

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended December 31, 2008

OR

**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**

(State or other jurisdiction of incorporation  
or organization)

**13-3831168**

(I.R.S. Employer identification number)

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

(Address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock \$0.001 par value	The NASDAQ Stock Market LLC

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

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

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  No

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  No

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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(Do not check if a smaller reporting company)

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

As of June 30, 2008, the aggregate market value of the Registrant's voting stock held by non-affiliates was \$538,607,470. 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, 2008 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 13, 2009, the registrant had 37,774,711 shares of common stock, par value \$0.001 per share, outstanding. The registrant does not have any non-voting stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2008. Portions of the proxy statement are incorporated herein by reference into the following parts of the Form 10-K:

Part III, Item 10, Directors, Executive Officers and Corporate Governance  
Part III, Item 11, Executive Compensation;  
Part III, Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters;  
Part III, Item 13, Certain Relationships and Related Transactions, and Director Independence;  
Part III, Item 14, Principal Accounting Fees and Services.



**ACORDA THERAPEUTICS, INC.**  
**2008 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" 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**

We are a commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis, or MS, spinal cord injury, or SCI, and other disorders of the central nervous system, or CNS. Our marketed product, Zanaflex Capsules, is approved by the U.S. Food and Drug Administration (FDA) for the management of spasticity. Our lead product candidate, Fampridine-SR, has completed two positive Phase 3 clinical trials for the improvement of walking ability in patients with MS and we submitted a New Drug Application (NDA) to the FDA at the end of January 2009 seeking approval to market it. We have discussed Fampridine-SR with national regulatory authorities in four European Union member states and believe that the current data are sufficient to file a centralized Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). Our preclinical programs target other aspects of MS, as well as SCI and other CNS disorders, and may also have application for other indications, such as stroke or congestive heart failure. We expect to file an Investigational New Drug (IND) application for Glial Growth Factor 2 (GGF2), the lead product candidate of our neuregulins program, for congestive heart failure in late 2009, pending the successful completion of toxicological and other work.

Approximately 400,000 people in the United States suffer from MS, and it is estimated that 64%-85% of those people experience walking disability. In Europe, approximately 600,000 people suffer from MS, and an additional 55,000-75,000 people in Canada are also diagnosed with this disease.

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

## Company Highlights

- Our lead product candidate, Fampridine-SR, completed a second positive Phase 3 clinical trial for improvement of walking ability in people with MS in June 2008 under a Special Protocol Assessment (SPA) from the FDA. An SPA is a process through which the sponsor of a trial seeks written agreement with the FDA regarding the design, size, and conduct of a Phase 3 clinical trial whose data will form the primary basis for an efficacy claim. In this trial, MS-F204, statistical significance was achieved on the primary outcome measure defined in the SPA. A significantly greater proportion of people taking Fampridine-SR had a consistent improvement in walking speed, compared to people taking a placebo. In addition, the effect was maintained throughout the eight-week treatment period, and there was a statistically significant improvement among Timed Walk responders compared to Timed Walk non-responders on the 12-Item MS Walking Scale (MSWS-12), a patient-reported self-rated assessment of walking disability. These clinical trial results were consistent with the results of our first Phase 3 trial, MS-F203, which we reported in September 2006 and which was also conducted under an SPA. The results of these two clinical trials formed the basis of our NDA filing in January 2009. A Thorough QT cardiac study was initiated in September 2007 and favorable results from that study were released in January 2008. This study evaluated the potential for the product candidate to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and supratherapeutic doses, was found to be no different than placebo. 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. We expect to promptly launch and commercialize Fampridine-SR ourselves in the U.S., if it is approved, and are in discussions with potential marketing partners regarding the commercialization of Fampridine-SR in the European Union and other non-U.S. markets. At the same time, we are preparing for the filing of a centralized MAA with the EMEA. We plan to maintain our flexibility in the timing of such a filing in order to optimize our ex-U.S. commercialization pathway and availability to patients.
- Sales of Zanaflex Capsules, which we launched in April 2005, and Zanaflex tablets increased from \$43.6 million for the year ended December 31, 2007 to \$53.4 million for the year ended December 31, 2008. Our Zanaflex Capsules and tablets commercial operations were cash flow positive in 2008. We acquired all marketing, sales and distribution rights in the United States to Zanaflex Capsules and Zanaflex tablets in 2004, based on the strategic fit of these products 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 drugs used to treat 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.
- As of February 13, 2009, our internal, field-based specialty sales force consisted of 61 sales professionals who call on neurologists, other specialists, and primary care physicians who treat patients with conditions that involve spasticity. We have a separate internal, field-based team responsible for payer strategy, as well as contracting and account management of managed care organizations, pharmacy benefit managers, specialty pharmacies, wholesale

drug distribution customers, the Veterans Affairs institutions and the Department of Defense. We also engage a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care physicians, specialty physicians and pharmacists. We believe that our sales and marketing infrastructure enables us to efficiently reach virtually all high-volume prescribers of Zanaflex tablets and generic tizanidine. We believe that many of these prescribers would also be potential high-volume prescribers for our lead product candidate, Fampridine-SR, if it is approved. We expect to approximately double the size of our existing sales force in anticipation of the potential launch of 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 may have applicability beyond the nervous system, including in such fields as cardiology, oncology, orthopedics and ophthalmology. In 2008, we began to work with a contract manufacturer to develop larger scale manufacturing and purification processes for one of the neuregulins, GGF2, under good manufacturing practices (cGMP) in preparation for a potential future IND application to support human clinical trials. We expect to file such an IND in late 2009, pending the successful completion of additional animal toxicology and other preclinical activities. We have also begun work with a contract manufacturer to scale up manufacturing of one of the remyelinating antibodies under cGMPs in preparation for a future IND application.

## **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 by the body. 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 may also 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 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 (NSCISC), approximately 253,000 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 40; life expectancies for persons with SCI continue to increase, but are still below life expectancies for those with no spinal cord injury. NSCISC estimates that the average lifetime costs directly attributable to SCI for an individual injured at age 25 varies from approximately \$650,000 to \$2.9 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:

- *Obtain regulatory approval for Fampridine-SR in MS in the U.S, the European Union and other key non-U.S. markets.* One of our key objectives is to obtain regulatory approval of Fampridine-SR for commercial sale in the U.S. and to seek such approval in other key markets as well. In January 2009, we filed an NDA with the FDA for Fampridine-SR for the improvement of walking ability in people with MS. In 2008, we met with national regulatory authorities in four European Union member states to discuss Fampridine-SR. As a result, we believe that the current data are sufficient to file a centralized MAA with the EMEA. We also believe we can file a New Drug Submission (NDS) with Health Canada with our existing clinical trial data.
- *Leverage the commercial presence of Zanaflex Capsules and our sales and marketing organization for the potential launch of Fampridine-SR in the U.S.* 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 Zanaflex Capsules and Fampridine-SR are likely to overlap substantially. We expect to promptly launch and commercialize Fampridine-SR ourselves in the U.S., if it is approved, and to approximately double the size of our existing sales force in anticipation of that potential launch. 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. We will also continue to focus on maximizing our revenue from Zanaflex Capsules.
- *Increase awareness of and help educate health care professionals and consumers about mobility and walking impairment issues for people with MS.* Through our increased commitment to educational programs focused on MS, and our relationships with MS physician and consumer communities, we have been working to increase awareness of MS-related mobility and walking impairment and the impact on the individuals living with MS and their families and caregivers, and to increase the dialogue between physicians and patients regarding this impairment. For example, we have provided educational materials to physicians at major neurological conferences. Our consumer-focused activities have included our sponsorship of the National Multiple Sclerosis Society Walk MS programs and a

published survey of patients and caregivers to assess the impact of walking disability on daily life.

- *Advance our pipeline of preclinical programs into clinical trials.* We have increased our investment in our preclinical programs, with one such 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. We have begun development of cGMP manufacturing processes for two of our preclinical programs, GGF2 (neuregulins) and recombinant human IgM22 (rHlgM22, a remyelinating antibody). Based on the promising animal data to date and pending the successful completion of additional animal toxicology and other preclinical activities, we expect to file an IND for GGF2 in congestive heart failure in late 2009.
- *Pursue marketing strategy for European Union and other markets.* We are in discussions with potential marketing partners regarding the commercialization of Fampridine-SR in the European Union and other non-U.S. markets. At the same time, we are preparing for the filing of a centralized MAA with the EMEA. We plan to maintain our flexibility in the timing of such a filing in order to optimize our ex-U.S. commercialization pathway and availability to patients.

## Our Product Pipeline

<u>Name</u>	<u>Status</u>	<u>Marketing Rights</u>
Zanaflex Capsules . . . . .	FDA-approved	U.S.
Zanaflex (tablets) . . . . .	FDA-approved	U.S.
Fampridine-SR . . . . .	NDA submitted	Worldwide
Neuregulin Program . . . . .	Preclinical	Worldwide
Remyelinating Antibodies 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 Pharmaceuticals, Inc.'s (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. Most prescriptions for tizanidine tablets are written as "Zanaflex," although the majority 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. Demand for the 4 mg Zanaflex tablet is also declining, but currently 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.

As sales have increased, we have seen an increase in the number of third-party payers who have implemented restrictions on the coverage of Zanaflex Capsules. These restrictions have included the implementation of prior authorization reviews or removal from formulary.

In 2008, retail sales of Zanaflex Capsules, Zanaflex tablets and generic equivalents of Zanaflex tablets totaled approximately \$315 million. For the same period, retail sales of baclofen totaled approximately \$178 million, for an approximate aggregate market of \$493 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 to 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 telesales team, is able to reach virtually all of these high-volume prescribers.

#### *Sales and promotional support for Zanaflex Capsules*

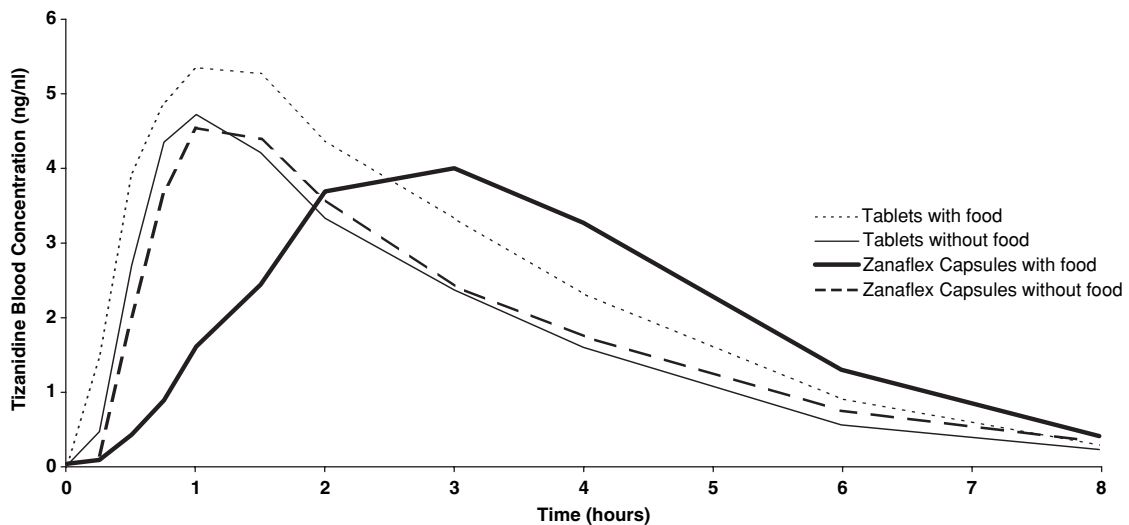
To support our commercialization of Zanaflex Capsules, we have established a sales and marketing infrastructure consisting of our internal specialty sales force and a pharmaceutical telesales group. As of February 13, 2009, our internal, field-based specialty sales force consisted of 61 sales professionals 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. We have a separate internal, field-based team responsible for payer strategy, as well as contracting and account management of managed care organizations, pharmacy benefit managers, specialty pharmacies, wholesale drug distribution customers, the Veterans Affairs institutions and the Department of Defense. 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 also would be potential high-volume prescribers for our lead product candidate, Fampridine-SR, if approved. Zanaflex Capsules and tablets commercial operations were cash flow positive in 2008 and are expected to be cash flow positive in 2009, with Zanaflex Capsules revenue expected to grow modestly during this period.

