 2/10/2006 and tracks it through 12/31/2006.

COMPARISON OF 10 MONTH CUMULATIVE TOTAL RETURN*

**Among Acorda Therapeutics, Inc, The NASDAQ Composite Index
And The NASDAQ Biotechnology Index**

* $100 invested on 2/10/06 in stock or 1/31/06 in index-including reinvestment of dividends. Fiscal year ending December 31.

	2/06	2/06	3/06	4/06	5/06	6/06	7/06	8/06	9/06	10/06	11/06	12/06
Acorda Therapeutics, Inc	**100**	**92**	**78**	**73**	**57**	**62**	**48**	**43**	**136**	**265**	**288**	**236**
NASDAQ Composite	**100**	**99**	**102**	**102**	**95**	**95**	**91**	**95**	**98**	**103**	**106**	**105**
NASDAQ Biotechnology	**100**	**103**	**101**	**96**	**92**	**90**	**91**	**92**	**94**	**100**	**99**	**97**

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Use of Proceeds from Registered Securities

Our registration statement on Form S-1 (Reg. No. 333-128827) in connection with our initial public offering was declared effective by the SEC on February 9, 2006. As of the date of the filing of this report, the offering has terminated and 6,075,614 shares of our common stock were sold pursuant to our registration statement. The underwriters of the offering were Banc of America Securities LLC, Lazard Capital Markets, Piper Jaffray and SG Cowen & Co. Net proceeds from the sale of the 6,075,614 shares of common stock sold by us, based on the initial public offering price of $6.00 per share, and after deducting the underwriting discount and offering expenses payable by us, were approximately $31.5 million. No payments for expenses relating to this offering were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more

of any class of our equity securities or (iii) any of our affiliates. We used the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

Dividend Policy

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business.

Equity Compensation Plans

We have two equity incentive plans: our 2006 Employee Incentive Plan, as amended (the 2006 Plan) and our 1999 Employee Stock Option Plan, as amended (the 1999 Plan and, together with the 2006 Plan, the Plans). As of December 31, 2006, a total of 5,481,334 shares of our common stock had been reserved for issuance under the Plans. All future awards will be made under the 2006 Plan.

The following table provides information as of December 31, 2006 with respect to shares of our common stock that may be issued under our equity compensation plans:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity Compensation Plans Approved by Security Holders(1)	2,551,532	$ 6.27	2,929,802 (2)
Total	2,551,532	6.27	2,929,802

(1) Includes options to purchase shares of our common stock and restricted stock awards under the Plans.

(2) Consists of shares available as of December 31, 2006 for future issuance under the 2006 Plan.

Item 6. Selected Financial Data

	Year Ended December 31, 2006	2005	Six Months Ended December 31, 2004	2003	Year Ended June 30, 2003	2002
	(in thousands, except per share data)					
Statement of Operations Data:						
Gross sales Zanaflex	$ 26,548	$ 5,923	$	$	$	$
Less: discounts and allowances	396	(1,114)	(4,417)			
Net sales	26,944	4,809	(4,417)			
Grant revenue	407	336	479	382	474	132
Total net revenue	27,351	5,145	(3,938)	382	474	132
Less: cost of sales	(7,123)	(5,132)	(885)			
Gross profit	20,228	13	(4,823)	382	474	132
Operating expenses:						
Research and development	12,055	12,890	21,999	16,743	17,527	11,147
Research and development related party				3,343	2,265	4,687
Sales and marketing	19,079	13,099	4,662			
General and administrative	12,561	8,435	13,283	17,069	6,388	6,636
Total operating expenses	43,695	34,424	39,944	37,155	26,180	22,470
Operating loss	(23,467)	(34,411)	(44,767)	(36,773)	(25,706)	(22,338)
Other income (expense):						
Interest and amortization of debt discount expense	(2,553)	(1,526)	(385)	(38)	(78)	
Interest and amortization of debt discount expense related party				(184)	(369)	(408)
Interest income	1,471	402	409	276	393	984
Other income	76	1	2	7	26	
Total other income (expense)	(1,006)	(1,123)	26	61	(28)	576
Minority interest related party						580
Cumulative effect of change in accounting principle(3)	454	3				
Net loss	(24,019)	(35,531)	(44,741)	(36,712)	(25,734)	(21,182)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders	(36,008)	(24,849)	(24,746)	(11,985)	(24,320)	(55)
Net loss allocable to common stockholders	$ (60,027)	$ (60,380)	$ (69,487)	$ (48,697)	$ (50,054)	$ (21,236)
Net loss per share allocable to common stockholders basic & diluted	$ (3.27)	$ (295.27)	$ (351.76)	$ (252.87)	$ (261.38)	$ (111.90)
Pro forma net loss per share allocable to common stockholders basic & diluted (unaudited)(1)		$ (.79)	$ (9.63)			
Weighted average shares of common stock outstanding used in computing net loss per share allocable to common stockholders basic & diluted	18,346	204	198	193	191	190
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)		13,547	13,536			

(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 years ended December 31, 2005 and 2004, respectively, 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 was computed assuming the initial public 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 3 to the consolidated financial statements). The pro forma net loss per share allocable to common stockholders for the year ended December 31, 2005 reflects the reversal of the accrued preferred dividend of $5.3 million, amortized beneficial conversion charge of $19.4 million and amortized issuance cost of $108,000 assuming that the automatic conversion occurred as of the beginning of the fiscal year ended December 31, 2004. Upon the Company s initial public offering in February 2006, all the preferred stock was converted into common stock.

(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.

(3) On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), Share-Based Payment (SFAS No. 123R), which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We adopted SFAS No. 123R using the modified prospective application method under which the provisions of SFAS No. 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the Consolidated Statement of Operations over the remaining service period after the adoption date based on the award s original estimate of fair value. Results for prior periods have not been restated. Upon adoption of SFAS No. 123R, we recorded a cumulative effect of change in accounting principle of $454,225 during the three-month period ended March 31, 2006, calculated as the difference between compensation cost recognized to date using actual forfeitures and the cost that would have been recognized to date using estimated forfeitures.

	As of December 31,			As of June 30,		
	2006	2005	2004	2003	2003	2002
	(in thousands)					
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 18,101	$ 11,761	$ 11,729	$ 8,965	$ 48,319	$ 27,012
Short term investments	35,656	2,001	9,397	32,250	12,250	2,836
Working capital	33,324	(10,394)	9,067	35,375	58,975	27,097
Total assets	84,368	33,912	30,982	45,960	64,807	33,597
Deferred product revenue Zanaflex Capsules	11,324	5,226				
Deferred product revenue Zanaflex tablets	9,117	11,510	6,668			
Current portion of notes payable	1,044	1,068	302	324	310	
Non current portion of notes payable	187	1,147	145	447	612	
Current portion of revenue interest liability PRF transaction	3,392	2,162				
Put/call option liability PRF transaction	350	400				
Non current portion of revenue interest liability PRF transaction	19,744	12,914				
Long term convertible notes payable	6,508	8,768	8,422	8,091	7,907	7,538
Mandatorily redeemable preferred stock		91,214	66,364	30,171	18,187	59,659
Total stockholders equity (deficit)	18,669	(116,536)	(60,571)	(130)	35,328	(36,910)

Item 7. 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 Annual Report on Form 10-K.

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. We announced positive results from a Phase 3 clinical trial of our lead product candidate, Fampridine-SR, for the improvement of walking ability in people with MS in September 2006, and we plan to initiate an additional Phase 3 clinical trial of Fampridine-SR in people with MS in the second quarter of 2007. 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 September 2003, 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.

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 and a Phase 3 clinical trial in MS, the results of which were announced in April 2004 and September 2006, respectively. In September 2006 we announced positive results from the Phase 3 clinical trial of our lead product candidate, Fampridine-SR in MS. Statistical significance was achieved on all three efficacy criteria defined by the FDA in the Special Protocol Assessment (SPA). We plan to initiate a second Phase 3 clinical trial in the second quarter of 2007.

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 recently completed 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 in the future.

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 three 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 was paid in the first quarter of 2006. The second milestone of $3.0 million was paid in March 2006. The third milestone of $5.0 million was paid in February 2007. 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 12 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 50 sales professionals as of December 31, 2006 and was expanded to 65 sales professionals by the first quarter of 2007. This sales force has targeted 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. In August 2005, we entered into an agreement with Cardinal Health, under which it had provided approximately 160 sales representatives to market Zanaflex Capsules, on a non-exclusive basis, to primary care physicians in the United States. Sales in the primary care market did not reach the targets specified in our agreement. We terminated the agreement with Cardinal Health and made a payment of $125,000 in connection with that termination during the third quarter of 2006.

In May 2005, we retained Access Worldwide Communications, Inc. (Access) to provide a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care, specialty physicians and pharmacists. In February 2006, we expanded the scope of the arrangement with Access and transferred some of the primary care physician contacts previously covered by Cardinal Health to Access. Our contract with Access is now serviced by TMS Professional Markets Group, LLC, which purchased various telesales assets from Access in 2006. In addition, we initiated a pilot program with Innovex Inc. that provided six part-time representatives making exclusive calls promoting Zanaflex Capsules to primary care physicians, focusing on some of the contacts previously covered by Cardinal Health. In October 2006, we gave notice to Innovex Inc. of termination of our contract sales force agreement.

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 which definition is different from our net revenues as determined in accordance with GAAP) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all such 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 $691,000 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. If our Zanaflex net revenues in 2005 had equaled or exceeded $11.0 million and our Zanaflex net revenues in the first six months of 2006 had equaled or exceeded $16.0 million, at our election, PRF would also have been required to loan us an additional $5.0 million. We did not meet this milestone.

In November 2006, we entered into an amendment to the revenue interests assignment agreement with PRF. Under the amendment, PRF is entitled to a royalty consisting of certain specified percentages of Zanaflex net revenues, based upon the level of net revenues. The amendment provides that the royalty rate will drop to 1% upon PRF s receipt of 2.1 times the aggregate amount PRF has paid us under the agreement, as amended. Previously, once PRF had received and retained payments under the agreement that are at least twice the aggregate amount PRF paid us under the Agreement, the royalty rate would drop to 1% of Zanaflex net revenues. Under the terms of the amendment, PRF paid us $5.0 million in November 2006 and agreed that we would be entitled to an additional $5.0 million is due if our net revenues during the fiscal year 2006 equaled or exceeded $25.0 million. This milestone has been met and the receivable is reflected in our December 31, 2006 financial statements. This milestone payment was received in February 2007. Under the terms of the

amendment, we are required to pay PRF $5.0 million on December 1, 2009 and an additional $5.0 million on December 1, 2010. For more information regarding our agreement with PRF, see Liquidity and Capital Resources Financing Arrangements.

We completed an initial public offering on February 9, 2006 in which 6,075,614 shares of our common stock were sold, resulting in net proceeds of approximately $31.5 million after deducting the underwriting discount and offering expenses.