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 series of studies. The largest study was 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 plasma levels and a lower peak concentration. (Plasma is the fluid portion of blood without red and white blood cells and other proteins normally found in blood.) 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 Plasma Concentration Over Time**



*Average plasma concentrations of tizanidine in subjects following a single dose of two 4 mg Zanaflex tablets or two 4 mg Zanaflex Capsules, taken either with or without food.*

As a result of the difference in absorption rate and plasma level when taken with food, the FDA determined that neither Zanaflex tablets nor generic tizanidine tablets are therapeutically equivalent, or AB-rated, to Zanaflex Capsules. Therefore, under most 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 produces lower peak and more sustained blood levels than 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 (NARCOMS), approximately 85% of people with MS experience some degree of walking impairment. This is considered one of the most limiting aspects of the disease. This figure includes individuals who report minimal walking disabilities through those who are no longer able to walk at all. Further research will be needed to identify the population of people with MS who are still able to walk but report regular problems with walking.
- Market research has shown that, while there is a high incidence of walking impairment in MS patients, the diagnosis and treatment of such a condition by healthcare professionals goes largely unaddressed. This is due in part to the lack of drugs to improve walking ability in

people with MS and the limited or short-lived effectiveness of other interventions, such as physical therapy.

- Our Phase 3 clinical trials of Fampridine-SR in MS patients have consistently shown improvement in walking ability.
- Based on its novel mechanism of action, Fampridine SR, if approved, could enhance the current standard of MS drug therapy that includes only disease modifying agents and therapies for symptom management.

#### *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 1,600 people have been treated with Fampridine-SR in over 32 clinical trials.

In September 2006, we announced positive results from MS-F203, our first Phase 3 clinical trial of Fampridine-SR for the improvement of walking in patients with MS, which was performed under an 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. In May 2007, we reached agreement with the FDA in a second SPA for the second Phase 3 trial of Fampridine-SR in MS, MS-F204. Under the SPA, a single efficacy criterion was required, to replicate the primary result of the first Phase 3 study in showing a significantly greater proportion of patients treated with Fampridine-SR experienced a consistent improvement in walking speed, compared to those treated with placebo. We completed this trial in June 2008 and the data met the primary endpoint, as defined in the SPA. Although the FDA did not require that this trial also demonstrate maintenance of effect over the treatment period, nor that there be a statistically significant improvement in the MSWS-12 for Timed Walk responders versus Timed Walk non-responders, subsequent analysis of the MS-F204 data showed that both these additional outcomes were consistent with the earlier study. Pending review of the clinical results, the FDA has agreed that this trial, together with our first Phase 3 trial, MS-F203, would be adequate to provide evidence of efficacy for an NDA for Fampridine-SR.

Consistent with the FDA's recently established standard requirements for all new compounds, a Thorough QT cardiac study was initiated in September 2007 and favorable results from that study were released in January 2008. This study evaluated the potential to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and supratherapeutic doses, was found to be no different than placebo.

#### *Completed Phase 3 Trials in Multiple Sclerosis*

*MS-F203.* Results of our first MS Phase 3 clinical trial, MS-F203, were published in the February 28-March 6, 2009 edition of the medical journal, *The Lancet*. The trial 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 12 Item MS Walking Scale (MSWS-12) questionnaire. The MSWS-12 is a subjective measure of the degree to which walking disability impacts walking-related 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 Timed Walk responders compared to Timed Walk non-responders in the MSWS-12.

Trial results were analyzed using our proprietary responder analysis that was accepted by the FDA in our SPA and for which we have applied for a patent. A subject was deemed to be a Timed Walk 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 Timed Walk responders in the Fampridine-SR group to the percentage of Timed Walk responders in the placebo group. To validate the clinical importance of improvements in the timed walk measurements, the MSWS-12 scores of the Timed Walk responders were compared against those of Timed Walk non-responders. This analysis was designed to ensure that being deemed a Timed Walk 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 Timed Walk 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.

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.

*MS-F204.* Our second Phase 3 clinical trial (MS-F204) was initiated in March 2007, pursuant to a separate SPA from the FDA. This was a double-blind trial for which we enrolled a total of 240 patients at 39 MS clinical centers in the United States and Canada. As in the MS-F203 study, subjects completed a Timed 25-Foot Walking Test at each visit during the clinical trial, which included a 9-week treatment period. Subjects were also asked to fill out the MSWS-12 questionnaire.

Statistical significance was achieved on the single primary efficacy criteria defined in the SPA. A significantly greater proportion of people taking Fampridine-SR had a consistent improvement in walking speed, compared to people taking a placebo, using the same Timed Walk responder criterion employed in study MS-F203.

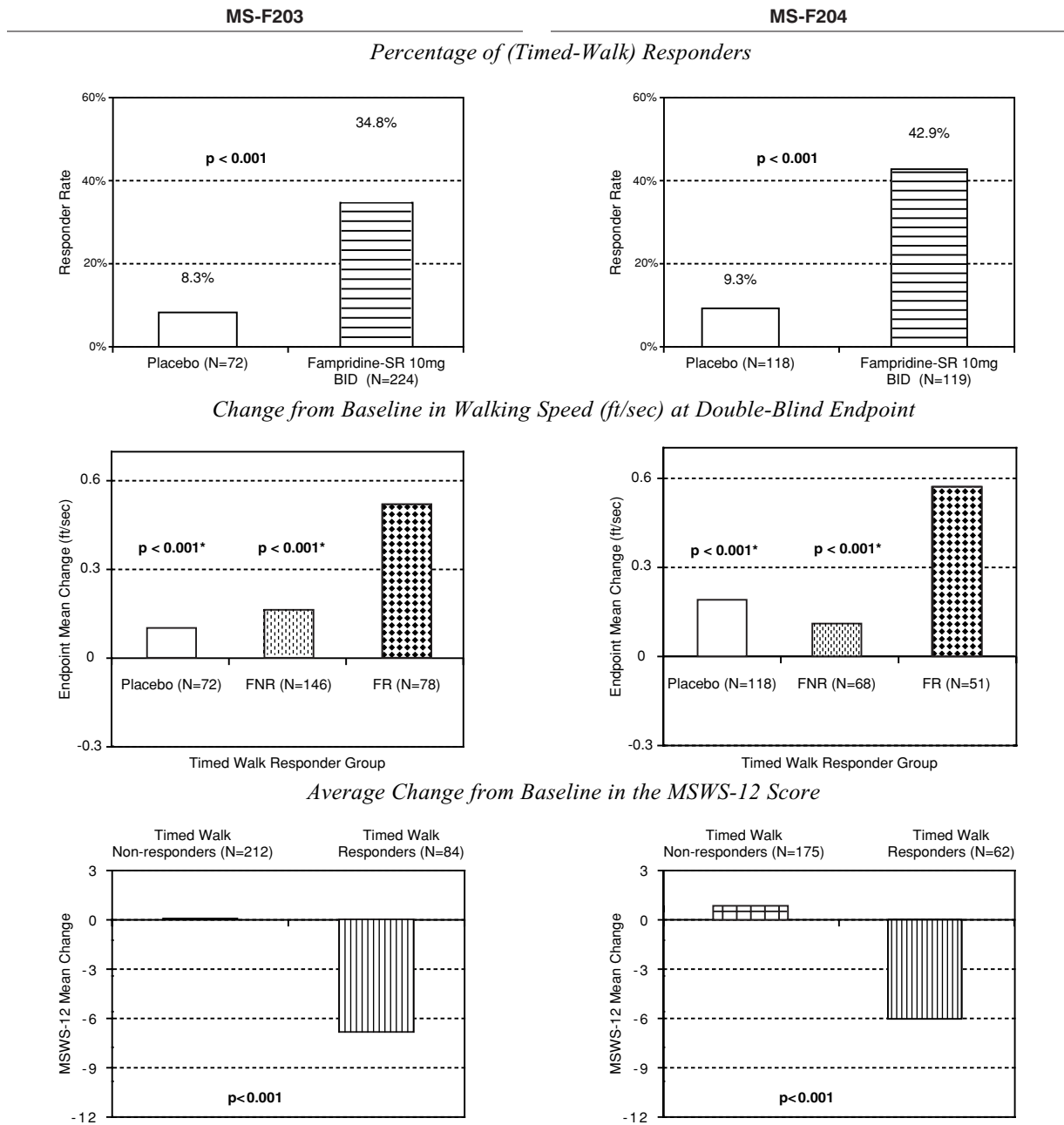
The only pre-defined secondary outcome in this trial was lower extremity muscle strength, as assessed by the LEMMT. Other measures were included in the study, without planned analysis, to

allow comparison of overall trends between the two Phase 3 studies. These included the MSWS-12, the subject global impression and clinician global impression, and the Ashworth score for spasticity.

Figure 2, below, summarizes the results of the MS-F203 and MS-F204 studies for the three criteria defined in the SPA for MS-F203. For both studies, statistical significance was achieved on all three efficacy criteria defined in the SPA for MS-F203, although only the increased response rate was required in the SPA for MS-F204. A significantly greater proportion of people taking Fampridine-SR had a consistent improvement in walking speed measured by the Timed 25-Foot Walk compared to people taking placebo (*MS-F203*: 34.8% vs. 8.3%; *MS-F204*: 42.9% vs. 9.3%) ( $p < 0.001$  for each study. A p-value is a statistical term that indicates the probability that the observed difference between the treatment groups could have been by chance alone. The smaller the p-value, the lower the likelihood that the observed 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 these studies throughout the efficacy treatment period (14 weeks for MS-F203 and eight weeks for MS-F204;  $p < 0.001$  for each study) and there was a statistically significant reduction in patient self-assessed walking disability as shown in the average change in the MSWS-12 for Timed Walk responders vs. Timed Walk non-responders (*MS-F203*:  $p < 0.001$ ; *MS-F204*:  $p < 0.001$ ).