Upon the closing of the initial public offering, all of our convertible preferred stock and mandatorily redeemable convertible preferred stock was converted into 13,338,278 shares of common stock. This conversion resulted in the following: (a) recognition of the unamortized portion of a beneficial conversion charge of $48.5 million; (b) recognition of the unamortized portion of issuance costs relating to Series E, Series I, Series J and Series K preferred stock of $271,000; and (c) reversal of accrued preferred dividends on Series J and Series K preferred stock of $12.7 million.

We completed a private placement on October 6, 2006 in which 3,230,769 shares of our common stock were sold, resulting in net proceeds of approximately $29.8 million after deducting issuance costs.

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, we expect to be able to reasonably estimate product returns and will then 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 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.

Under our revenue interests assignment agreement with PRF, as amended in November 2006, 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 (as defined in the agreement) generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. Under the agreement, PRF is entitled to a certain portion of such Zanaflex net revenues. For more information regarding our agreement with PRF, see Liquidity and Capital Resources Financing Arrangements.

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. The majority of this product was sold by us during July 2004 through March 2005. We deferred recognition of any revenue from sales of the partial lot inventory until the return period for the product expired in June 2006 (12 months following product expiration). We could not use prescription data to recognize revenue associated with the partial lot inventory acquired from Elan because we could not determine whether the prescription was filled with product that Elan sold prior to our acquisition of Zanaflex or with product we sold. We received returns of the product sold by Elan through June 2006 at which point the right of return expired and we recognized the remaining $2.2 million deferred revenue balance as gross sales.

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 recorded a charge of $4.1 million in the year ended December 31, 2004, for the estimated returns of Zanaflex tablets sold by Elan. Our obligation to continue to accept these returns ended in June 2006. As a result of the returns we accepted since 2004, the net balance remaining on this liability was approximately $1.8 million. We reversed this liability in June 2006 which resulted in a reduction in discounts and allowances of $1.8 million and a corresponding reduction of the product return liability on our balance sheet.

Discounts and Allowances

Reserves for cash discounts, rebates and chargebacks have been established. At the time product is shipped to wholesalers a charge is recorded to discounts and allowances and the appropriate reserves are credited. Allowances are established on a product-by-product basis. These allowances are established by management as its best estimate of each product s historical experience adjusted to reflect known changes in the factors that impact such reserves. Allowances for chargebacks, rebates and discounts are established based on contractual terms with customers, analyses of historical usage of discount, chargeback and rebate reserves, communications with customers, the level of inventory remaining in the distribution channel, expectations about the market for each product and any 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 the 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, expense due to inventory reserves, royalty expense, 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. Any payments we make to PRF in connection with the revenue interests assignment transaction entered into in December 2005 will not constitute royalty expense or otherwise affect our cost of sales. 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 for 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 years ended December 31, 2006, 2005 and 2004. 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 December 31,		
	2006	**2005**	**2004**
Clinical development:			
Contract expense MS	$ 6,004	$ 4,011	$ 2,850
Contract expense SCI		32	5,853
Other contract expense	751	3,960	4,945
Operating expense	1,553	1,300	2,652
Total clinical development	8,308	9,303	16,300
Preclinical research & development:			
Research contracts	120	115	628
Contract expense	33	79	113
Operating expense	3,057	3,393	4,958
Total preclinical research & development	3,210	3,587	5,699
Regulatory affairs	537		
Total	$ 12,055	$ 12,890	$ 21,999

Sales and Marketing Expenses

Sales and marketing expenses include 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 pharmaceutical telesales services provided by Access.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, medical affairs, 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, investor relations and accounting services

Stock-Based Compensation

Historically, we accounted for share-based compensation costs under the provisions of Statement of Financial Accounting Standards 123 (SFAS No. 123), Accounting for Stock-Based Compensation, using a fair-value-based method of accounting for stock-based employee compensation plans.

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), Share-Based Payment (SFAS No. 123R), which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We adopted SFAS No. 123R using the modified prospective application method under which the provisions of SFAS No. 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the Consolidated Statement of Operations over the remaining service period after the adoption date based on the award s original estimate of fair value. Results for prior periods have not been restated.

In connection with the adoption of SFAS No. 123R, we changed from recognizing the effect of forfeitures as they occur to estimating the number of outstanding instruments for which the requisite service is not expected to be rendered. Prior to the adoption of SFAS No. 123R, we recognized forfeitures associated with its share-based awards as they occurred rather than estimating forfeitures. Upon adoption of SFAS No. 123R, we recorded a cumulative effect of change in accounting principle of $454,225 during the three-month period ended March 31, 2006, calculated as the difference between compensation cost recognized to date using actual forfeitures and the cost that would have been recognized to date using estimated forfeitures. We estimate that our future annual forfeiture rate will be 5%.

We account for stock options granted to non-employees on a fair-value basis in accordance with EITF 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 Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25.

Beneficial Conversion Feature

In May 2003, we completed a private placement of 112,790,233 shares of Series J convertible preferred stock for an aggregate purchase price of approximately $55.3 million. As a result of this financing, our Series A through Series I preferred stockholders original conversion prices were reduced due to anti-dilution adjustments, which resulted in a beneficial conversion of $80.7 million in accordance with EITF No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* and EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. The beneficial conversion of $20.9 million was recorded as an immediate charge to additional paid-in capital, relating to our Series A, Series B, Series C, Series F and Series H convertible preferred stock, which were not mandatorily redeemable and could be converted to common stock at any time at the option of the holders. The remaining beneficial conversion of $59.9 million, relating to our Series E and Series I convertible preferred stock, which were mandatorily redeemable at any time on or after June 30, 2008, was being accreted ratably over the mandatory redemption period. Such accretion amounted to $29.1 million, $11.6 million and $11.6 million for the years ended December 31, 2006, 2005 and 2004, respectively, and was charged to additional paid-in capital. Upon completion of the Company s initial public offering on February 9, 2006, the remaining beneficial conversion amount was fully accreted.

The issuance of Series J mandatorily redeemable convertible preferred stock resulted in a beneficial conversion amounting to $40.0 million in accordance with EITF No. 98-5. The beneficial

conversion was calculated based on the estimated fair value of our common stock price per share at the date of issuance of Series J preferred stock of approximately $10.14 per share of common stock, which was calculated based on the estimated projected midpoint of the range of our initial public offering price per common share, which was planned in the fourth calendar quarter of 2003, and the stock price appreciation in comparable public companies from May 2003 to August 2003. The beneficial conversion feature was being accreted ratably over the mandatory redemption period, with a charge to additional paid-in capital of $19.4 million, $7.8 million and $7.8 million for the years ended December 31, 2006, 2005 and 2004, respectively. Upon completion of the Company s initial public offering on February 9, 2006, the remaining beneficial conversion amount was fully accreted.

Other Income (Expense)

Interest income consists of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of interest expense related to our revenue interest liability, our GE Capital notes, amortization of debt discount and accrued interest on our convertible notes. Other income consists primarily of New York State tax refunds.

Results of Operations

Year Ended December 31, 2006 Compared to Year Ended December 31, 2005

Gross Sales

We recognized gross sales from the sale of Zanaflex Capsules and Zanaflex tablets of $26.5 million for the year ended December 31, 2006, as compared to $5.9 million for the year ended December 31, 2005, an increase of approximately $20.6 million, or 349.2%. The increase was due to 12 months of Zanaflex Capsule sales in 2006 versus 7 months in 2005 in addition to an increase in Zanaflex Capsule prescriptions primarily attributable to our increased sales force. We recognize product sales using a deferred revenue recognition model meaning that shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported.

Gross sales in the year ended December 31, 2005 consisted of Zanaflex tablet revenue recognized based on gross prescription data that we began receiving in March 2005, which is when we began receiving prescription data for tablets containing a code that identified these prescriptions as having been filled with product we sold. We did not recognize revenue from Zanaflex Capsules prescription data until after our launch of the product in April 2005.

As part of the Zanaflex acquisition, the Company purchased certain tablet inventory from Elan that expired within one year. The majority of this product was sold by the Company during July 2004 through March 2005. The Company deferred revenue for this product due to the uncertainty of future returns. The Company received returns of the product sold by Elan through June 2006, at which point the right of return expired and the Company recognized the remaining $2.2 million deferred revenue as gross sales.

Discounts and Allowances

We recorded negative discounts and allowances of $396,000 for the year ended December 31, 2006 as compared to an expense $1.1 million for the year ended December 31, 2005, a decrease of approximately $1.5 million, or 135.5%. As part of the Zanaflex acquisition in 2004, we agreed to accept any 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 that date were the responsibility of Elan. As a result of this agreement, in December 2004 we recorded a return liability of $4.1 million which was our best estimate of the Zanaflex tablet returns for which we could potentially become liable. Our obligation to continue to accept these returns ended in June 2006. As a result of the returns we accepted since 2004, the net balance remaining on this liability was approximately $1.8 million in June 2006. We reversed this liability in June 2006, which resulted in a reduction in discounts

and allowances of $1.8 million and a corresponding reduction of the product return liability on our balance sheet.

Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the year ended December 31, 2006 consisted of a negative $1.8 million due to the Elan product return liability reversal described above, $664,000 in cash discounts and $742,000 in allowances for chargebacks and rebates. Discounts and allowances for the year ended December 31, 2005, consisted of $710,000 in cash discounts and allowances of $404,000 for chargebacks and rebates.

Grant Revenue

Grant revenue for the year ended December 31, 2006 was $407,000 compared to $336,000 for the year ended December 31, 2005, an increase of approximately $71,000, or 21.1%. Grant revenue is recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied.

Cost of Sales

We recorded cost of sales of $7.1 million for the year ended December 31, 2006 as compared to $5.1 million for the year ended December 31, 2005, an increase of approximately $2.0 million, or 39.2%. Cost of sales for the year ended December 31, 2006 consisted of $2.9 million in royalty fees, $2.6 million in inventory costs, $775,000 in amortization of intangible assets, $676,000 in charges for excess inventory and $215,000 in costs related to packaging, freight and stability testing. The charges for excess inventory were taken due to lower than anticipated primary care sales of Zanaflex Capsules. Cost of sales for the year ended December 31, 2005 consisted of $1.6 in royalty fees, $434,000 in amortization of intangible assets, $1.0 million in inventory costs, $1.8 million in charges for excess inventory and $333,000 in costs related to packaging, freight, and stability testing. The charges for excess inventory were taken due to lower than anticipated primary sales of Zanaflex Capsules and because the current Zanaflex Capsules inventory has 36 month dating.

Research and Development

Research and development expenses for the year ended December 31, 2006 were $12.1 million as compared to $12.9 million for the year ended December 31, 2005, a decrease of approximately $800,000, or 6.2%. The decrease in research and development expenses was primarily due to a decrease in expenses related to the termination of our former valrocemide collaboration agreement with Teva Phamaceutical Industries, Ltd. in June 2005. Our MS clinical development program expense increased from $4.0 million for the year ended December 31, 2005 to $6.0 million for the year ended December 31, 2006, an increase of $2.0 million or 50%, due to the continuation of increased activity in our Phase 3 clinical trial program.