**Figure 2. Summary Study Results for the SPA Criteria (Intent to Treat Population)**



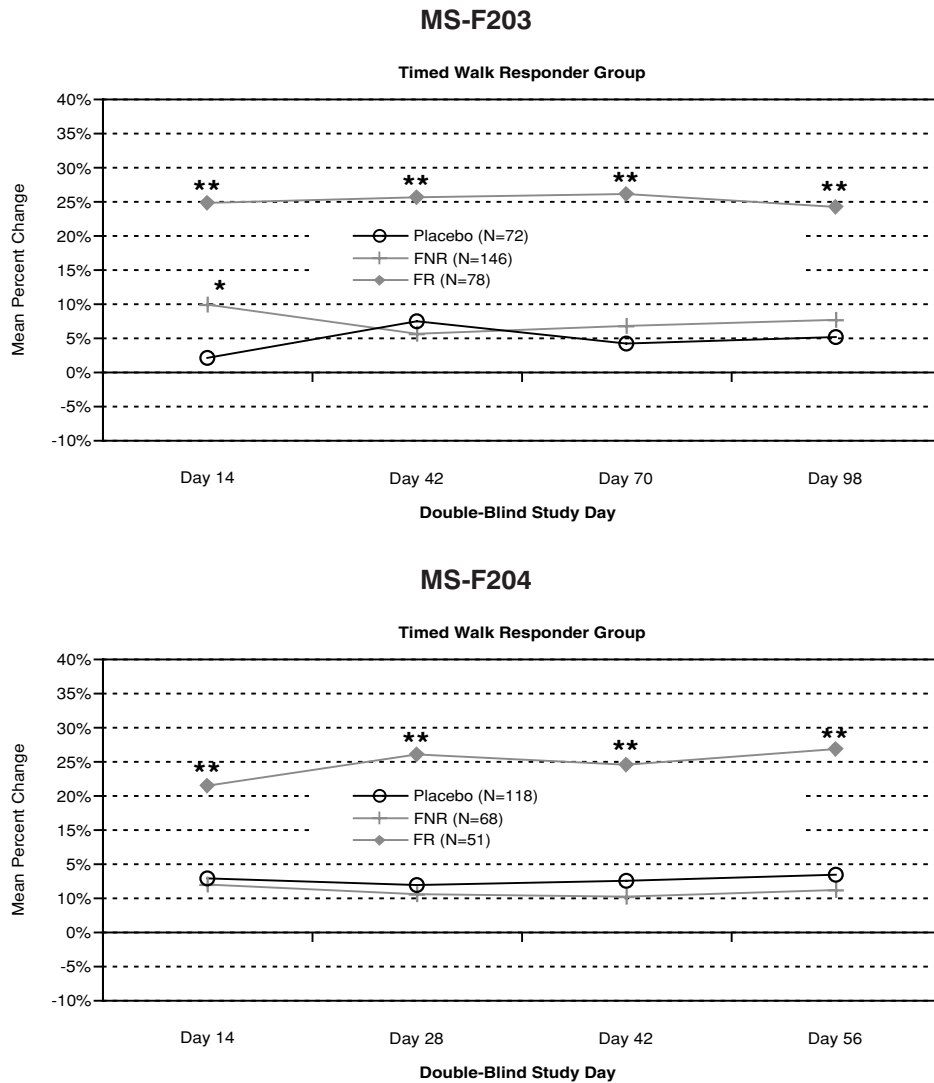
ABBREVIATIONS: FNR=Fampridine-SR Timed Walk Non-responders; FR=Fampridine-SR Timed Walk Responders

\* p-value versus Fampridine-SR Timed Walk Responder group.

## Change in Walking Speed over Time

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

**Figure 3. Percent Changes from Baseline in Walking Speed at each Double-Blind On-Treatment Efficacy Visit (Intent to Treat Population)**



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

Note (Imputed): If a double-blind walking assessment was missing at scheduled time point, then the double-blind average was imputed for the missing value.

\*\* : Significantly better than placebo and Fampridine-SR Timed Walk Non-responders.

\* : Significantly better than placebo only.

Results for the Fampridine-SR Timed Walk non-responders are also illustrated in this figure and show that there was a relatively small, transient improvement in average walking speed at the earliest visit in MS-F203, two weeks after initiation of treatment, though this was not seen in the MS-F 204 study. At later visits, there was no consistent difference between the non-responders and the placebo-treated groups.

*Leg strength.* A statistically significant improvement in leg strength, as measured by the average change from baseline in the LEMMT, was seen in Fampridine-SR Timed Walk responders compared to the placebo treated patients in both studies ( $p < 0.001$  in MS-F203 and  $p = 0.028$  in MS-F204). The Fampridine-SR Timed Walk 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 the MS-F203 study ( $p < 0.046$ ) but not the MS-F204 study. This suggests that improved leg strength may contribute to walking speed improvement in some patients, but, based on data from individual patients, does not account for the improvement in walking ability among Timed Walk responders as compared to Timed Walk 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.

*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 walking-related 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 35-43% 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 Timed Walk responders was approximately 25%. Consistent with previous data on the clinical impact of changes in the Timed Walk, our trials showed that Timed Walk responders as a group reported significantly greater improvement in their self-assessed walking disability, as measured by the MSWS-12. 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 Timed Walk responders were distributed across the full range of baseline disability, defined by our inclusion criterion 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. Response to Fampridine-SR also appears to be independent of gender, age, type or duration of MS, or concomitant treatment with other drugs.

#### *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*

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 clinic 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. Under guidelines produced by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, also known as the ICH Guidelines, it is usually expected that for consideration for drug approval at least 1,500 people will have been exposed to the drug, at least 300 for six months and at least 100 people for one year. Overall, Fampridine-SR has been taken by more than 1,600 subjects in our clinical studies. As of December 31, 2008, our extension studies in people with MS have included treatment of approximately 601 people for more than six months and 482 people treated for more than one year. Therefore we believe we have sufficient drug exposure to exceed the ICH Guidelines.

As of December 31, 2008, 177 subjects from MS-F202 had been enrolled in an extension trial and 92, or approximately 52%, remained active in the trial, with duration of treatment ranging over four years. As of the same date, 269 patients from MS-F203 had been enrolled in an extension

study and 186 of these, or approximately 69%, remained active, with duration of treatment ranging over three years. Also, as of this same date, 214 patients from MS-F204 had been enrolled in a third extension study and 185, or approximately 86%, remained active, with a duration of treatment ranging up to 17 months. The total exposure to Fampridine-SR in our MS studies to that date, including both double-blind and open label studies, is over 1400 patient-years. By contrast, in our controlled trials we have collected safety data on placebo treatment that totals to approximately 54 patient-years.

The adverse events most commonly experienced in the MS-F203 and MS-F 204 studies were urinary tract infection, falls, insomnia, dizziness, headache, nausea, asthenia (weakness), upper respiratory track infection, back pain, balance disorder and fatigue. The majority of these events were mild to moderate in intensity. Among these types of event, only insomnia, dizziness, headache, nausea, back pain and balance disorder were seen at more than double the frequency in the Fampridine-SR-treated than the placebo-treated patients in our controlled trials.

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. 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. The incidence of seizures appears to be dose-related. Overall, the incidence of seizures at the current dose of 10 mg twice a day has been within the rates reported for placebo-treated groups in long-term, controlled studies of interferon drugs in MS patients. These rates have ranged up to 2% of patients in a two year study, or 1 seizure per 100 patient years. Incidence of seizures has been reported to be higher in actively treated groups in studies of interferon drugs, ranging up to 5% over a two year study or 2.5 seizures per 100 patient years. The proportion of patients treated with beta interferons in our studies of Fampridine-SR has been in the range of 40-45%.

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, which was not the case for studies of interferon drugs. We have therefore also compared the incidence of seizure events in the open label extension studies with the expected incidence rates for a first seizure in the MS population, based on the epidemiological literature, and find these rates to be comparable for the 10 mg twice a day dose of Fampridine-SR. With our current knowledge, there are no means of determining in advance which individual patient may face an increased seizure risk when taking Fampridine-SR

Depending on dose, 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. A Thorough QT cardiac study was initiated in September 2007 and favorable results from that study were released in January 2008. This study evaluated the potential to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and suprathreshold doses, was found to be no different than placebo. In addition 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.

## **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, neuregulins/GGF2 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/GGF2*

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 GGF2, 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, including 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 animal models of stroke. Therefore, the neuregulins offer us the potential for multiple CNS and cardiac indications, including MS, stroke and congestive heart failure as well as protection from chemotherapy-induced damage. In 2008, we began to work with a contract manufacturer to develop production and purification methods for manufacturing GGF2 under cGMP in preparation for a potential future IND application to support human clinical trials. We anticipate filing an IND in late 2009, subject to the results of ongoing toxicological studies and other preclinical activities.

#### *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 Clinic 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. In May 2006, Mayo Clinic and the FDA had a pre-IND meeting to discuss the details of a preclinical development program. We have been working with a contract manufacturer to produce rHIgM22, one of these antibodies, under cGMP, and had previously anticipated filing an IND in late 2009, but this activity has been delayed due to the manufacturer's filing for bankruptcy in 2008.

### ***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 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, field-based specialty sales force and an external telesales group.

- *Internal, Field-Based 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. Our sales professionals have had an average of approximately 14 years of sales experience prior to joining us. Our specialty sales force of 61 sales professionals calls on neurologists, other specialists, and primary care prescribers treating patients with conditions that involve spasticity, and who are high volume prescribers of tizanidine. We expect to approximately double the size of our sales force in anticipation of the potential launch of Fampridine-SR, if approved.

- *Internal Managed Care Team.* We employ an internal and field-based team responsible for payer strategy, as well as contracting and account management of managed care organizations, pharmacy benefit managers, specialty pharmacies, wholesale drug distribution customers, the Veterans Affairs institutions and the Department of Defense.
- *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 scientific 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.

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, 2008, Cardinal Health, McKesson Corporation and AmerisourceBergen Corporation accounted for approximately 46.4%, 33.7% and 14.7% of our shipments, respectively.

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 promptly launch and market Fampridine-SR ourselves in the United States and possibly in Canada, if it is approved in both countries. We are currently developing and implementing programs to educate consumers, physicians, and other healthcare professionals about the challenges of walking disability in the MS population. For example, in 2008, Acorda was a national sponsor of the National Multiple Sclerosis Society's Walk MS program. This sponsorship allowed us to engage thousands of people with MS, as well as their families, physicians and caregivers, in a discussion about the impact of walking disability on their lives. We will be a national sponsor once again in 2009 and in 2010.



## **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.

## **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, 2008.

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 obligated us to pay a combination of sales-based milestone payments of up to \$19.5 million, all of which have been achieved and paid, and royalties on sales of Zanaflex Capsules and Zanaflex tablets. We have no further Zanaflex milestone payment obligations with Elan. 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 are in contract negotiations 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 Arrangements.”

## ***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 2003 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 \$850,000 and royalties based on net sales of the product for neurological indications. We have made an aggregate of \$100,000 in payments under this agreement through December 31, 2008. 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, 2008. 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, 2008. 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, or Mayo Clinic, 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, 2008. 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 Clinic. 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, or CeNeS. 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 GGF2 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, 2008. 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, 2008.

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 to 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. (Patheon) 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 to supply us with Zanaflex Capsules. 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, we relied on a single manufacturer, Novartis, for the manufacture of Zanaflex tablets and for the supply of tizanidine, the active pharmaceutical ingredient (API) in

Zanaflex Capsules and Zanaflex tablets. Novartis has discontinued production of tizanidine and will no longer supply tizanidine to Elan for the production of Zanaflex Capsules or to us for the production of Zanaflex tablets. We have recently received FDA approval to use the tizanidine manufactured by a new supplier, Farmak, as the active ingredient in the production of Zanaflex Capsules. However, we are still required to obtain FDA approval for a new supplier of the tizanidine needed for the production of Zanaflex tablets. Elan has agreed to supply us with Novartis-manufactured tizanidine for the manufacture of Zanaflex tablets to satisfy supply requirements through the first quarter of 2010. If we fail to gain FDA approval of a new tizanidine supplier for Zanaflex tablets prior to February 2010, we may experience an interruption in our supply.

We are currently in contract negotiations with Patheon regarding the manufacture of Zanaflex tablets, and Patheon has agreed to manufacture 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.

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 have contracted for testing and manufacturing development activities for GGF2 to be performed by an outside contractor. In March 2008, we signed a Master Services Agreement with CMC ICOS Biologics to develop methods to produce GGF2 under cGMPs.

### **Intellectual Property**

As of February 13, 2009, our intellectual property portfolio included intellectual property rights to over 35 U.S. patents, over 110 foreign patents and over 100 pending patent applications world-wide. There are five major families of subject matter in our patent portfolio: Fampridine-SR, Zanaflex, neuregulins, remyelinating antibodies, and chondroitinase. Our intellectual property also includes confidential and trade secret information as well as a portfolio of trademarks.

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

We have a patent portfolio with multifaceted coverage on fampridine-related subject matter. Overall, our fampridine intellectual property estate includes approximately 18 fampridine and responder analysis-related patent applications. A total of 54 fampridine-related patents are issued and are being maintained world-wide (six in the U.S., 38 in the European Union, and ten in other jurisdictions).

We hold an exclusive, worldwide license from Elan to three U.S. patents, with over 20 corresponding foreign patents and pending applications in a number of foreign countries. These patents and applications relate to timed delivery formulations of a family of aminopyridine compounds, including fampridine, and methods of treatment directed to classes of relevant neurological conditions. One of the three U.S. patents expires in 2011 and the other two U.S. patents expire in 2013.

In addition to those Elan patents, we have two pending U.S. patent applications and corresponding applications in a number of foreign countries covering methods of using aminopyridines, such as Fampridine-SR. If granted, a patent resulting from any of these applications would be expected to expire in 2025.

We hold an exclusive license from Cornell University for an issued U.S. 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 hold an exclusive, worldwide license from the Canadian Spinal Research Association (CSRO) for one U.S. patent and over 20 foreign counterpart patents covering the use of fampridine in the treatment of spasticity and chronic pain in patients with SCI. The U.S. patent expires in 2013.

In February 2008, we acquired certain assets of Neurorecovery, Inc. (NRI). This acquisition enabled us to broaden our intellectual property portfolio on fampridine, and explore additional therapeutic indications for Fampridine-SR, as well as provide access to pre-clinical compounds that may have utility in nervous system disorders. Under the terms of the purchase agreement, we were assigned two key licensing and research agreements relating to the use of aminopyridines in peripheral neuropathies and to two early stage development candidates. We also acquired NRI's pre-clinical and clinical data, regulatory filings (including Orphan Drug designations), copyrights, trademarks and domain names relating to the three products. Two Phase 2 studies of the aminopyridine compound Ampydin® (IR) for the treatment of chronic functional motor and sensory deficits resulting from Guillain-Barre Syndrome (GBS) have been completed. During the past year, we evaluated the technologies acquired from NRI. Based on this evaluation, we identified certain non-aminopyridine technologies and devices that were not sufficiently relevant to our goals or business interests, and have begun the requisite process for returning the intellectual property relating to those technologies to their original licensor, the University of Alabama. We will continue to retain intellectual property that includes an issued U.S. patent and corresponding foreign patents covering the use of mono-aminopyridines, such as fampridine, to treat GBS.

### **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.

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.

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) for patent infringement in relation to the filing of



the ANDA by Apotex. The defendants have answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. We have denied those counterclaims. In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing the Company's request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(4) or 285. The court ruled in our favor and denied Apotex' motion in December 2008. We and Apotex are currently proceeding with discovery in the case. If the FDA approves the ANDA and Apotex is successful in challenging the validity of the patent, Apotex could be permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex tablets.

### ***Neuregulins***

Our neuregulin patent portfolio contains over 20 pending applications, and over 80 Neuregulin-related issued patents.

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 GGF2. Collectively, these patents claim the use of particular neuregulins to treat various pathophysiological conditions, particularly uses to stimulate myelinating cells in order to treat conditions of the central and peripheral nervous system that involve demyelination. These patents also claim a number of additional potential uses of neuregulins, including stimulation of growth in cardiac and mammalian muscle cells, as well as treating cardiac failure, ischemic brain events, peripheral neuropathy and nerve injury.

In June 2008, we obtained an issued patent which covers methods for eliciting muscle cell survival, cell division or development by use of neuregulins. In January 2009, we received a Notice of Allowance on a U.S. application directed to neuregulin subject matter, which we expect will issue in 2009. This allowed case covers using specified neuregulin sequences to treat a central or peripheral nervous system injury associated with demyelination.

### ***Remyelinating Antibodies***

We have approximately ten remyelinating antibody-related patent applications, along with 13 corresponding issued patents (two in the U.S. and 11 foreign). 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 for the treatment of CNS disorders. We have two U.S. patents, one of which was issued in January 2009 and is directed to antibody compositions that can induce remyelination, as well as several issued related foreign counterparts.

There are numerous pending U.S. and foreign pending applications in our portfolio. Work actively continues on this subject matter and the remyelinating antibodies patent portfolio is expected to expand with relevant new patent filings expected throughout 2009.

### ***Chondroitinase***

We have two chondroitinase-related U.S. patents, obtained in 2008, an issued Australian patent, and over 50 pending chondroitinase patent applications.

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 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 U.S. applications and foreign equivalents relating to chondroitinase enzymes, including fusion proteins of chondroitinase, chimeric proteins including

chondroitinase, deletion mutants and certain methods relating to chondroitinase. One of the issued U.S. patents covers chondroitinase ABCI mutant enzymes and related methods of use, while the other covers novel chondroitinase compositions.

### **Trademarks**

In addition to patents, our intellectual property portfolio includes trademarks. The marks “Acorda Therapeutics,” and our stylized Acorda Therapeutics logo are registered trademarks that we own. We also own the rights to the marks “Zanaflex” and “Zanaflex Capsules” in the U.S. Our trademark portfolio also includes several pending trademark applications for potential product names and for disease awareness activities.

### **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 Merck 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 Sanofi-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 MS and, depending on the results of those trials, any resulting product might compete with Fampridine-SR. We also believe that EUSA Pharma is developing a 3,4-diaminopyridine compound that is in clinical development for use in Lambert Eaton Syndrome. If this product were successfully developed and approved, physicians might prescribe it instead of Fampridine-SR even if it were not approved for MS. 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 compounded 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 the function of nerve fibers in subjects with MS. We are not aware of other companies in clinical development with products that specifically address improvement of 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. As noted earlier, the Company is in litigation with Apotex with regard to its filing of an ANDA for the approval of a purported generic version of Zanaflex Capsules and certification against the Company's patent. In addition, several companies have reported that they are working on potential new delivery formulations of tizanidine. 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, including Fampridine-SR, 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 regulated under both the Federal Food, Drug, and Cosmetic Act, as amended, and the Public Health Service Act, as amended. Violations of regulatory requirements at any stage may result in various adverse consequences, including the 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. Similar civil or criminal penalties could be imposed by other government agencies or agencies of the states and localities in which our products are manufactured, sold or distributed.

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.

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 conduct of the clinical trial. 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 before it commences at that center. 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) 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.

Federal and state law requires the submission of registry and results information for most clinical trials. These requirements do not apply to Phase 1 clinical trials. Many of the federal law requirements for submission of results information have not yet been implemented and will be phased-in over time. Once fully implemented, the federal requirements will preempt similar requirements at the state and local level.

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 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 cGMP requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products. The FDA may also inspect clinical trial sites and will not approve the product unless the clinical studies have been conducted in compliance with GCP.

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. For the FDA's fiscal year

2009, the NDA or BLA review fee alone is \$1,247,200, 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 or clinical trials 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 risk evaluation and mitigation strategy (REMS), or otherwise limit the scope of any approval or post-approval, or limit labeling. Under a REMS, the FDA may impose significant restrictions on distribution and use of a marketed product, may require the distribution of medication guides, patient labeling and/or communication plans, and may impose a timetable for submission of assessments of the effectiveness of a REMS. 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. The FDA may also impose a REMS post-approval if it becomes aware of new safety information that it believes necessitates a REMS. 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, among other things, 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. On its own initiative, FDA may require safety labeling changes to the labeling of an approved drug if it becomes aware of new safety information that the agency believes should be included in the approved drug's labeling. 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 cGMP, 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 cGMP 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. Similar provisions exist at the state level.

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. The FDA also may conduct periodic inspections regarding our review and reporting of adverse events, or related to compliance with the requirements of the PDMA concerning the handling of drug samples. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe 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. For example, the FDA conducted an inspection in February 2009. This was the first FDA inspection we have had since a previous inspection the FDA conducted in 2006, which had resulted in a Form FDA 483 regarding our reporting of adverse events for marketed products. Although the 2009 inspection showed that we had resolved issues from the previous inspection, it also resulted in a Form FDA 483 with five inspectional observations. The observations cited the failure to submit NDA field alert reports for Zanaflex Capsules in a timely manner, the failure to review adequately complaints concerning distributed product, the late submission of NDA annual reports, and inadequate written procedures for our quality control unit, NDA field alert reporting, and the training of our personnel. We intend to undertake corrective and preventive actions in order to address the FDA's concerns cited in the Form FDA 483. However, we cannot assure you that the FDA will find our remedial actions to be adequate or that the FDA will not identify different or additional deficiencies in subsequent inspections.

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. Requests for orphan drug designation must be submitted before the submission of an NDA or BLA. 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. If a product that has an orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity. This means that, subsequent to approval, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. 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. If the FDA approves someone else's application for the same drug that has orphan exclusivity, but for a different use, 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.

Many states require or permit 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 the entire European Economic Area (EEA) or in more than one individual EC member state. This foreign regulatory approval process involves all of the risks associated with FDA approval 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 federal reimbursement for physician-administered drugs covered by Medicare. 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 added an outpatient prescription drug benefit to Medicare, effective January 2006. This benefit is provided primarily through private entities, which attempt to negotiate price concessions from pharmaceutical manufacturers.

Public and private health care payers 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 payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA and/or 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, provides for Medicare coverage of unapproved uses of an FDA-approved drug if the unapproved use is reasonable and necessary and is supported by one or more citations in the American Hospital Formulary Service Drug Information, the national Comprehensive Cancer Network Drugs and Biologics Compendium, Thompson Micromedex, DrugDex, or Clinical Pharmacology. 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 and may limit or restrict reimbursement. 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 February 13, 2009, we had 174 employees. Of the 174 employees, 42 perform research and development activities, including preclinical programs, clinical trials, regulatory affairs and biostatistics, 98 work in sales, marketing, medical affairs, business development, manufacturing and communications, and 34 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](http://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).