Other contract expenses decreased to $751,000 in the year ended December 31, 2006, from $4.0 million in the year ended December 31, 2005, a decrease of $3.2 million or 81.2%. This decrease was primarily due to a decrease in expenses related to the termination of the valrocemide collaboration agreement in June 2005.

Sales and Marketing

Sales and marketing expenses for the year ended December 31, 2006 were $19.1 million compared to $13.1 million for the year ended December 31, 2005, an increase of approximately $6.0 million, or 45.8%. This increase was primarily attributable to an increase of $3.0 million in salaries and benefits related to the expansion of our Zanaflex Capsules specialist sales force, an increase of $1.7 million in other selling related expenses resulting from the expansion of our Zanaflex Capsules specialist sales force and an increase of $1.3 million for marketing and distribution and sales administration expense related to the distribution of Zanaflex Capsules and Zanaflex tablets.

General and Administrative

General and administrative expenses for the year ended December 31, 2006 were $12.6 million compared to $8.4 million for the year ended December 31, 2005, an increase of approximately $4.2 million, or 50.0%. The increase was attributable to the addition of a medical affairs department with $1.7 million of related expenses, $1.4 million due to increased general and administrative staff and salary costs related to being a public company and $875,000 related to increases in insurance expenses.

Other Income (Expense)

Other income (expense) was a loss of $1.0 million for the year ended December 31, 2006 compared to a loss of $1.1 million for the year ended December 31, 2005, a decrease of approximately $100,000, or 9.1%. Interest expense increased by $1.0 million principally due to interest expense related to the Paul Royalty Fund revenue interest agreement, partially offset by a $1.1 million increase in interest income due to an increase in cash balances resulting from the completion of our initial public offering of common stock in February 2006 and a private placement of our common stock in October 2006 and a $75,000 increase in other income primarily due to a New York State tax refund.

Cumulative effect of change in accounting principle

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), Share-Based Payment (SFAS No. 123R), which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We adopted SFAS No. 123R using the modified prospective application method under which the provisions of SFAS No. 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the consolidated statement of operations over the remaining service period after the adoption date based on the award s original estimate of fair value. Results for prior periods have not been restated. In connection with the adoption of SFAS No. 123R, the Company changed its method of recognizing the number of outstanding instruments for which the requisite service is not expected to be rendered from an actual basis to an estimate. This change resulted in the recognition of a cumulative effect of change in accounting principle as of January 1, 2006 of $454,000 compared to none for the year ended December 31, 2005. The cumulative effect adjustment represents the difference between compensation cost recognized through the date of adoption using actual forfeitures and the cost that would have been recognized to date using estimated forfeitures.

Beneficial Conversion Feature, Accretion of Issuance Costs, Preferred Dividends and Fair Value of Warrants Issued to Convertible Preferred Stockholders

Charges related to preferred stock increased to $36.0 million for the year ended December 31, 2006, from $18.6 million for the year ended December 31, 2005, an increase of approximately $17.4 million, or 93.6%, due to the recognition of the remaining unamortized portion of beneficial conversion charges of $48.5 million and issuance costs of $271,000 upon our completion of our initial public offering of our common stock in February 2006. These charges primarily comprised accretion of issuance costs on Series E, Series I and Series J mandatorily redeemable convertible preferred stock, accrual of preferred dividends of Series J and Series K mandatorily redeemable convertible preferred stock, accretion of beneficial conversion feature on Series A through Series I preferred stock for reset in conversion price, accretion of beneficial conversion feature on Series J preferred stock (see Note 3 to our consolidated financial statements). These charges were partially offset by the reversal of the cumulative preferred dividends of $12.7 million on Series J and Series K mandatorily redeemable convertible preferred stock during the year ended December 31, 2006, as they have been forfeited through completion of the initial public offering.

Year Ended December 31, 2005 Compared to Year Ended December 31, 2004

Gross Sales

We recognized revenue from the sale of Zanaflex Capsules and Zanaflex tablets of $5.9 million for the year ended December 31, 2005, as compared to $0 for the year ended December 31, 2004. We recognize product sales using a deferred revenue recognition model meaning that shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. Product sales in the year ended December 31, 2005, consist of Zanaflex tablet sales beginning in March 2005, which is when we began receiving prescription data for tablets containing a code clearly identifying these prescriptions as having been filled with product we sold, and Zanaflex Capsules prescription data beginning after our launch of the product in April 2005.

Deferred revenue from Zanaflex Capsules was $5.2 million as of December 31, 2005, as compared to $0 as of December 31, 2004. The increase in deferred revenue of Zanaflex Capsules was a result of our launch of the product in April 2005. We expect deferred revenue from Zanaflex Capsules to increase in the future as our sales and marketing efforts ramp up, and prescription data continues to lag wholesaler shipments made in anticipation of demand.

Deferred revenue from Zanaflex tablets was $11.5 million as of December 31, 2005, an increase of $4.8 million since December 31, 2004, as compared to $6.7 million as of December 31, 2004. The increase in deferred revenue of Zanaflex tablets resulted from increased shipment levels. Approximately $2.3 million of the deferred revenue at December 31, 2005 relates to product that we acquired from Elan that had an expiration date of less than 12 months at the time we sold it during 2004. We believe there is a high likelihood that this product will be returned, which would result in our inability to recognize the deferred revenue related to that shipped product. We expect deferred revenue from Zanaflex tablets to decline over time as we attempt to convert Zanaflex tablet sales to Zanaflex Capsules sales.

Discounts and Allowances

We recorded discounts and allowances of $1.1 million for the year ended December 31, 2005 as compared to $4.4 million for the year ended December 31, 2004. Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the year ended December 31, 2005 consisted of $710,000 in cash discounts and $403,000 in allowances for chargebacks and rebates. Discounts and allowances for the year ended December 31, 2004, consisted of $128,000 in cash discounts and allowances of $207,000 for chargebacks and rebates. Additionally, 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 prior to our acquisition of Zanaflex. As part of the acquisition of Zanaflex, we agreed to accept any returns of Zanaflex tablets that were returned subsequent to January 17, 2005, including returns of product that was originally sold by Elan. As part of our April 2005 launch of Zanaflex Capsules, in April, May and June 2005 we extended a 6% promotional cash discount over and above the standard 2% discount provided to drug wholesalers and a 4% rebate on products resold by the wholesalers to pharmacies, hospitals and other third parties. We expect cash discounts to decrease in future periods as a percentage of sales.

Grant Revenue

Grant revenue for the year ended December 31, 2005 was $336,000 compared to $479,000 for the year ended December 31, 2004. Grant revenue is recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied.

Cost of Sales

We recorded cost of sales of $5.1 million for the year ended December 31, 2005 as compared to $885,000 for the year ended December 31, 2004. Cost of sales for the year ended December 31, 2005 consisted of $1.6 million in royalty fees, $434,000 in milestone amortization of intangible assets, $1.0 million in inventory costs, $1.8 million in charges for excess inventory and $333,000 in costs related to packaging, freight, and stability testing. The charges for excess inventory were taken due to lower than anticipated primary care sales of Zanaflex Capsules and because the initial Zanaflex Capsules launch inventory was purchased with only 24 month dating. The remaining Zanaflex Capsule inventory was purchased with 36 month dating. Cost of sales for the year ended December 31, 2004 consisted of $519,000 in royalty fees, $114,000 in milestone amortization of intangible assets and $252,000 in inventory costs related to the sale of Zanaflex tablets. We began incurring cost of sales upon the acquisition of Zanaflex in July 2004.

Research and Development

Research and development expenses for the year ended December 31, 2005, were $12.9 million as compared to $22.0 million for the year ended December 31, 2004, a decrease of approximately $9.1 million, or 41.4%. The decrease in research and development expenses was primarily attributable to completion of two Phase 3 clinical trials of Fampridine-SR in SCI, and one Phase 2 clinical trial of Fampridine-SR in MS, during the first quarter of 2004. The SCI clinical development program expense decreased from $5.9 million for the year ended December 31, 2004 to $32,000 for the year ended December 31, 2005, due to our decision to put the program on hold. The MS clinical development program expense increased from $2.9 million for the year ended December 31, 2004 to $4.0 million for the year ended December 31, 2005, an increase of 37.9%, due to the launch of our Phase 3 clinical trial.

Other contract expenses decreased to $4.0 million in the year ended December 31, 2005, from $4.9 million in the year ended December 31, 2004, a decrease of 18.4%. This decrease is primarily due to a $1.7 million decrease in expenses for the manufacture of clinical supplies from the period ended December 31, 2004, offset by an increase in expenses related to the valrocemide collaboration, primarily due to termination expense of $3.1 million.

Operating expenses for clinical development and preclinical research and development decreased to $4.7 million in the year ended December 31, 2005, from $7.6 million in the year ended December 31, 2004, a decrease of $2.9 million, or 38.2%. This decrease was primarily due to a decrease in non-cash stock-based compensation expense of $1.2 million, to $625,000 for the year ended December 31, 2005 from $1.8 million for the year ended December 31, 2004. In addition, salaries and benefits decreased by $914,000 due to a staff reduction in early 2005.

Sales and Marketing

Sales and marketing expenses for the year ended December 31, 2005, were $13.1 million compared to $4.7 million for the year ended December 31, 2004, an increase of approximately $8.4 million or 178.7%. This increase was primarily attributable to $4.0 million for marketing and distribution and sales administration expense related to the launch of Zanaflex Capsules and the distribution of Zanaflex tablets and $3.2 million in salaries and benefits related to our Zanaflex Capsules specialist sales force.

General and Administrative

General and administrative expenses for the year ended December 31, 2005, were $8.4 million compared to $13.3 million for the year ended December 31, 2004, a decrease of approximately $4.9 million, or 36.8%. Total general and administrative expenses include non-cash stock based compensation expense of $2.4 million for the year ended December 31, 2005, as compared to $6.5 million for the year ended December 31, 2004, primarily attributable to the repricing in the first

quarter of 2004 of options granted prior to 2004. In addition, the year ended December 31, 2004 included approximately $1.2 million in outside NDA preparation services related to our Phase 3 trials of Fampridine-SR in SCI.

Other Income (Expense)

Other income (expense) was a loss of $1.1 million for the year ended December 31, 2005, versus a gain of $26,000 in the year ended December 31, 2004, a difference of $1.1 million. Interest expense for the year ended December 31, 2005 increased by $1.1 million primarily related to the $6.0 million secured term loan with GE Capital entered into in January 2005 as well as from interest costs related to the agreement with PRF entered into in December 2005.