### Item 1A. Risk Factors.

*An investment in our common stock involves a high degree of risk. You should consider carefully the following risk factors and the other information contained in this prospectus and the documents incorporated by reference herein before you decide to purchase our common stock. Additional risks that are not currently known or foreseeable to us may materialize at a future date. Our business and financial results could be adversely affected in a material way if any of these risks or uncertainties occur and you might lose all or part of your investment.*

### Risks related to our business

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

As of December 31, 2008, we had an accumulated deficit of approximately \$344.4 million. We had net losses of \$74.3 million, \$38.0 million, and \$60.0 million for the years ended December 31, 2008, 2007 and 2006, 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, prepare for the potential launch of Fampridine-SR, and continue product development and research and development activities.

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

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

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

***If we are unable to obtain regulatory approval for Fampridine-SR in the U.S., the European Union, or other markets, or any approval is unduly limited in scope or delayed, our business prospects will be materially adversely affected.***

We have filed an NDA for approval of Fampridine-SR for the improvement of walking in patients with MS, based on positive results from two Phase 3 clinical trials conducted pursuant to SPAs from the FDA. If the FDA determines that our NDA is incomplete or otherwise not adequate to support review, it will refuse to accept the NDA for filing and will not proceed to further review. If the FDA accepts the NDA for filing but determines that there is a new substantial scientific issue regarding walking in the MS population or Fampridine-SR, the FDA may alter its opinion expressed in the prior SPAs regarding the adequacy of the design of the Phase 3 studies. The FDA or the regulatory authorities in the European Union or other markets where we may apply for approval may also determine that the risks and benefits shown by the data that we have submitted do not support approval, or support only a limited approval, or an approval conditioned on burdensome post-approval commitments.

The FDA may identify a need for further studies in order to confirm efficacy or to examine safety or other properties or characteristics of Fampridine-SR. For example, in October 2007, we met with the FDA to discuss the completed preclinical studies proposed for the NDA for Fampridine-SR and the FDA asked us to complete a series of bridging studies to bring our older preclinical toxicology studies to current scientific standards. This included a requirement to complete new studies to fully characterize the toxicokinetics of fampridine in the blood of experimental animals given doses that were used in the full range of our previously performed preclinical toxicology studies, so the FDA can evaluate the suitability of those doses and routes of administration of drug in its evaluation of safety. These additional studies were completed before the submission of our NDA in January 2009. The FDA also required us to execute a Thorough QT study of cardiac safety which was completed in January 2008. Although our QT consultants concluded that this study showed no safety signal for a risk of cardiac QT prolongation with Fampridine-SR at a therapeutic or supra-therapeutic dose, the FDA will make its own evaluation of the data as part of the NDA review and its interpretation of the results may differ.

We may also determine, on our own, to conduct additional studies from time to time to support our filing of an NDA or regulatory filings in other markets or to otherwise provide additional data regarding the safety or efficacy of Fampridine-SR. If the studies that we are required to conduct, or any studies that we determine, on our own, to conduct, cause us to incur unanticipated expenses or delays, or yield unfavorable results, our ability to obtain regulatory approval of Fampridine-SR could be seriously delayed or impaired, in which case our business prospects will be materially adversely affected.

In June 2008, we submitted a request to the FDA for Fast Track designation for Fampridine-SR. The FDA did not grant our request, stating that we had not at that time demonstrated that Fampridine-SR addresses an unmet medical need under the criteria for Fast Track designation. We presented additional information on the ways in which Fampridine-SR improves walking ability in patients with MS and differs in its effects from existing MS therapies as part of our request for reconsideration of that decision, but the FDA did not change its decision. We did not apply for Priority Review, and our NDA is therefore subject to FDA's normal 10 month review time under the Prescription Drug User Fee Act, rather than an expedited review time of six months.

Notwithstanding the results of our clinical trials and pre-clinical studies, the FDA could determine that the overall balance of risks and benefits for Fampridine-SR is not adequate to support approval, or only justifies approval for a narrow set of uses or approval with restricted distribution or other burdensome post-approval requirements and limitations. Subjects taking Fampridine-SR have experienced adverse events, including falls, urinary tract infection, insomnia,

dizziness, asthenia, headache, fatigue, nausea and balance disorder. A small number of subjects have also experienced seizures while taking Fampridine-SR, and there is a possibility that additional seizures will occur even at low doses of the drug. If the FDA denies approval of Fampridine-SR in MS, if FDA approval is substantially delayed, if approval is granted on a narrow basis or with restricted distribution or other burdensome post-approval requirements, or if the Fampridine-SR program is terminated, our business prospects will be materially adversely affected.

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

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

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

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

Our internal sales force has increased to 61 people as part of our strategy to increase sales of Zanaflex Capsules, which increased our fixed expenses significantly. We expect to further increase our sales force, approximately doubling it, in anticipation of the possible launch of Fampridine-SR, if approved. If we expand our sales force and an NDA is not approved by the FDA, or, if approved, we are not able to achieve our expected level of sales of Zanaflex Capsules and Fampridine-SR, our cash flow and our prospects for achieving profitability will be adversely affected. In addition, we may not be able to hire, 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, 2008, 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 payers, such as government health administrative authorities, including Medicaid and Medicare, private health insurers and other such organizations that these differences justify the higher price of Zanaflex Capsules. Despite our increased investment in sales personnel, we may be unable to convert a significant additional number of current users of Zanaflex tablets or generic tizanidine tablets to Zanaflex Capsules. If that is the case, our ability to continue to generate meaningful revenue from this product will be adversely affected.

***We will need to obtain regulatory approval in foreign jurisdictions where we seek to market our products.***

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. We may fail to obtain foreign regulatory approvals on a timely basis, if at all. In addition, individual countries, within the European Union or elsewhere, may require additional steps after regulatory approval to gain access to national markets, such as agreements with pricing authorities and other agencies, that may affect our ability to market and sell our products outside the United States. 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.

During 2008, we met with national regulatory authorities in four European Union member states regarding Fampridine-SR and we believe, based on these discussions, that our current data are sufficient to allow us to file a centralized MAA with the EMEA. The EMEA may determine that such an MAA cannot be filed centrally, in which case we would be required to seek approval separately from each member state in which we wish to market Fampridine-SR through the European Union's decentralized or mutual recognition procedures. The EMEA may also determine that the data we submit are not sufficient to support an application for marketing approval of Fampridine-SR, which could lead to additional information requirements, including the submission of data from supplemental clinical trials other than those that support our U.S. filings with the FDA. Any requirements to conduct supplemental trials would add to the cost of developing our product candidates. Additional or supplemental trials could also produce findings that are inconsistent with the trial results we have previously submitted to the FDA, in which case we would be obligated to report those findings to the FDA.

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

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

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

- negative or ambiguous results regarding the efficacy of the product candidate;
- undesirable side effects that delay or extend the trials, or other unforeseen or undesirable safety issues that make the product candidate not medically or commercially viable;
- inability to locate, recruit and qualify a sufficient number of patients for our trials;
- difficulty in determining meaningful end points or other measurements of success in our clinical trials;
- regulatory delays or other regulatory actions, including changes in regulatory requirements;

- difficulties in obtaining sufficient quantities of our product candidates manufactured under current good manufacturing practices;
- delays, suspension or termination of the trials imposed by us, an independent institutional review board for a clinical trial site, or clinical holds placed upon the trials by the FDA;
- FDA approval of new drugs that are more effective than our product candidates;
- change in the focus of our development efforts or a re-evaluation of our clinical development strategy; and
- a change in our financial position.

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

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

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

Our preclinical programs may not lead to commercially viable products for several reasons. For example, we may fail to identify promising product candidates, our product candidates may fail to be safe and effective in preclinical tests or clinical trials, or we may have inadequate financial or other resources to pursue discovery and development efforts for new product candidates. In addition, because we have limited resources, we are focusing on product candidates that we believe are the most promising. As a result, we may delay or forego pursuit of opportunities with other product candidates. From time to time, we may establish and announce certain development goals for our product candidates and programs; however, given the complex nature of the drug discovery and development process, it is difficult to predict accurately if and when we will achieve these goals. For example, the contract manufacturer with whom we had begun work to produce rHIgM22, one of our antibodies, under cGMP, filed for bankruptcy in 2008, delaying a projected future IND application. If we are unsuccessful in advancing our preclinical programs into clinical testing or in obtaining regulatory approval, our long-term business prospects will be harmed.

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

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

Additional adverse events that could impact commercial success, or even continued regulatory approval, might emerge with more extensive post-approval patient use. Of the large number of

drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

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

Clinical trials are subject to oversight by institutional review boards and the FDA to ensure compliance with the FDA's good clinical practice requirements, as well as other requirements for the protection of clinical trial participants. We depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices required by regulators. If any such standards are not complied with in our clinical trials, the resulting data from the clinical trial may not be usable or we, an institutional review board or the FDA may suspend or terminate such trial, which would severely delay our development and possibly end the development of such product candidate. We also depend upon third party manufacturers of our products to qualify for FDA approval and to comply with good manufacturing practices required by regulators. We cannot be certain that our present or future manufacturers and suppliers will comply with current good manufacturing practices. The failure to comply with good manufacturing practices may result in the termination of clinical studies, restrictions in the sale of, or withdrawal of the products from the market. Compliance by third parties with these standards and practices is outside of our direct control. For example, in January 2007, we and other pharmaceutical companies 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 payers, 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 payers.***

Our commercial success will depend in part on third-party payers, 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 payers 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 payers limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate.

Third-party payers frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. Although we do not have any such agreements with private third-party payers and only a small number of such agreements with government payors, as sales of Zanaflex Capsules continue to increase, we expect increasing pressure to offer larger discounts or discounts to a greater number of third-party payers 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. A number of third-party payers now also require prior authorization for, or even refuse to provide, reimbursement for Zanaflex Capsules, and others may do so in the future. 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.

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

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

Competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, including MS and SCI. We are aware of a company developing a sodium/potassium channel blocker and of another Company that is developing a 3,4-diaminopyridine product, which may compete with Fampridine-SR, if approved. In certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis. We are aware that at present compounded fampridine is used by some people with MS or SCI and it is possible that some people will want to continue to use compounded formulations even if Fampridine-SR were approved. Several companies are engaged in developing products that include novel immune system approaches and cell transplant approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Fampridine-SR or our preclinical candidates.

Composition of matter patents on tizanidine, the active ingredient in Zanaflex Capsules and Zanaflex tablets, expired in 2002. As of January 1, 2009, 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. For example, Apotex advised us in August 2007 that it had submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking marketing approval for generic versions of Zanaflex Capsules (see Risk Factor, “If we cannot protect, maintain, and, if necessary, enforce our intellectual property”, below). If a generic tizanidine hydrochloride capsule were approved and commercialized by any other company, Zanaflex Capsules would face significant competition, which would likely cause significant declines in our revenue from this product, which is currently our only marketed product, and in our profit margin. Should sales of Zanaflex Capsules materially decline due to generic competition, we might have to write off a portion of the intangible assets associated with Zanaflex Capsules and Zanaflex.

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, 2008, we had approximately \$246.0 million in cash, cash equivalents and short-term investments. Although we anticipate this will be sufficient to fund our operations and meet our financial obligations through 2010 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 complete our product development activities, and could require substantial funding to commercialize any products that we successfully develop. We may not be able to raise additional capital on favorable terms or at all. To the extent that we are able to raise additional capital through the sale of equity securities, the issuance of those securities would result in dilution to our stockholders. Holders of such new equity securities may also have rights, preference or privileges that are senior to yours. If additional capital is raised through the incurrence of indebtedness, we may become subject to various restrictions and covenants that could limit our ability to respond to market conditions, provide for unanticipated capital investments or take advantage of business opportunities. To the extent funding is raised through collaborations or intellectual property-based financings, we may be required to give up some or all of the rights and related intellectual property to one or more of our products, product candidates or preclinical programs. If we are unable to obtain sufficient financing on favorable terms when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs or devote less resources to marketing Zanaflex Capsules and Fampridine-SR, if approved.

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

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

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

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

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

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

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

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

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

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

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

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

Any product for which we currently have or may obtain marketing approval, along with the associated manufacturing processes, any post-approval clinical data that we might be required to collect and the advertising and promotional activities for the product, are subject to continual recordkeeping and reporting requirements, review and periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, any approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. For example, we are required to inform the FDA if certain issues arise in the manufacturing or packaging of our commercialized products. In December 2007, we filed a field alert with the FDA notifying them that two bottles of Zanaflex Capsules were packaged without the required lot and expiration date information on their labels. We worked with the packager of Zanaflex Capsules to identify and correct any issues that could have caused this, but there can be no assurance that other bottles of Zanaflex Capsules are or will be labeled properly or that other similar issues will not occur. Additionally, in December 2008, we filed a field alert with the FDA notifying them that we had received a complaint from a patient that samples of Zanaflex Capsules that she had received from her physician did not appear to contain any drug substance. We worked closely with the manufacturer and packager to investigate the product complaint and were unable to substantiate it, but we cannot assure you that this investigation uncovered all of the relevant information, that there will not be similar product complaints in the future, or that FDA will determine that our investigation was adequate or that the complaint does not reflect a broader issue with our manufacturing or quality assurance systems.

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

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

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

In addition, proposed legislation may impose additional requirements. For example, in January 2009, Senators Grassley and Kohl introduced a federal physician payment disclosure bill—the Physician Payments Sunshine Act of 2009—which, if enacted, will require pharmaceutical manufacturers to report certain gifts and payments to physicians, which will then be placed on a public database. Failure to so report could subject companies to significant financial penalties.

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

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials and chemicals that are subject to federal, state and local laws and regulations governing their use, storage, handling and disposal. These materials include ketamine, buprenorphine, sodium pentobarbital, ether, acetonitrile, hexanes, chloroform, xylene, dehydrated alcohol, methanol, ethyl alcohol, isopropanol and formaldehyde. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. If we fail to comply with environmental regulations, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any substantial liability could exceed our resources.

We currently maintain a general liability insurance policy that has a \$2 million per claim limit and also caps aggregate claims at \$2 million. In addition, we have an umbrella insurance policy that covers up to \$9 million of liability in excess of the general liability policy's \$2 million limit. This amount of insurance coverage may not be adequate to cover all liabilities or defense costs we

might incur. In addition, the cost of compliance with environmental and health and safety regulations may be substantial.

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

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

**Risks related to our dependence on third parties**

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

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

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

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

Prior to March 2007, we relied on a single manufacturer, Novartis, for the manufacture of Zanaflex tablets and for the supply of tizanidine, the active pharmaceutical ingredient in Zanaflex Capsules and Zanaflex tablets. Novartis has discontinued production of tizanidine and will no longer supply tizanidine to Elan for the production of Zanaflex Capsules or to us for the production of Zanaflex tablets. We have recently received FDA approval to use the tizanidine manufactured by a new supplier, Farmak, as the active ingredient in the production of Zanaflex Capsules. However, we are still required to obtain FDA approval for a new supplier of the tizanidine needed for the production of Zanaflex tablets. Elan has agreed to supply us with Novartis-manufactured tizanidine for the manufacture of Zanaflex tablets to satisfy supply requirements through the first quarter of



2010. If we fail to gain FDA approval of a new tizanidine supplier for Zanaflex tablets prior to February 2010, we may experience an interruption in our supply. Beginning in May 2007, the chemical stability of Elan's inventory of Novartis-manufactured tizanidine must be retested within 30 days of each manufacturing run. If Elan's tizanidine inventory fails its retest prior to FDA approval of a new supplier for Zanaflex tablets, a delay or interruption in our supply of our Zanaflex tablets could result.

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

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

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

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

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

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We rely and will continue to rely on clinical investigators, third-party contract research organizations and consultants to perform some or all of the functions associated with preclinical testing and clinical trials. The failure of any of these vendors to perform in an acceptable and timely manner in the future, including in accordance with any applicable regulatory requirements, such as good clinical and laboratory practices, or preclinical testing or clinical trial protocols, could cause a delay or other adverse effect on our preclinical testing or clinical trials and ultimately on the timely advancement of our development programs. For example, the contract manufacturer that we were working with to produce rHlgM22 under cGMP filed for bankruptcy in 2008, delaying an IND filing that we had targeted for late 2009.

## **Risks related to our intellectual property**

***If we cannot protect, maintain and, if necessary, enforce 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 or intend to use, other companies could offer substantially identical products for sale without incurring the sizable discovery, research, 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 invented, in-licensed or are the assignee of over 35 U.S. patents, over 110 foreign patents and over 100 patent applications pending worldwide for technologies we invented or in-licensed. 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, it may not issue in a timely manner, 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 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 allowed or issued 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 for a variety of legal and public policy reasons. From time to time we may receive notices from third parties alleging infringement of their intellectual property rights. Any litigation, whether to enforce our rights to use our or our licensors' patents or to defend against allegations that we infringe third party rights, would be costly, time consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in 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, collaborators, 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, collaborators, key

employees or other third parties apply technological information independently developed by them or by others to our proposed products, joint ownership may result, which could undermine the value of the intellectual property to us or disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements or that our trade secrets become known or independently discovered by competitors, could adversely affect us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.

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

In November 2007, Apotex filed an answer to our complaint, asserting affirmative defenses of invalidity and non-infringement of U.S. Patent No. 6,455,557, and also filed counterclaims for declaratory judgment of invalidity and non-infringement. Apotex' defenses or counterclaims may change during the course of the litigation and its arguments and/or the underlying bases for its arguments may change. In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing the Company's request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(4) or 285. The court ruled in our favor and denied Apotex' motion in December 2008. We and Apotex are currently proceeding with discovery in the case. Although we intend to vigorously defend our intellectual property rights related to Zanaflex Capsules, there is no assurance that we will prevail or that the ANDA filed by Apotex will not be approved by the FDA. The resolution of this patent litigation could be lengthy and at substantial cost, even if resolved in our favor, and could absorb significant management time, all of which may materially and adversely affect our financial position and results of operations. In addition, if Apotex is successful in challenging our patent, and if the FDA approves that ANDA, it could be permitted to sell a generic tizanidine hydrochloride capsule. Further, other third parties may bring similar claims. We would face significant competition from any generic brand of tizanidine hydrochloride capsule, which would cause significant declines in our revenue and profit margin. If a generic tizanidine hydrochloride capsule were approved and commercialized, Zanaflex Capsules would face significant competition, which would likely cause significant declines in our revenue from this product, which is currently our only marketed product. Should sales of Zanaflex Capsules materially decline due to generic competition, we might have to write off a portion of the intangible assets associated with Zanaflex Capsules and Zanaflex.

***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;
- significantly delay product commercialization activities;
- 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 may 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 or clinical programs. In addition, any such litigation would be costly, time consuming, and might distract management from other important tasks.

***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, 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 NDA-equivalent. We could also lose our rights under our license agreement with Elan if we fail to launch a product in such countries, including the United States, within 180 days of NDA or equivalent approval. Elan could also terminate our license agreement if we fail to make payments due under the license agreement. If we lose our rights to Fampridine-SR our prospects for generating revenue and recovering our substantial investment in the development of this product would be materially harmed.

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

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

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

- achievement or rejection of regulatory approvals by us or by our competitors;
- publicity regarding actual or potential clinical trial results or updates relating to products under development by us or our competitors;

- announcements of new corporate partnerships, alliances, financings or other transactions, or of technological innovations or new commercial products by our competitors or by us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- economic or other crises or other external factors;
- conditions or trends in the pharmaceutical or biotechnology industries;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- governmental regulation and legislation in the United States and foreign countries;
- changes in securities analysts' estimates of our performance or our failure to meet analysts' expectations;
- sales of substantial amounts of our stock;
- delay or failure in initiating, completing or analyzing pre-clinical trials or unsatisfactory design or result of these trials;
- variations in product revenue and profitability;
- variations in our anticipated or actual operating results; and
- delays in completing Phase IV trials if required by the FDA.

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

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

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

If our existing stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. Sales of substantial amounts of shares of our common stock in the public market by our executive officers, directors, 5% or greater stockholders or other stockholders, or the prospect of such sales, could adversely affect the market price of our common stock. As of February 13, 2009, we have outstanding 37,774,711 shares of voting common stock. We have registered 6,625,910 shares of common stock that are authorized for issuance under our equity compensation plans, including outstanding options to acquire 3,181,056 shares of common stock outstanding as of February 13, 2009, exercisable at an average exercise price of \$13.55 per share. To the extent that option holders exercise outstanding options, there may be further dilution and the sales of shares issued upon such exercises could cause our stock price to drop further.

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

As of December 31, 2008, our officers, directors and holders of 5% or more of our outstanding common stock beneficially own approximately 45.9% 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 in the foreseeable future, 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.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our principal executive offices are located in an approximately 46,103 square foot facility in Hawthorne, NY, which houses offices and laboratory space. The current annual rent for this facility is approximately \$1.0 million. We believe that our facility is currently adequate for our purposes however there may be a need to rent additional space in the future depending upon the possible growth of the company. The lease for this facility expires in December 2012.

**Item 3. Legal Proceedings.**

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

In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing our request for relief on the ground that the case is “exceptional” under U.S.C. §§ 271(e)(4) or 285. The court ruled in our favor and denied Apotex’ motion in December 2008. We and Apotex are currently proceeding with discovery in the case.

**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 2008.

**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.

	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended December 31, 2008</b>		
Fourth Quarter . . . . .	\$24.03	\$14.42
Third Quarter . . . . .	\$35.65	\$23.03
Second Quarter . . . . .	\$33.70	\$17.74
First Quarter . . . . .	\$28.14	\$17.03
	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended December 31, 2007</b>		
Fourth Quarter . . . . .	\$23.40	\$16.84
Third Quarter . . . . .	\$21.41	\$15.80
Second Quarter . . . . .	\$26.58	\$16.69
First Quarter . . . . .	\$25.88	\$15.06

Registrar and Transfer Company is the transfer agent and registrar for our common stock. As of February 13, 2009, we had approximately 42 registered holders of record of our common stock.