Beneficial Conversion Feature, Accretion of Issuance Costs, Preferred Dividends and Fair Value of Warrants Issued to Convertible Preferred Stockholders

Charges related to preferred stock remained relatively flat at $24.8 million for the year ended December 31, 2005, and $24.8 million for the year ended December 31, 2004. These charges primarily comprised accretion of issuance costs on Series E, Series I and Series J mandatorily redeemable convertible preferred stock, accrual of preferred dividend on Series J and Series K mandatorily redeemable convertible preferred stock, accretion of beneficial conversion feature on Series A through Series I preferred stock for reset in conversion price and accretion of beneficial conversion feature on Series J preferred stock (see Notes 3, 8 and 11 to our consolidated financial statements).

Liquidity and Capital Resources

We have incurred annual operating losses since inception and, as of December 31, 2006, we had an accumulated deficit of approximately $232.1 million. We have financed our operations primarily through private placements of our securities, and, to a lesser extent, from loans, government grants and, more recently, our financing arrangement with PRF, our initial public offering of common stock in February 2006 and our private placement of common stock in October 2006.

Our initial public offering in February 2006 resulted in the issuance of approximately 6.1 million shares of our common stock and the conversion of all of our outstanding convertible and mandatorily convertible preferred stock. In connection with the offering of common shares, we raised approximately $31.5 million, net of issuance costs.

We completed a private placement in October 2006 in which approximately 3.2 million shares of our common stock were sold, resulting in net proceeds to us of approximately $29.8 million, net of issuance costs.

Financing Arrangements

In January 1997, Elan International Services, Ltd. (EIS) loaned us an aggregate of $7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities. On December 23, 2005, EIS transferred these promissory notes to funds affiliated with Saints Capital. In December 2006, Saints Capital exercised the conversion option of their $2.5 million note and received 210,863 shares of common stock. The remaining $5.0 million convertible promissory note is convertible into 67,476 shares of common stock. In August and September 2002, we financed certain of our fixed assets through two financing agreements with General Electric Capital Corporation, or GE Capital, in the aggregate amount of approximately $1.2 million, which was repaid in full in September 2006. In January 2005, we entered into a $6.0 million senior secured term loan, which is collateralized by all of our personal property and fixtures, other than the property that secures our revenue interests assignment arrangement with PRF, of which $1.2 million was outstanding as of December 31, 2006.

On December 23, 2005, we entered into a revenue interests assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) 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. Our agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, we entered into an amendment to the revenue interests assignment agreement with PRF. Under the terms of the amendment, PRF paid us $5.0 million in November 2006 and an additional $5.0 million is due as our net revenues during the fiscal year 2006 exceeded $25.0 million. This receivable is reflected in our 2006 financial statements. Under the terms of the amendment, we are required to pay PRF $5.0 million on December 1, 2009 and an additional $5.0 million on December 1, 2010.

Under the agreement and the amendment, 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 2.1 times the aggregate amount PRF has paid us under the agreement, PRF will only be entitled to 1% of Zanaflex net revenues. In connection with the transaction, we have a liability recorded, referred to as the revenue interest liability, of approximately $23.1 million in accordance with EITF 88-18, *Sales of Future Revenues*. We will impute interest expense associated with this liability using the effective interest rate method and will record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 4.5%. Payments made to PRF as a result of Zanaflex sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability.

In consideration for our assignment of the right to receive a portion of Zanaflex net revenues (as defined in the agreement), PRF paid us $15.0 million at signing of the original agreement. We used approximately $3.0 million of the signing payment to repay a portion of the amount we owe to GE Capital, approximately $200,000 of the signing payment for fees and expenses associated with such repayment and $691,000 of the signing payment to reimburse PRF for expenses it estimated it incurred in the transaction. Under our agreement with PRF, we were required to use the remainder of the amount we received at signing and any other amounts we receive under the agreement or amendment to support commercialization, sales, marketing, clinical and regulatory activities and other financial obligations related specifically and solely to our Zanaflex operations. We may not use any proceeds from our agreement or amendment with PRF to support any of our other products unless such use is ancillary to the support of commercialization of Zanaflex.

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 we make under the agreement, PRF may (i) require us to repurchase the rights we sold them 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, which we refer to as PRF s put option, 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. If we experience a change of control we have the right, which we refer to as our call option, to repurchase the rights we sold to PRF 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) 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. We have determined that PRF s put option and our call option meet the criteria to be considered an embedded derivative and should be accounted for as such. Therefore, we recorded a net liability of approximately $350,000 as of December 31, 2006 related to the put/call option to reflect its estimated fair value as of the date of the agreement, in accordance with SFAS No. 133, *Accounting for Derivatives Instruments and Hedging Activities.* This liability is revalued on a quarterly basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings.

During any period during which PRF has the right to receive 15% of Zanaflex net revenues (as defined in the agreement), then 8% of the first $30.0 million in payments from Zanaflex sales we receive from wholesalers will be distributed to PRF on a daily basis. Following the end of each fiscal quarter, if the aggregate amount actually received by PRF during such quarter exceeds the amount of net revenues PRF was entitled to receive, PRF will remit such excess to us. If the amount of net revenues PRF was entitled to receive during such quarter exceeds the aggregate amount actually received by PRF during such quarter, we will remit such excess to PRF.

PRF also has the right to appoint a representative to receive all notices and materials provided to our board of directors and to attend as an observer all meetings of our board of directors, subject to certain exceptions. This right will terminate on the earlier to occur of February 10, 2010 (the fourth anniversary of the completion of our initial public offering of shares of our common stock) or termination of the revenue interests assignment agreement.

Investment Activities

At December 31, 2006, cash and cash equivalents and short-term investments were approximately $53.8 million, as compared to $13.8 million at December 31, 2005. Our cash and cash equivalents consist of highly liquid investments with original maturities of three months or less at date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions and high-quality government and investment grade corporate bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. As of December 31, 2006, our cash and cash equivalents were $18.1 million, as compared to $11.8 million as of December 31, 2005. Our short-term investments consist of corporate debt securities with remaining maturities greater than three months and less than one year. The balance of these investments was $35.7 million as of December 31, 2006, as compared to $2.0 million as of December 31, 2005.

Net Cash Used in Operations

Net cash used in operations was $23.5 million and $20.1 million for the years ended December 31, 2006 and 2005, respectively. Cash used by operations for the year ended December 31, 2006 was primarily attributable to a net loss of $24.0 million, a decrease in accounts payable, accrued expenses, and other liabilities of $4.5 million, an increase in accounts receivable of

$3.7 million, a decrease in tablet deferred product revenue of $2.4 million and a decrease in returns liability of $1.8 million. Cash used in operations for the year ended December 31, 2006, was partially offset by non-cash stock compensation expense of $3.8 million, an increase in capsule deferred product revenue of $6.1 million, depreciation and amortization expense of $1.8 million and a decrease in prepaid expenses and other current assets of $1.3 million. Cash used in operations for the year ended December 31, 2005 was primarily attributable to a net loss of $35.5 million, an increase in inventory of $2.9 million, a decrease in returns liability of $2.3 million and an increase in prepaid expenses and other current assets of $2.9 million. Cash used in operations for the year ended December 31, 2005, was partially offset by an increase in tablet deferred product revenue of $5.2 million, an increase in capsule deferred product revenue of $4.8 million, non-cash stock compensation expense of $4.4 million, an increase in accounts payable, accrued expenses and other current liabilities of $7.4 million and a decrease in accounts receivable of $1.3 million.

Net Cash Used in/Provided by Investing

Net cash used in investing activities for the year ended December 31, 2006 was $33.8 million, primarily due to $33.3 million in net purchases of short-term investments. In addition, we purchased property and equipment of $527,000 in the year ended December 31, 2006.

Net Cash Used in/Provided by Financing

Net cash provided by financing activities for the year ended December 31, 2006 was $63.6 million, primarily due to $31.5 million of initial public offering net proceeds, $29.8 million in private placement net proceeds, $5.0 million in net proceeds received from the PRF transaction and $670,000 in proceeds from option exercises, which was offset by $2.2 million in repayments to PRF and $1.0 million in repayments of notes payable.

Future Capital Needs

Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Zanaflex Capsules, the continued progress of our research and development activities, the timing and outcome of regulatory approvals, the amount and timing of milestone or other payments made under collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights and the acquisition of licenses to new products or compounds. We expect to incur losses from operations for at least the next several years as we continue to expand our sales and marketing infrastructure and increase our marketing efforts to support the commercialization of Zanaflex Capsules, continue our clinical development of Fampridine-SR and advance our preclinical programs.

We believe our existing cash and cash equivalents and short-term investment will be sufficient to fund our operating expenses, debt repayments and capital equipment requirements through the first quarter of 2008. We may seek additional financing in the near future to ensure the completion of Fampridine-SR s clinical development. To the extent our capital resources are insufficient to meet future operating requirements, we will need to raise additional capital, reduce cash expenditures or incur indebtedness to fund our operations. We may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, we may be required to curtail our sales and marketing efforts, delay, reduce the scope of or eliminate some of our research and development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Contractual Obligations and Commitments

In January 2005, we entered into a $6.0 million senior secured term loan with GE Capital. In December 2005, we used a portion of the initial payment we received under our revenue interest assignment arrangement with PRF to repay approximately $3.0 million of this loan. We are required to pay monthly installments until February 2008, with interest-only payments for the first six months followed by principal and interest payments for the remaining 29 months. Interest is fixed at the rate of 9.93% per annum. The loan is secured by all of our personal property and fixtures, other than the property that secures our arrangement with PRF.

In January 1997, EIS loaned us an aggregate of $7.5 million pursuant to two convertible promissory notes. One promissory note in the principal amount of $5.0 million bears interest at a rate of 3% which began on the first anniversary of the note. The other promissory note in the amount of $2.5 million was non-interest bearing. On December 23, 2005, EIS transferred these promissory notes to funds affiliated with Saints Capital. In December 2006, Saints Capital exercised the conversion option of the $2.5 million convertible promissory note at an exercise price of $11.856 per share and received 210,863 shares of common stock. The remaining $5.0 million convertible promissory note is convertible into 67,476 shares of common stock. Principal and interest are repayable, if not converted, ratably over a seven-year period, beginning one year after we receive regulatory approval for certain products to be developed, subject to limitations related to gross margin on product sales. If we and Sants Capital determine that regulatory approval will not likely occur, the $5.0 million promissory note will automatically convert into the underlying common stock unless Saints Capital elects to have the amount due on the note cancelled. If our license and supply agreements with Elan are terminated for any other reason, the principal and interest is repayable ratably over 15 years. The $5.0 million promissory note restricts our ability to incur indebtedness that is senior to the note, subject to certain exceptions, including for our revenue interests assignment arrangement with PRF.

Under our Zanaflex purchase agreement with Elan, we are obligated to make milestone payments to Elan of up to $19.5 million based on cumulative gross sales of Zanaflex tablets and Zanaflex Capsules. As of December 31, 2006, we have made or accrued $9.5 million of these milestone payments in the consolidated financial statements. Under our Zanaflex supply agreement with Elan, we are required to provide to Elan an 18-month rolling forecast at the beginning of each month and a two-year forecast not later than July 1 of each year. We are required to order 100% of the forecast required quantities for each five-month period immediately following each monthly forecast report. At December 31, 2006, the forecast requirement for the five-month period following December 31, 2006 amounted to approximately $2.6 million.

Under our Fampridine-SR license agreement with Elan, we are obligated to make milestone payments to Elan of up to $15.0 million over the life of the contract and royalty payments as a percentage of product sales. In addition, under our various other research, license and collaboration agreements with other parties we are obligated to make milestone payments of up to an aggregate of approximately $16.8 million over the life of the contracts.

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 which definition is different from our net revenues as determined in accordance with GAAP) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all such 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 $691,000 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. If our Zanaflex net revenues in 2005 had equaled or exceeded $11.0 million and our Zanaflex net revenues in the first six months of 2006 had equaled or exceeded $16.0 million, at our election, PRF would also have been required to loan us an additional $5.0 million. We did not meet this milestone.

In November 2006, we entered into an amendment to the revenue interests assignment agreement with PRF. Under the amendment, PRF is entitled to a royalty consisting of certain specified percentages of Zanaflex net revenues, based upon the level of net revenues. Previously, once PRF had received and retained payments under the agreement that are at least twice the aggregate amount PRF paid us under the Agreement, the royalty rate would drop to 1% of Zanaflex net revenues. The amendment provides that the royalty rate will drop to 1% upon PRF s receipt of 2.1 times the aggregate amount PRF has paid us under the agreement, as amended. Under the terms of the amendment, PRF paid us $5.0 million in November 2006 and agreed that we would be entitled to an additional $5.0 million is due if our net revenues during the fiscal year 2006 equaled or exceeded $25.0 million. This milestone has been met and the receivable is reflected in our December 31, 2006 financial statements. This milestone payment was received in February 2007. Under the terms of the amendment, we are required to pay PRF $5.0 million on December 1, 2009 and an additional $5.0 million on December 1, 2010.

The following table summarizes our minimum contractual obligations as of December 31, 2006. This table does not reflect contingent milestone or royalty payments that may result in future periods from our collaborations, alliances and/or license agreements. This table should be read in conjunction with the accompanying notes to our consolidated financial statements:

Twelve Month Period Ending December 31,	Notes Payable(1) (in thousands)	Operating Leases	Inventory Purchase Commitment
2007	$ 1,140	$ 732	$ 2,599
2008	190	857	
2009		860	
Total	$ 1,340	$ 2,449	$ 2,599

(1) Notes payable represents the principal and interest payable on the GE Capital notes payable and does not include the $5.0 million aggregate principal amount of convertible notes payable to Saints Capital or milestone payments under our license agreements as these amounts are payable on contingent events.

Under the terms of the employment agreement with our chief executive officer, Ron Cohen, we are obligated to pay severance under certain circumstances. If the employment agreement is terminated by us or by our chief executive officer for reasons other than for cause, we must pay an amount equal to (i) the base salary the chief executive officer would have received during the 15-month period immediately following the date of termination, plus (ii) the last annual bonus received by the chief executive officer multiplied by a fraction, the numerator of which is the number of days in the calendar year elapsed as of the termination date and the denominator of which is 365.

Under the terms of the employment agreements with our chief scientific officer, Andrew Blight, our chief operating officer, Mary Fisher, our chief financial officer, David Lawrence and our general counsel, Jane Wasman, we are obligated to pay severance under certain circumstances. In the event we terminate our employment agreement with Dr. Blight, Ms. Fisher, Mr. Lawrence or Ms. Wasman without cause, or if one of them voluntarily terminates his or her agreements with good reason, we are obligated to make severance payments equal to nine months base annual salary, in the case of Dr. Blight and Ms. Fisher, and seven months base annual salary, in the case of Mr. Lawrence and Ms. Wasman, as well as COBRA premium payments for the severance period. In such event, all

options, stock appreciation rights awards and restricted stock awards that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination. If Dr. Blight, Ms. Fisher, Mr. Lawrence or Ms. Wasman voluntarily terminates his or her employment without good reason or if we terminate his or her employment without cause within 18 months after a change in control, we are obligated to make severance payments equal to one year s base annual salary, in the case of Dr. Blight and Ms. Fisher, and nine months base annual salary, in the case of Mr. Lawrence and Ms. Wasman, in each case paid in a lump sum within 30 days after termination, as well as COBRA premium payments for the severance period plus a bonus equal to the prior year s bonus pro rated for the number of days worked prior to termination. We are also obligated to pay salary earned but not paid, vacation and sick leave days that have accrued, and reimbursable business expenses incurred through the date of termination. In such event, not less than 50% of the unvested options, stock appreciation rights and restricted or other stock awards shall become immediately and full vested and shall remain exercisable for 18 months following such date. All options that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination.

Effects of Inflation

Our most liquid assets are cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, primarily employee compensation and contract services, which could increase our level of expenses.

Critical Accounting Policies and Estimates

The following discussion of critical accounting policies identifies the accounting policies that require application of management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. It is not intended to be a comprehensive list of all of our significant accounting policies, which are more fully described in Note 2 of the notes to the consolidated financial statements included in this prospectus. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management s judgment in their application. There are also areas in which the selection of an available alternative policy would not produce a materially different result. We have identified the following as our areas of critical accounting policies: sales revenue recognition, research and development, income taxes, and stock-based compensation.

Revenue Recognition

We apply the revenue recognition guidance in SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. Under SFAS 48 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 do not believe we can 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 shipped as inventory held by others. We recognize revenue when prescriptions are filled to an end-user because once a prescription is filled the product cannot be returned. We use monthly prescription data that we purchase to determine the amount of revenue to be recognized. We estimate prescription sales until the data becomes available, at which time adjustments are made to revenue and cost of sales to account for any differences between our estimates and the actual data. To date such differences have been immaterial. The estimated prescription sales are based on the average of the prior two months prescriptions for both Zanaflex tablets and Zanaflex Capsules. 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.

In addition to the prescription data we purchase, we also receive data that we use to monitor trends in sales from wholesalers to their customers. We receive this data from an outside vendor on a monthly basis. This data includes the number of bottles shipped from certain wholesalers to their customers. We also compare our shipments to wholesalers to prescription reports to further assess inventory in the distribution channel on a monthly basis. We use the wholesaler sales trend data and the wholesaler vs. prescription comparison to better understand market conditions, but not as a basis for recognizing revenue.

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.

Research and Development

Research and development expenses include the costs associated with our internal research and development activities including, salaries and benefits, occupancy costs, and research and development conducted for us by third parties, such as sponsored university-based research, and clinical trial vendors. In addition, research and development expenses include expenses related to grant revenue and the cost of clinical trial drug supply shipped to our clinical study vendors. We account for our clinical study costs by estimating the patient cost per visit in each clinical trial and recognizing this cost as visits occur, beginning when the patient enrolls in the trial. This estimated cost includes payments to the trial site and patient-related costs, including laboratory costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, and the length of the treatment period for each patient. As actual costs become known to us, we adjust our accrual; such changes in estimate may be a material change in our clinical study accrual, which could also materially affect our results of operations.

Income Taxes

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the asset and liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We have not recorded any tax provision or benefit for the years ended December 31, 2006 and 2005. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry-forwards cannot be sufficiently assured at December 31, 2006.

As of December 31, 2006, we had available net operating loss carry-forwards of approximately $144.7 million for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2010 and 2026 and research and development tax credit carry-forwards of approximately $1.3 million for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2018. Since our inception, we have incurred substantial losses and expect to incur substantial and recurring losses in future periods. The Internal Revenue Code of 1986, as amended, the Code, provides for a limitation of the annual use of net operating loss and research and development tax credit carry forwards (following certain ownership changes, as defined by the Code) that could significantly limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Code, as a result of past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry forwards may be applied against future taxes we may not be able to take full advantage of these attributes for federal income tax purposes.

Stock-Based Compensation

Historically, we accounted for share-based compensation costs under the provisions of Statement of Financial Accounting Standards 123 (SFAS No. 123), Accounting for Stock-Based Compensation, using a fair-value-based method of accounting for stock-based employee compensation plans.

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), Share-Based Payment (SFAS No. 123R), which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We adopted SFAS No. 123R using the modified prospective application method, under which the provisions of SFAS No. 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the Consolidated Statement of Operations over the remaining service period after the adoption date based on the award s original estimate of fair value. Results for prior periods have not been restated.

In connection with the adoption of SFAS No. 123R, we changed from recognizing the effect of forfeitures as they occur to estimating the number of outstanding instruments for which the requisite service is not expected to be rendered. Prior to the adoption of SFAS No. 123R, we recognized forfeitures associated with its share-based awards as they occurred rather than estimating forfeitures. Upon adoption of SFAS No. 123R, we recorded a cumulative effect of change in accounting principle of $454,225 during the three-month period ended March 31, 2006, calculated as the difference between compensation cost recognized to date using actual forfeitures and the cost that would have been recognized to date using estimated forfeitures. We estimate that our future annual forfeiture rate will be 5%.

We account for stock options granted to non-employees on a fair-value basis in accordance with EITF 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 Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist of cash and cash equivalents, short-term investments, grant receivable, notes payable, convertible notes payable, accounts payable, warrant liability, and put/call liability. The estimated fair values of all of our financial instruments, excluding convertible notes

payable to Saints Capital, approximate their carrying amounts at December 31, 2006. The terms of these notes are disclosed at Note 10 to the consolidated financial statements.

We have cash equivalents and short-term investments at December 31, 2006, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the short-term nature of our investments in money market funds and corporate debt securities, the carrying value of our cash equivalents and short-term investments approximate their fair value at December 31, 2006.

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

As required by Rule 13a-15 under the Exchange Act, within 90 days prior to filing this report, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer. Based on that evaluation, these officers have concluded that, as of December 31, 2006, our disclosure controls and procedures were effective and designed to ensure that material information relating to us required to be included in our reports filed under the Exchange Act would be made known to them. There have been no changes in our internal controls over financial reporting (as defined in Rules 13a-15(b) and 15(d)-15(f) under the Exchange Act) or in other factors that has materially affected or is reasonably likely to materially affect internal controls over financial reporting.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and regulations. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding disclosure.

Change in internal control over financial reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

Item 9B. Other Information.

None.

PART III

Item 10. Directors and Executive Officers of the Registrant.

Set forth below is certain information regarding our directors and executive officers.