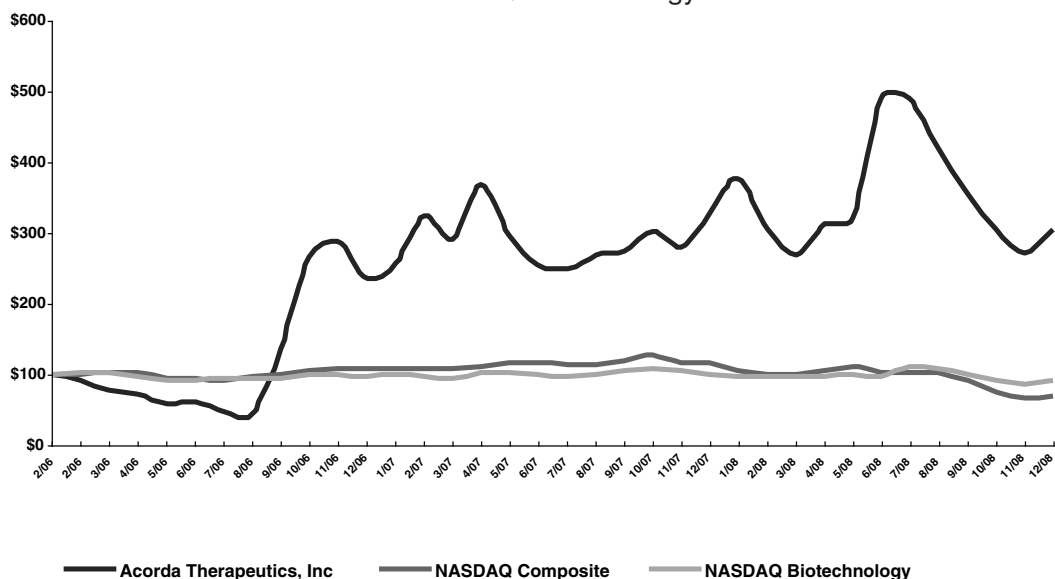


## Stock Price Performance Graph

The following graph compares the cumulative 34-month total return attained by stockholders on Acorda Therapeutics, Inc's common stock relative to the cumulative total returns of the NASDAQ Composite index and the NASDAQ Biotechnology index. An investment of \$100 is assumed to have been made in our common stock and in each of the indexes on 2/10/2006 and its relative performance is tracked through 12/31/2008.

### COMPARISON OF 34 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 & 1/31/06 in index—including reinvestment of dividends. Fiscal year ending December 31.

	2/06	3/06	4/06	5/06	6/06	7/06	8/06	9/06	10/06	11/06	
<b>Acorda Therapeutics, Inc</b> . . . . .	100.00	92.26	77.68	72.92	57.29	62.05	47.62	43.45	136.16	264.73	288.10
<b>NASDAQ Composite</b> . . . . .	100.00	98.94	101.92	101.51	95.35	95.19	92.07	96.20	99.30	104.20	107.17
<b>NASDAQ Biotechnology</b> . . . . .	100.00	103.61	101.75	95.72	92.16	91.09	92.89	93.37	95.18	100.89	99.74

	12/06	1/07	2/07	3/07	4/07	5/07	6/07	7/07	8/07	9/07	10/07	11/07	12/07
	235.71	257.29	323.07	288.99	368.75	296.13	253.87	249.70	267.71	273.07	301.64	278.42	326.79
	106.87	108.97	106.93	107.36	111.33	114.98	114.93	112.53	114.32	119.77	126.45	117.37	116.69
	97.60	100.45	97.23	94.38	102.67	101.43	98.70	97.27	98.85	104.54	109.02	105.77	99.24

	1/08	2/08	3/08	4/08	5/08	6/08	7/08	8/08	9/08	10/08	11/08	12/08
	377.38	304.17	267.11	313.24	320.83	488.54	488.24	418.90	354.91	303.57	269.64	305.21
	104.89	100.30	100.28	106.34	111.15	101.31	101.24	102.63	89.90	73.71	65.99	67.98
	97.27	95.94	96.08	96.75	98.85	97.19	110.37	107.25	100.80	91.94	85.49	91.64

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

## 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.

## Item 6. Selected Financial Data.

The following unaudited selected consolidated financial data for each of the five years in the period ended December 31, 2008 are derived from our audited consolidated financial statements. These data should be read in conjunction with our audited consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K and with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Item 7 below.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Gross sales—Zanaflex . . . . .	\$ 53,398	\$ 43,586	\$ 26,548	\$ 5,923	\$ —
Less: discounts and allowances . . . . .	(5,670)	(4,160)	396	(1,114)	(4,417)
Net sales . . . . .	47,728	39,426	26,944	4,809	(4,417)
Grant revenue . . . . .	99	60	407	336	479
Total net revenue . . . . .	47,827	39,486	27,351	5,145	(3,938)
Less: cost of sales . . . . .	(11,355)	(8,356)	(7,123)	(5,132)	(885)
Gross profit . . . . .	36,472	31,130	20,228	13	(4,823)
Operating expenses:					
Research and development . . . . .	36,604	22,410	12,055	12,890	21,999
Sales and marketing . . . . .	49,070	30,737	19,079	13,099	4,662
General and administrative . . . . .	24,237	17,431	12,561	8,435	13,283
Total operating expenses . . . . .	109,911	70,578	43,695	34,424	39,944
Operating loss . . . . .	(73,439)	(39,448)	(23,467)	(34,411)	(44,767)
Other income (expense):					
Interest and amortization of debt discount expense . . . . .	(5,591)	(2,664)	(2,553)	(1,526)	(385)
Interest income . . . . .	4,682	4,087	1,471	402	409
Other income . . . . .	8	51	76	1	2
Total other income (expense) . . . . .	(901)	1,474	(1,006)	(1,123)	26
Cumulative effect of change in accounting principle(3) . . . . .	—	—	454	3	—
Net loss . . . . .	(74,340)	(37,974)	(24,019)	(35,531)	(44,741)
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)
Net loss allocable to common stockholders . . . . .	(74,340)	(37,974)	<u>\$(60,027)</u>	<u>\$(60,380)</u>	<u>\$(69,487)</u>
Net loss per share allocable to common stockholders—basic & diluted . . . . .	<u>\$ (2.19)</u>	<u>\$ (1.45)</u>	<u>\$ (3.27)</u>	<u>\$(295.27)</u>	<u>\$(351.76)</u>
Pro forma net loss per share allocable to common stockholders—basic & diluted (unaudited)(1) . . . . .				<u>\$ (.79)</u>	<u>\$ (9.63)</u>
Weighted average shares of common stock outstanding used in computing net loss per share allocable to common stockholders—basic & diluted . . . . .	<u>33,939</u>	<u>26,237</u>	<u>18,346</u>	<u>204</u>	<u>198</u>
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) . . . . .				<u>13,547</u>	<u>13,536</u>

(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. 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 our 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,				
	2008	2007	2006	2005	2004
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents . . . . .	\$ 29,613	\$ 16,810	\$18,101	\$ 11,761	\$ 11,729
Short term investments . . . . .	216,435	78,310	35,656	2,001	9,397
Working capital . . . . .	207,445	71,770	33,324	(10,394)	9,067
Total assets . . . . .	281,501	127,306	84,368	33,912	30,982
Deferred product revenue—Zanaflex tablets . . . . .	7,867	7,914	9,117	11,510	6,668
Deferred product revenue—Zanaflex Capsules . . . . .	16,436	13,924	11,324	5,226	—
Current portion of notes payable . . . . .	—	188	1,044	1,068	302
Non current portion of notes payable . . . . .	—	—	187	1,147	145
Current portion of revenue interest liability—PRF transaction . . . . .	6,181	1,785	3,392	2,162	—
Put/call option liability—PRF transaction . . . . .	338	463	350	400	—
Non current portion of revenue interest liability—PRF transaction . . . . .	12,498	17,444	19,744	12,914	—
Long term convertible notes payable . . . . .	6,905	6,703	6,508	8,768	8,422
Mandatorily redeemable preferred stock . . . . .	—	—	—	91,214	66,364
Total stockholders' equity (deficit) . . . . .	207,157	63,433	18,669	(116,536)	(60,571)

## **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. A second Phase 3 trial of Fampridine-SR in MS, MS-F204, was initiated in June 2007 and favorable results from that study were released in June 2008. The objective of this study was to show that individuals treated with Fampridine-SR are significantly more likely to have consistent improvements in their walking than those treated with placebo. A Thorough QT cardiac study was initiated in September 2007 and favorable results from that study were released in January 2008. This study evaluated the potential to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and suprathreshold doses, was found to be no different than placebo. On January 30, 2009, we submitted a New Drug Application to the FDA for Fampridine-SR. We have also discussed Fampridine-SR with national regulatory authorities of four European Union member states and believe that the current data are sufficient to file a centralized MAA with the European Medicines Agency. We are in discussions with potential marketing partners regarding the commercialization of Fampridine-SR in the European Union and other non-U.S. markets. At the same time, we are preparing for the filing of a centralized MAA with the EMEA. We plan to maintain our flexibility in the timing of such a filing in order to optimize our ex-U.S. commercialization pathway and availability to patients. 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.

On February 1, 2008 the Company acquired certain assets of Neurorecovery, Inc. (NRI). These assets will enable Acorda to explore additional therapeutic indications for its investigational compound Fampridine-SR, as well as gain access to pre-clinical compounds that may have utility in nervous system disorders. Under the terms of the purchase agreement, Acorda was assigned two key licensing and research agreements relating to the use of aminopyridines in peripheral neuropathies and two early stage development candidates. Acorda also acquired NRI's pre-clinical and clinical data, regulatory filings (including Orphan Drug designations), copyrights, trademarks and domain names relating to the three products. Acorda issued 100,000 shares of its Common Stock as the purchase price for these assets which were valued at \$26.86 per share. The transaction was accounted for as an acquisition of in-process research and development assets and, as such, resulted in a non-cash expense in the first quarter of 2008 of \$2,686,000.

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 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 clinical trial, the results of which were announced in April 2004 and the Phase 3 clinical trials for MS described above.

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 we will also be obligated to pay royalties upon the achievement of specified sales levels. Through December 31, 2008, we achieved and paid all required milestones totaling \$19.5 million in the aggregate, based on the achievement of specified levels of sales. 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 and pre-launch activities associated with the commercialization of Fampridine-SR, if approved. 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 until we begin to generate sales of Fampridine-SR if approved. Zanaflex Capsules and tablets commercial operations were cash flow positive in 2008 and are expected to be cash flow positive in 2009, with Zanaflex Capsules revenue expected to grow modestly during this period.

In late 2004, we began establishing our own specialty sales force in the U.S., which consisted of 61 sales professionals as of December 31, 2008. This sales force has targeted neurologists and other prescribers who specialize in treating people with conditions that involve spasticity. We also employ an internal and field-based team who call on managed care organizations, pharmacists and distribution customers. In addition, we retain TMS Professional Markets Group, LLC to provide a small, dedicated sales force of pharmaceutical telesales professionals who contact primary care, specialist physicians and pharmacists.

In December 2005, we entered into a revenue interest 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. Under the agreement, PRF is entitled to a royalty consisting of certain specified percentages of Zanaflex net revenues, based upon the level of net revenues. The agreement 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 agreement, 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 our initial public offering in February 2006, in which we sold 6,075,614 shares of our common stock, resulting in net proceeds of approximately \$31.5 million. Since then, we have completed a \$29.8 million private placement of our common stock in October 2006 and three follow-on common stock offerings, raising an aggregate of approximately \$273.4 million, in July 2007 and in February and August 2008.

In September 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it had filed an ANDA with the FDA for generic versions of each of the three Zanaflex Capsules (tizanidine hydrochloride) dosage strengths marketed by us. In response to the filing of the ANDA, in October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) in the United States District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557 relating to multiparticulate tizanidine compositions, including those sold by us as Zanaflex Capsules. The patent expires in 2021. The defendants have answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. We have denied those counterclaims. If the ANDA were approved by the FDA and Apotex were successful in challenging the validity of the patent, Apotex could be permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules.