Name	Age	Position(s)
Ron Cohen, M.D.	51	President, Chief Executive Officer and Director
Andrew R. Blight, Ph.D.	56	Chief Scientific Officer
Mary Fisher	45	Chief Operating Officer
David Lawrence, M.B.A.	49	Chief Financial Officer
Jane Wasman, J.D.	50	Executive Vice President, General Counsel and Secretary
Barry Greene(4)	43	Director
Sandra Panem, Ph.D.(1)(3)	60	Director
Barclay A. Phillips(2)(3)	44	Director
Lorin J. Randall(2)(3)	63	Director
Steven M. Rauscher(1)(3)	53	Director
Ian Smith(2)	41	Director
Wise Young, Ph.D., M.D.(1)	57	Director

(1) Member of the Compensation Committee

(2) Member of the Audit Committee

(3) Member of the Nominations Committee

(4) Member of the Compliance Committee

Information Concerning Directors

Our board of directors currently consists of eight members. Our common stock is quoted on The Nasdaq Global Market and we are subject to the National Association of Securities Dealers listing standards. Our board of directors has determined that the majority of our directors are independent, or an Independent Director, under Rule 4200(a)(15) of the National Association of Securities Dealers listing standards.

Directors Whose Terms Expire in 2007 Class II Directors

Sandra Panem, Ph.D., has been a member of our Board of Directors since 1998. She is currently a partner at Cross Atlantic Partners, which she joined in 2000. From 1994 to 1999, Dr. Panem was President of Vector Fund Management, the then asset management affiliate of Vector Securities International. Prior thereto, Dr. Panem served as Vice President and Portfolio Manager for the Oppenheimer Global BioTech Fund, a mutual fund that invested in public and private biotechnology companies. Previously, she was Vice President at Salomon Brothers Venture Capital, a fund focused on early and later-stage life sciences and technology investments. Dr. Panem was also a Science and

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Public Policy Fellow in economic studies at the Brookings Institution, and an Assistant Professor of Pathology at the University of Chicago. She received a B.S. in biochemistry and Ph.D. in microbiology from the University of Chicago. Dr. Panem currently serves on the boards of directors of Gene-IT, Inc. and Labcyte, Inc.

Wise Young, Ph.D., M.D., has been a member of the board of directors and of our scientific advisory board since the founding of the company in 1995. Dr. Young has been at Rutgers University since 1997, where he serves as Professor and Chair of the Department of Cell Biology and Neuroscience, Professor II and Director of the Neuroscience Center and Founding Director of the W.M. Keck Center for Neuroscience. Dr. Young is one of the preeminent scientists in the fields of spinal cord injury and neurotrauma, SCI animal models, and the pharmacological therapy of SCI. He was the Principal Investigator for the Multicenter Animal Spinal Cord Injury Study, funded by the National Institutes of Health; is editor-in-chief of *Current Concepts in Critical Care and Trauma*; and serves on numerous editorial boards, including those of *Experimental Neurology, Journal of Neurotrauma, Brain Research* and *Stroke*. Dr. Young has received the Wakeman Award for Research in Neurosciences, and a Jacob Javits Neuroscience Award from the National Institute of Neurological Disorder and Stroke. He is also a member of the Scientific Advisory Council of the American Paralysis Association and of the National Acute Spinal Cord Injury Study executive committee. Dr. Young received a B.A. in biology and chemistry from Reed College, a Ph.D. in physiology and biophysics from the University of Iowa and an M.D. from Stanford University.

Directors Whose Terms Expire in 2008 Class III Directors

Ron Cohen, M.D., has served as our President and Chief Executive Officer since he founded Acorda in 1995. Dr. Cohen previously was a principal in the startup of Advanced Tissue Sciences, Inc., a biotechnology company engaged in the growth of human organ tissues for transplantation uses. Dr. Cohen received his B.A. degree with honors in Psychology from Princeton University, and his M.D. from the Columbia College of Physicians & Surgeons. He completed a residency in Internal Medicine at the University of Virginia Medical Center, and is Board Certified in Internal Medicine. Dr. Cohen serves on the Emerging Company Section of the Board of the Biotechnology Industry Organization (BIO). He is Chairman Emeritus and a Director of the Board of the New York Biotechnology Association and also serves as on the Scientific Advisory Board of the Daniel Heumann Fund and as a member of the Columbia-Presbyterian Health Sciences Advisory Council.

Lorin J. Randall has been a member of our Board of Directors since January 2006. Mr. Randall is an independent financial consultant and previously was Senior Vice President and Chief Financial Officer of Eximias Pharmaceutical Corporation, a development-stage drug development company from 2004 to 2006. From 2002 to 2004, Mr. Randall served as Senior Vice President and Chief Financial Officer of i-STAT Corporation, a publicly-traded manufacturer of medical diagnostic devices which was acquired by Abbott Laboratories in 2004. From 1995 to 2001, Mr. Randall was Vice President and Chief Financial Officer of CFM Technologies, Inc. a publicly-traded manufacturer of semiconductor manufacturing equipment. Mr. Randall previously served on the board of Quad Systems Corporation, a publicly-traded manufacturer of electronics manufacturing equipment where he served as Chairman of the Audit Committee. Mr. Randall currently serves on the boards of directors of Point 5 Technologies, Inc. and Rapid Micro Biosystems, Inc. Mr. Randall received a B.S. in accounting from The Pennsylvania State University and an M.B.A. from Northeastern University.

Steven M. Rauscher has served on our Board of Directors since 2005. He is President and CEO of Oscient Pharmaceuticals Corporation, a commercial stage biopharmaceutical company. He joined Oscient in 2000 having served as a member of the Board of Directors since 1993. Previously, Mr. Rauscher was CEO of AmericasDoctor, a company providing clinical research services to the pharmaceutical industry. Prior to AmericasDoctor, he held a number of leadership positions at Abbott

Laboratories, including Vice President of Corporate Licensing, Vice President of Business Development, International Division and Vice President of Sales, U.S. Pharmaceuticals. Mr. Rauscher received a B.S. from Indiana University and an M.B.A. from the University of Chicago.

Barclay A. Phillips has been a member of our Board of Directors since September 2004. Mr. Phillips has been a Managing Director of Vector Fund Management, a venture capital firm focused on investments in the life sciences and healthcare industry, since 1999. From 1991 to 1999, Mr. Phillips served in various roles including Director of Private Placements and Biotechnology Analyst for INVESCO Funds Group, Inc. From 1985 to 1990, Mr. Phillips held positions in sales and trading with Paine Webber, Inc. and Shearson Lehman Hutton, Inc. Over the last twelve years, Mr. Phillips has served on the boards of a number of private companies and served as a Director of CancerVax Corp. Mr. Phillips received a B.A. in economics from the University of Colorado.

Directors Whose Terms Expire in 2009 Class I Directors

Barry Greene has been a member of our board of directors since January 2007. Mr. Greene currently serves as Chief Operating Officer of Alnylam Pharmaceuticals, Inc. Mr. Greene joined Alnylam in October 2003, bringing over 15 years of experience in healthcare industries and consulting. Prior to Alnylam, he was General Manager of Oncology at Millennium Pharmaceuticals, Inc., where he led the company s global strategy and execution for its oncology business including strategic business direction and execution, culminating in the successful approval and launch of VELCADET (bortezomib) in mid 2003. Prior to joining Millennium in February 2001, Mr. Greene served as Executive Vice President and Chief Business Officer for Mediconsult.com. Prior to Mediconsult.com, Mr. Greene s past experiences include Vice president of Marketing and Customer Services for AstraZeneca formerly AstraMerck; Vice President Strategic Integration with responsibility for the AstraZeneca North American post merger integration; and Partner, Andersen Consulting responsible for the pharmaceutical/biotechnology marketing and sales practice. Mr. Greene received his B.S. in Industrial Engineering from University of Pittsburgh and serves as a Senior Scholar at Duke University, Fuqua School of Business.

Ian Smith has been a member of our board of directors since February 2007. Mr. Smith currently serves as Executive Vice President and Chief Financial Officer of Vertex Pharmaceuticals, Inc., a position he has held since February 2006. From November 2003 to February 2006, he was Senior Vice President and Chief Financial Officer, and from October 2001 to November 2003, he served as Vice President and Chief Financial Officer at Vertex. Prior to joining Vertex, Mr. Smith served as a partner in the Life Science and Technology Practice Group of Ernst & Young LLP from 1999 to 2001. Mr. Smith initially joined Ernst & Young s U.K. firm in 1987, and then joined its Boston office in 1995. Mr. Smith currently is a member of the Board of Directors of Predix Pharmaceuticals, Inc. and TolerRx Inc. Mr. Smith holds a B.A. in accounting and finance from Manchester Metropolitan University, U.K., is a member of the American Institute of Certified Public Accountants and is a Chartered Accountant of England and Wales.

Information Concerning Executive Officers

Andrew R. Blight, Ph.D., has been our Chief Scientific Officer since January 2004 and previously served as our Executive Vice President, Research and Development from 2000 to 2004, and Vice President, Research and Development, from 1998 to 2000. Prior to joining Acorda, Dr. Blight spent approximately six years as Professor and Director of the Neurosurgery Research Laboratory at the University of North Carolina at Chapel Hill. Dr. Blight held prior academic positions at Purdue University and New York University. Dr. Blight is a leader in SCI pathophysiology research and has made several important contributions to the field, particularly on the role of demyelination in SCI. He also pioneered the therapeutic application of 4-AP in SCI animal models and in human clinical trials. Dr. Blight is a member of the editorial board of the Journal of Neurotrauma and has served as a

member of the NIH NSDA review committee. He was previously Secretary, Treasurer and Vice President of the National Neurotrauma Society. Dr. Blight received his B.S. in Zoology and his Ph.D. in Zoology/Neurobiology from the University of Bristol, U.K.

Mary Fisher has been our Chief Operating Officer since January 2005 and previously served as our Vice President, Commercial Operations from 2003 through 2004 and Vice President, Marketing and Strategic Planning from 2000 to 2003. From 1999 to 2000, Ms. Fisher was an independent consultant to various pharmaceutical companies. From 1994 to 1999, Ms. Fisher was Vice President, Strategic Healthcare and Commercial Operations for Cephalon, Inc. In that capacity she was responsible for the company s corporate sales, managed care marketing, pricing, reimbursement, health economics, patient support programs, product planning, commercial manufacturing, distribution and customer service. From 1990 until joining Cephalon, Ms. Fisher was Corporate Communications Manager for Immunex Corporation.

David Lawrence, M.B.A., has been our Chief Financial Officer since January 2005. He previously served as our Vice President, Finance from January 2001 through 2004, and Director, Finance from 1999 to 2001. From 1991 to 1999, Mr. Lawrence held several positions for Tel-Air Communications, Inc. including Vice President and Controller. Prior to Tel-Air, he held financial management positions of Controller and Finance Manager for Southwestern Bell and Metromedia Telecommunications respectively. Mr. Lawrence received his undergraduate degree in Accounting from Roger Williams College, and an M.B.A in Finance from Iona College. Mr. Lawrence is a founding member and currently serves on the Board of Directors as Treasurer of The Brian Ahearn Children s Fund.

Jane Wasman, J.D., has been our Executive Vice President, General Counsel and Corporate Secretary since May 2004. From 1995 to 2004, Ms. Wasman held various leadership positions at Schering-Plough Corporation, including Staff Vice President and Associate General Counsel responsible for legal support for U.S. Pharmaceuticals operations, including sales, marketing and compliance; FDA regulatory matters; global research and development; and, corporate licensing and business development. She served as Staff Vice President, International in 2001 and as Staff Vice President, European Operations Legal from 1998 to 2000. Previously, Ms. Wasman specialized in litigation at Fried, Frank, Harris, Shriver & Jacobson. She also served as Associate General Counsel to the U.S. Senate Committee on Veteran s Affairs. Ms. Wasman graduated Magna Cum Laude from Princeton University and earned her J.D. from Harvard Law School.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee, a nominations committee and a compliance committee as standing committees, each of which is comprised solely of Independent Directors. Pursuant to our bylaws, our board of directors may from time to time establish other committees to facilitate the management of our business and operations.

Audit Committee and Audit Committee Financial Experts

Our audit committee currently consists of three members: Mr. Randall (chairperson), Mr. Phillips and Mr. Smith. Our board of directors has determined that Mr. Randall and Mr. Smith each qualify as an audit committee financial expert as that term is defined in Item 401(h) of Regulation S-K of the Securities Act. Our board of directors has determined that the composition of our audit committee meets, and the functioning of our audit committee will comply with, the applicable requirements of the Sarbanes-Oxley Act of 2002, the Nasdaq Global Market and SEC rules and regulations.

Our audit committee is responsible for:

- approving and retaining the independent auditors to conduct the annual audit of our books and records;

- reviewing the proposed scope and results of the audit;
- reviewing and pre-approving the independent auditors audit and non-audit services rendered;
- approving the audit fees to be paid;
- reviewing accounting and financial controls with the independent auditors and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- recognizing and preventing prohibited non-audit services;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions; and
- overseeing non-financial compliance.

All audit services and non-audit services to be provided to us by our independent auditor must be approved in advance by our audit committee. KPMG LLP currently serves as our independent auditor. Our board of directors has adopted a written charter for the audit committee which is available on our website, http://www.acorda.com under Corporate Governance Committee Charters.

Compensation Committee

Our compensation committee consists of three members: Dr. Panem (chairperson), Mr. Rauscher and Dr. Young. We believe that the composition of our compensation committee meets, and the functioning of our compensation committee complies with, the applicable requirements of the Nasdaq Global Market and SEC rules and regulations. Our compensation committee is responsible for:

- reviewing and recommending the compensation arrangements for executives, including the compensation for our president and chief executive officer;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals; and
- administering our stock incentive plan and annual bonus pool.

Our board of directors has adopted a written charter for the compensation committee which is available on our website, http://www.acorda.com under Corporate Governance Committee Charters.

Nominations Committee

Our nominations committee consists of four members: Mr. Randall (Chairperson), Dr. Panem, Mr. Phillips and Mr. Rauscher. The nominations committee is responsible for identifying potential candidates to serve on our board and overseeing an annual evaluation of the board. Our board of directors has adopted a written charter for the nominations committee which is available on our website, http://www.acorda.com under Corporate Governance Committee Charters.

Compliance Committee

Our compliance committee currently consists of one member, Mr. Greene (Chairperson). The compliance committee is responsible for overseeing our compliance with non-financial legal and regulatory requirements, including those related to product safety and quality and the development, manufacturing, distribution and sale of our products.

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Compensation Committee Interlocks and Insider Participation

Our compensation committee currently determines the compensation levels of our executive officers as described above. None of our executive officers has served as a director or member of the compensation committee, or other committee serving an equivalent function, of any entity of which an executive officer is expected to serve as a member of our compensation committee.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and the holders of more than 10% of our common stock to file reports with the SEC. Such reports include initial reports of ownership of our common stock and other equity securities on a Form 3 and reports of changes in such ownership on a Form 4 or Form 5. Executive officers, directors and 10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms that they file.

To our knowledge, based solely on our review of the copies of Forms 3, 4 and 5, and amendments thereto, received by us during or with respect to the year ended December 31, 2006, all filings applicable to our officers, directors, holders of more than 10% of our common stock and other persons subject to Section 16 of the Securities Exchange Act of 1934, were timely, except that one Form 4 reporting a stock option exercise by Dr. Blight was inadvertently filed late.

Code of Ethics

The Company has adopted a code of ethics as defined by applicable rules of the SEC and the Nasdaq Global Market, which is applicable to all employees. This code is publicly available on our website, http://www.acorda.com under Corporate Governance Governance Documents. If the Company makes any amendments to the code of ethics for its senior officers, financial and reporting persons or directors (other than technical, administrative, or other non-substantive amendments), or grants any waivers, including implicit waivers, from a provision of this code to such persons, the Company will disclose the nature of the amendment or waiver, its effective date and to whom it applies on its website or in a report on Form 8-K filed with the SEC.

Item 11. Director and Executive Compensation.

Compensation Discussion and Analysis

The compensation committee has the responsibility to review, approve and recommend for the approval of the full board of directors the annual compensation and compensation procedures for our five executive officers: the president and chief executive officer, the chief operating officer, the chief financial officer, the chief scientific officer and the executive vice president and general counsel.

Compensation Philosophy and Objectives

The primary objective of our compensation program, including executive compensation, is to align compensation opportunities with individual performance and achievement of our overall corporate and financial results. It is designed to tie annual and long-term cash and stock incentives to the achievement of established goals and to align executives incentives with the creation of value for our stockholders. To achieve these objectives, the compensation committee intends to implement and maintain compensation plans that tie a substantial portion of executives overall compensation to key strategic goals. The compensation committee evaluates individual executive performance with the goal of setting compensation at levels that the committee believes are comparable with executives at other companies in the biotechnology industry of similar size and stage of development, while taking into account our relative performance and strategic goals.

A further objective of our compensation program is to attract and retain highly talented, qualified executives who are dedicated to our mission and culture. We also endeavor to ensure that our compensation program is perceived as fundamentally fair to all stakeholders.

Setting Executive Compensation

With the objectives described above in mind, the compensation committee has retained Arnosti Consulting Inc. to conduct an annual review of the total compensation program for the executive team, as well as for other key executives. Arnosti Consulting also provides the compensation committee with relevant market data and alternatives to consider when making compensation decisions for the executive team and to confirm that our compensation program is in a competitive market position. The compensation committee reviews several salary surveys when making compensation decisions, including surveys produced by Radford Surveys + Consulting and Equilar, Inc. The committee also reviews a competitive analysis of relevant peers prepared by Arnosti Consulting, Inc. that compares each element of total compensation against a group of over 60 publicly-traded and privately-held biotechnology companies. The companies used in this analysis are companies against which the compensation committee believes Acorda Therapeutics competes both for talent and for stockholder investment. Comparable companies are also chosen based on revenues and size of employee population.

Elements of Compensation

Executive Compensation consists of the following elements:

Base Salary: Base salaries for our executives are established taking into account the scope of the executive s responsibilities, the individual s qualifications and experience and the compensation paid by other biotechnology companies for similar positions. Generally, we believe that executive base salaries should be targeted near the median of the range of salaries for executives in similar positions with similar responsibilities and experience at comparable companies.

Base salaries are reviewed annually as part of our performance review process and are adjusted to realign salaries with market levels, with appropriate consideration paid to individual responsibilities, performance and experience. For 2007 salaries, this review occurred in the fourth quarter of 2006, with new salaries taking effect on January 1, 2007.

During this review of base salaries for executives, the compensation committee primarily considers:

- market data gathered both internally and by the compensation committee s outside consultant;
- internal review of each executive s compensation, both individually and relative to other officers; and
- individual performance of the executive.

Cash Bonus Program: In addition to base salaries, we believe that performance-based cash bonuses play an important role in providing incentives to our executives to achieve defined annual goals. In the first quarter of the year, the board of directors works collaboratively with management in developing a detailed set of overall corporate performance goals tied to that year s operating plan. These goals, as well as individual executive goals, are weighed in developing a program that can be utilized to measure performance at year-end.

At the end of each year, the board of directors, upon recommendation of the compensation committee, determines the level of achievement for each corporate goal and awards an overall grade for the achievement of corporate goals. Final determination of bonus levels are then based on the achievement of these corporate goals and an assessment of the Company s overall success and an

assessment of each individual s performance. Actual bonus target amounts are near the median for target bonus amounts for comparable companies, based both on our internal research and the information provided by the compensation committee s outside consultant. Based on the overall grade granted by the board of directors and the individual performance levels of each executive, bonuses may be above or below target bonus levels, at the discretion of the board of directors. Actual bonuses are paid to the executives in the first quarter of the following year.

In December 2006, the compensation committee and the board of directors determined that corporate performance in 2006 merited an A overall grade (on a scale of A to C, where A meant that we achieved our corporate goals for the year). Based on target levels approved by the board of directors earlier in the year, this grade resulted in cash bonuses for executive officers in an amount ranging from 42.3% to 60.8% of their base salaries. The individual cash bonuses were 60.8% of the 2006 salary paid to the president and chief executive officer, 50.8% of the 2006 salary paid to the chief scientific officer, 46.6% of the 2006 salary paid to the chief financial officer, 44.9% of the 2006 salary paid to the chief operating officer and 42.3% of the 2006 salary paid to the executive vice president and general counsel.

The compensation committee s outside consultant, Arnosti Consulting, Inc. will be conducting a competitive analysis to provide information for setting the bonus targets that will be established for 2007 year-end awards.

Equity Awards: We believe that providing a significant portion of our executives total compensation package in stock options and other equity awards aligns the incentives of our executives with the interests of our stockholders and with our long-term success. The compensation committee and the board of directors develop their equity award determinations based on their judgments as to whether the complete compensation packages provided to our executives, including prior equity awards, are sufficient to retain, motivate and adequately award the executives. This judgment is based on benchmarking information provided both by the company and by the compensation committee s outside compensation consultant and also includes a recommendation by the president and chief executive officer for all vice presidents and above, including the executive officers.

We grant equity awards under our 2006 Employee Incentive Plan, as amended, which serves as the successor to the Company s 1999 Employee Stock Option Plan, as amended. This plan was adopted by our Board to permit the grant of stock options, stock appreciation rights, restricted stock, performance shares and other stock-based awards to our directors, officers, employees, independent contractors, agents and consultants.

For the year ended December 31, 2006, on the recommendation of the compensation committee, and following discussion by the full board of directors, the board of directors issued to Ron Cohen, our president and chief executive officer, options to purchase 106,094 shares of our common stock with an exercise price at the closing price of our common stock on the Nasdaq Global Exchange on December 21, 2006, the grant date. In addition, on the recommendation of the compensation committee, and following discussion by the full board of directors, the board of directors issued to the chief scientific officer, chief operating officer, chief financial officer and the executive vice president and general counsel, options to purchase 77,340, 67,010, 63,183 and 63,183 shares of our stock, respectively. All options were granted with an exercise price of the closing price of our common stock on the Nasdaq Global Exchange on February 14, 2007, the grant date. See Compensation Discussion and Analysis Summary Compensation Table for more information.

The Compensation Committee has not yet considered whether to recommend a grant of additional equity awards to our executives in 2007.

Employment Agreements and Change of Control Agreements

We have entered into employment agreements with our executive officers, the terms of which are summarized below.

We are a party to an employment agreement with Dr. Cohen that governs the terms and conditions of his employment as our President and Chief Executive Officer. The employment agreement originally provided for a base annual salary of $280,000, subject to annual increases and bonuses at the discretion of the board of directors. Dr. Cohen s current base salary, as approved by the board of directors, is $440,000. Dr. Cohen is eligible to receive annual performance-based stock options to purchase common stock in an amount recommended by the compensation committee and approved by the board of directors based on Dr. Cohen s individual performance and the achievement of our goals and objectives.

Dr. Cohen s employment agreement would have expired in January 2004, but is subject to automatic successive one-year renewal periods unless either Dr. Cohen or we give the other written notice at least 60 days prior to the expiration date that Dr. Cohen or we do not intend to renew the contract. Dr. Cohen s employment agreement has been renewed effective January 2007 for a one-year period.

We are party to an employment agreement with Dr. Blight that governs the terms and conditions of his employment as our Chief Scientific Officer. The employment agreement originally provided for a base annual salary of $215,000, subject to annual review by Dr. Cohen and by the compensation committee of the Board of Directors. His current base salary, as approved by the board of directors, is $275,100.

We are party to an employment agreement with Ms. Fisher that governs the terms and conditions of her employment as our Chief Operating Officer. The employment agreement originally provided for a base annual salary of $225,000, subject to annual review by Dr. Cohen and by the compensation committee of the Board of Directors. Her current base salary, as approved by the board of directors, is $290,200.

We are party to an employment agreement with Mr. Lawrence that governs the terms and conditions of his employment as our Chief Financial Officer. The employment agreement originally provided for a base annual salary of $180,000, subject to annual review by Dr. Cohen and by the compensation committee of the Board of Directors. His current base salary, as approved by the board of directors, is $235,600.

We are party to an employment agreement with Ms. Wasman that governs the terms and conditions of her employment as our Executive Vice President, General Counsel and Corporate Secretary. The employment agreement originally provided for a base annual salary of $225,000, subject to annual review by Dr. Cohen and by the compensation committee of the Board of Directors. Her current base salary, as approved by the board of directors, is $270,000.

Pursuant to their employment agreements, Dr. Blight, Ms. Fisher, Mr. Lawrence and Ms. Wasman are eligible to receive an annual bonus and to receive annual performance-based stock options to purchase common stock, stock appreciation rights awards and/or restricted stock awards of common stock in an amount to be recommended by the compensation committee and approved by the board of directors based on their respective performances and upon the achievement of our goals and objectives. Each of their employment agreements expires on December 19, 2007 but shall be automatically renewed for successive one year terms unless either we or they provide written notice of non-renewal at least 60 days prior to the expiration of the then-current term.

Executive Officer Severance Plans

In the event we terminate the agreement with Dr. Cohen without cause, or if Dr. Cohen voluntarily terminates the agreement with good reason, we are obligated to make severance payments equal to 15 months base annual salary and COBRA premium payments for the severance period plus a bonus equal to his prior year s bonus pro rated for the number of days worked prior to termination. This amount would be paid in a lump sum within 30 days after such termination. In such event, all of Dr. Cohen s options will become immediately exercisable and will remain exercisable for 48 months following termination.

If Dr. Cohen s employment terminates for death or disability, we are obligated to pay his base salary for three months and COBRA premiums for the COBRA coverage period and 65% of his outstanding options will become immediately vested and remain exercisable for 48 months following such termination.

If Dr. Cohen voluntarily terminates his employment without good reason following a change in control, we are obligated to make severance payments equal to 12 months base annual salary and COBRA premium payments for the severance period and he is entitled to receive the same severance and bonus package described above, however, only 65% of his outstanding options will become immediately vested and remain exercisable for 48 months following termination. Following his termination of employment, Dr. Cohen will remain subject to confidentiality, non-competition and non-solicitation covenants for one year in the case of non-competition and non-solicitation and five years in the case of confidentiality.

In the event we terminate our employment agreement with Dr. Blight, Ms. Fisher, Mr. Lawrence or Ms. Wasman without cause, or if one of them voluntarily terminates his or her agreements with good reason, we are obligated to make severance payments equal to nine months base annual salary, in the case of Dr. Blight and Ms. Fisher, and seven months base annual salary, in the case of Mr. Lawrence and Ms. Wasman, as well as COBRA premium payments for the severance period. In such event, all options, stock appreciation rights awards and restricted stock awards that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination.

If Dr. Blight, Ms. Fisher, Mr. Lawrence or Ms. Wasman voluntarily terminates his or her employment with good reason or if we terminate his or her employment without cause within 18 months after a change in control, we are obligated to make severance payments equal to one year s base annual salary, in the case of Dr. Blight and Ms. Fisher, and nine months base annual salary, in the case of Mr. Lawrence and Ms. Wasman, in each case paid in a lump sum within 30 days after termination, as well as COBRA premium payments for the severance period plus a bonus equal to a prior year s bonus pro rated for the number of days worked prior to termination. We are also obligated to pay salary earned but not paid, vacation and sick leave days that have accrued, and reimbursable business expenses incurred through the date of termination. In such event, not less than 50% of the unvested options, stock appreciation rights and restricted or other stock awards shall become immediately and full vested and shall remain exercisable for 18 months following such date. All options that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination.

Other Compensation: All of our executives are eligible to participate in our health and welfare benefit plans. These plans are available to all employees and do not discriminate in favor of executive officers. It is generally our policy to not extend significant perquisites to our executives that are not available to all of our employees. We have no current plans to make changes to levels of benefits and perquisites provided to executives.

Tax and Accounting Considerations

We have structured our compensation program to comply with Section 409A of the Internal Revenue Code of 1986, as amended, or Section 409A. If an executive is entitled to nonqualified deferred compensation benefits that are subject to Section 409A, and such benefits do not comply with Section 409A, then the benefits are taxable in the first year they are not subject to a substantial risk of forfeiture. In such case, the executive is subject to regular federal income tax, interest and an additional federal income tax of 20% of the benefit includible in income.

The following table sets forth information regarding compensation earned in 2006 by our president & chief executive officer, chief operating officer, chief financial officer, chief scientific officer and executive vice president & general counsel, who are the five most highly compensated executives. (These individuals are collectively referred to as our named executive officers).

2006 Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Changes in Pension Value and NQDC Earnings ($)	All other Compensation ($)	Total ($)
Ron Cohen, M.D. President and Chief Executive Officer	2006	$ 370,000	$ 225,000	(2) $ 634,254	$ 181,968	(3) $	$	$	$ 1,411,222
Andrew R. Blight, Ph.D. Chief Scientific Officer	2006	236,000	120,000	(2) 237,213	35,829	(4)			629,042
Mary Fisher Chief Operating Officer	2006	265,000	119,000	(2) 382,988	317,254	(5)			1,084,242
Jane Wasman, J.D. Executive VP & General Counsel	2006	248,000	105,000	(2) 189,057	118,449	(6)			660,506
David Lawrence M.B.A Chief Financial Officer	2006	204,000	95,000	(2) 156,456	173,268	(6)			628,724

(1) The method and assumptions used to calculate the value of the awards and options granted to our named executive officers are discussed in note 2 to our financial statements.

(2) 2006 bonus paid in 2007

(3) Includes 2006 performance award granted in December 2006

(4) Excludes 2006 performance award granted in February 2007 (77,340 shares with a grant date fair value of $14.98)

(5) Excludes 2006 performance award granted in February 2007 (67,010 shares with a grant date fair value of $14.98)

(6) Excludes 2006 performance award granted in February 2007 (63,183 shares with a grant date fair value of $14.98)

The following table sets forth information regarding plan-based awards to our named executive officers in 2006.

2006 Grants of Plan-Based Awards Table

Name and Principal Position	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Closing Market Price of Option Awards ($/Sh)	Grant Date Fair Value ($)
		Threshold ($)	Target ($)	Maximum ($)	Threshol (#)	Target (#)	Maximum (#)					
Ron Cohen, M.D.	9/25/2006	$	$	$				500	$8.50	$8.50	$2,730	
President and Chief Executive Officer	12/21/2006 (1)							106,094	$15.49	$15.49	$1,023,807	
Andrew R. Blight, Ph.D.	9/25/2006							500	$8.50	$8.50	$2,730	
Chief Scientific Officer	2/14/2007 (2)							77,340	$22.13	$22.13	$1,158,553	
Mary Fisher	9/25/2006							500	$8.50	$8.50	$2,730	
Chief Operating Officer	2/14/2007 (2)							67,010	$22.13	$22.13	$1,003,810	
Jane Wasman, J.D.	9/25/2006							500	$8.50	$8.50	$2,730	
Executive VP & General Counsel	2/14/2007 (2)							63,183	$22.13	$22.13	$946,481	
David Lawrence M.B.A	9/25/2006							500	$8.50	$8.50	$2,730	
Chief Financial Officer	2/14/2007 (2)							63,183	$22.13	$22.13	$946,481	

(1) 2006 performance award granted in December 2006

(2) 2006 performance award granted in February 2007

The following table provides information regarding each unexercised stock option held by each of our named executive officers as of December 31, 2006.

Outstanding Equity Awards at December 31, 2006

	Option Awards					Stock Awards				
Name and Principal Position		Number of Securities Underlying Unexercised Options (# Exercisable)	Number of Securities Underlying Unexercised Options (# Unexercisable)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date		Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (#)
Ron Cohen, M.D.		38,728			$ 2.60	1/1/2011	(2)	260,384	$ 4,124,483		
President and Chief		6,410			$ 2.60	12/31/2011					
Executive Officer		569,307			$ 2.60	9/5/2013					
		38,461			$ 2.60	10/17/2013					
	(1)	22,429	28,836		$ 8.14	1/1/2015					
	(1)	2,403	10,413		$ 6.00	2/15/2016					
	(1)	15,935	69,065		$ 5.85	3/17/2016					
	(1)	31	469		$ 8.50	9/25/2016					
	(1)		106,094		$ 15.49	12/21/2016					
Andrew R. Blight, Ph.D.		6,410			$ 2.60	8/1/2008	(3)	30,433	$ 482,059		
Chief Scientific Officer		2,564			$ 2.60	1/1/2011					
		1,923			$ 2.60	12/31/2011					
		78,777			$ 2.60	9/5/2013					
	(1)	22,898	29,440		$ 8.14	1/1/2015					
	(1)	2,454	10,631		$ 6.00	2/15/2016					
	(1)	6,093	26,407		$ 5.85	3/17/2016					
	(1)	31	469		$ 8.50	9/25/2016					
Mary Fisher		2,564			$ 2.60	6/1/2010	(3)	49,135	$ 778,298		
Chief Operating Officer		1,602			$ 2.60	1/1/2011					