In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing our request for relief on the ground that the case is “exceptional” under U.S.C. §§ 271(e)(4) or 285. The court ruled in our favor and denied Apotex' motion in December 2008. We and Apotex are currently proceeding with discovery in the case.

### **Product Revenue and Returns**

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 interest 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.

### ***Discounts and Allowances***

Reserves for wholesaler fees for services, cash discounts, Medicaid and patient program 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. These allowances are established by management as its best estimate of historical experience adjusted to reflect known changes in the factors that impact such reserves. Allowances for wholesaler fees for services, chargebacks, rebates and discounts are established based on contractual terms with customers and analyses of historical usage of discount, chargeback and rebate reserves.

### ***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 interest 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 employee compensation and benefits, 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 and depreciation of capital

resources used to develop our products. Share-based compensation is classified between clinical development and preclinical research and development based on employee job function. We expense research and development costs as incurred.

The following table summarizes our research and development expenses for the years ended December 31, 2008, 2007 and 2006. Clinical development contract expense—MS consists of our external research and development costs, consisting largely of clinical trial and research services provided by outside laboratories and vendors in connection with each product candidate in clinical development. Clinical development other contract expense primarily consists of costs associated with Fampridine-SR manufacturing development. Preclinical research and development research contracts consists of our external research and development costs provided by outside laboratories and vendors in connection with each product candidate in all preclinical programs as a group. Our internal research and development costs, which are included in operating expenses, include personnel costs, related benefits and share-based compensation, that are not attributable to any individual project because we use these resources across several development projects. Regulatory affairs includes internal and external costs related to the preparation of the Fampridine-SR NDA and regulatory support for Fampridine-SR clinical studies and pre-clinical research and development.

	<u>Year Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
<b>Clinical development:</b>			
Contract expense—MS . . . . .	\$ 8,887	\$10,823	\$ 6,004
Other contract expense . . . . .	2,120	1,368	751
NRI acquisition . . . . .	2,687	—	—
Operating expense . . . . .	5,290	3,496	1,553
<b>Total clinical development</b> . . . . .	<u>18,984</u>	<u>15,687</u>	<u>8,308</u>
<b>Preclinical research and development:</b>			
Research contracts . . . . .	6,425	681	153
Operating expense . . . . .	3,018	2,406	3,057
<b>Total preclinical research and development</b> . . . . .	<u>9,443</u>	<u>3,087</u>	<u>3,210</u>
<b>Regulatory affairs</b> . . . . .	<u>8,177</u>	<u>3,636</u>	<u>537</u>
<b>Total</b> . . . . .	<u>\$36,604</u>	<u>\$22,410</u>	<u>\$12,055</u>

**Sales and Marketing Expenses**

Sales and marketing expenses include personnel costs, related benefits and share-based compensation for our sales and marketing personnel and the cost of Zanaflex sales and marketing initiatives and pre-launch activities associated with the possible commercialization of Fampridine-SR.

**General and Administrative Expenses**

General and administrative expenses consist primarily of personnel costs, related benefits and share-based compensation 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 and accounting services.



### ***Other Income (Expense)***

Interest income consists of income earned on our cash, cash equivalents and short-term investments. Interest expense consists of interest expense related to our revenue interest liability and accrued interest on our convertible notes.

### **Results of Operations**

#### ***Year Ended December 31, 2008 Compared to Year Ended December 31, 2007***

##### *Gross Sales*

We recognized gross sales from the sale of Zanaflex Capsules and Zanaflex tablets of \$53.4 million for the year ended December 31, 2008, as compared to \$43.6 million for the year ended December 31, 2007, an increase of approximately \$9.8 million, or 23%. The increase was due to an increase in prescriptions written for our products that we believe is the result of expanding our sales force activities as well as an increase in our marketing efforts. We have not increased products' prices since a 10% increase effective January 1, 2007. 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.

##### *Discounts and Allowances*

We recorded discounts and allowances of \$5.7 million for the year ended December 31, 2008 as compared to a \$4.2 million for the year ended December 31, 2007, an increase of approximately \$1.5 million or 36%. The increase in discounts and allowances was the result of a higher level of Zanaflex revenues and related shipments. Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers.

Discounts and allowances for the year ended December 31, 2008, consisted of \$2.3 million for fees for services payable to wholesalers, \$1.9 million for chargebacks and rebates and \$1.5 million in cash discounts and patient program rebates. Discounts and allowances for the year ended December 31, 2007 consisted of \$1.6 million for fees for services payable to wholesalers, \$1.5 million for chargebacks and rebates, and \$1.1 million in cash discounts and allowances.

##### *Grant Revenue*

Grant revenue for the year ended December 31, 2008 was \$99,000 compared to \$60,000 for the year ended December 31, 2007, an increase of approximately \$39,000, or 65%. 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 \$11.4 million for the year ended December 31, 2008 as compared to \$8.4 million for the year ended December 31, 2007, an increase of approximately \$3.0 million, or 36%. The increase was primarily due to the increase in gross sales and the amortization of the Zanaflex intangible asset achieved in the beginning of 2008. Cost of sales for the year ended December 31, 2008 consisted of \$5.3 million in inventory costs, \$3.4 million in royalty fees, \$2.4 million in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$251,000 in costs related to packaging, freight and stability testing. Cost of sales for the year ended December 31, 2007 consisted of \$3.0 million in royalty fees, \$3.9 million in inventory costs, \$1.2 million in amortization of intangible

assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$222,000 in costs related to packaging, freight and stability testing.

#### *Research and Development*

Research and development expenses for the year ended December 31, 2008 were \$36.6 million as compared to \$22.4 million for the year ended December 31, 2007, an increase of approximately \$14.2 million, or 63%. The increase in research and development expenses was primarily due to an increase of \$5.8 million from \$602,000 to \$6.4 million for the development of our preclinical pipeline products for a potential IND filing in late 2009 for one of these products and the Company's acquisition of certain in-process research and development assets of NRI resulted in a non-cash expense of approximately \$2.7 million in accordance with SFAS No. 2, *Accounting for Research and Development Expenses*.

These increases were partially offset by a decrease in MS clinical development program expense of \$1.9 million or 18% to \$8.9 million. This decrease was primarily due to an initial ramp-up of our second Phase 3 clinical trial of Fampridine-SR during 2007 and the Thorough QT cardiac study which was conducted during the second half of 2007.

Operating expenses for clinical development, pre-clinical research and development and regulatory were \$16.5 million for the year ended December 31, 2008, compared to \$9.5 million for the year ended December 31, 2007, an increase of \$7.0 million, or 74%. This increase was primarily attributable to an increase in regulatory expenses of \$4.4 million for the preparation of an NDA for Fampridine-SR and related consulting fees and an increase in research and development staff and compensation of approximately \$2.8 million to support pre-clinical research and development, Fampridine-SR clinical studies and NDA preparation.

Other contract expenses increased to \$2.2 million for the year ended December 31, 2008, from \$1.4 million for the year ended December 31, 2007, an increase of \$800,000 or 55%. This increase is primarily the result of an increase of \$753,000 for manufacturing and stability fees related to Fampridine-SR.

#### *Sales and Marketing*

Sales and marketing expenses for the year ended December 31, 2008 were \$49.1 million compared to \$30.7 million for the year ended December 31, 2007, an increase of approximately \$18.4 million, or 60%. This increase was primarily attributable to an increase of \$12.4 million for pre-launch activities associated with the possible commercialization of Fampridine-SR, if approved. In addition, we realized an increase in sales and marketing staff and compensation of \$4.4 million to support promotion of Zanaflex Capsules and Fampridine-SR pre-launch activities, an increase in other selling related expenses of \$752,000 to support our field staff, an increase in corporate communications of \$550,000 and an increase in Zanaflex Capsules marketing expenses of \$211,000.

#### *General and Administrative*

General and administrative expenses for the year ended December 31, 2008 were \$24.2 million compared to \$17.4 million for the year ended December 31, 2007, an increase of approximately \$6.8 million, or 39%. This increase was the result of an increase in staff and compensation and other expenses related of \$3.4 million to supporting the growth of the overall organization, an increase in legal fees of \$2.4 million primarily related to the Apotex patent infringement litigation and an increase in costs associated with medical affairs research and educational programs of \$1.1 million.

Sales and marketing and general and administrative expenses are expected to increase in 2009 and 2010 primarily due to an increase in our expected pre-launch activities and an approximate doubling of the size of our existing sales force in anticipation of the potential launch of Fampridine-SR, if approved.

#### *Other Income (Expense)*

Other expense was \$901,000 in expense for the year ended December 31, 2008 compared to other income of \$1.5 million for the year ended December 31, 2007, a decrease of approximately \$2.4 million, or 161%. The decrease was primarily due to an increase in interest expense of \$2.9 million. This increase in interest expense was the result of a \$1.5 million increase in interest expense under the PRF revenue interest agreement as a result of increased shipments and the impact of a \$1.4 million out-of-period adjustment made during the second quarter of 2008 to correct an error identified in the previously recorded effective interest expense related to the November 2006 amended revenue interests assignment agreement with PRF. This out-of-period adjustment did not increase the total interest expense associated with this agreement. The increase in interest expense was partially offset by a \$500,000 increase in interest income as a result of the investment of net proceeds from our follow-on public offerings in February and August 2008.

#### **Year Ended December 31, 2007 Compared to Year Ended December 31, 2006**

##### *Gross Sales*

We recognized gross sales from the sale of Zanaflex Capsules and Zanaflex tablets of \$43.6 million for the year ended December 31, 2007, as compared to \$26.5 million for the year ended December 31, 2006, an increase of approximately \$17.1 million, or 64%. The increase was due to an increase in prescriptions written for our products that we believe was the result of our sales force expansion as well as a 10% price increase effective January 1, 2007. Also included in gross sales for the year ended December 31, 2007 was \$462,000 of revenue recognized associated with our 2mg tablet deferred revenue. In August 2007, the right to return this product expired, allowing us to recognize the remaining \$462,000 deferred revenue as gross sales. 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.

##### *Discounts and Allowances*

We recorded discounts and allowances of \$4.2 million for the year ended December 31, 2007 as compared to a negative \$396,000 for the year ended December 31, 2006, an increase of approximately \$4.6 million. 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. Also contributing to the increase in discounts and allowances in 2007 versus 2006 was the higher level of Zanaflex revenues and related shipments.

Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the year ended December 31, 2007, consisted of \$1.6 million for fees for services to wholesalers, \$1.5 million for chargebacks and rebates and \$1.1 million in cash discounts and allowances. 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.

### *Grant Revenue*

Grant revenue for the year ended December 31, 2007 was \$60,000 compared to \$407,000 for the year ended December 31, 2006, a decrease of approximately \$347,000, or 85%. 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 \$8.4 million for the year ended December 31, 2007 as compared to \$7.1 million for the year ended December 31, 2006, an increase of approximately \$1.3 million, or 17%. Cost of sales for the year ended December 31, 2007 consisted of \$3.0 million in royalty fees, \$3.9 million in inventory costs, \$1.2 million in amortization of intangible assets, and \$222,000 in costs related to packaging, freight and stability testing. 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 in 2006 due to lower than anticipated sales of Zanaflex Capsules and because Zanaflex Capsules inventory had 36 month dating at the time. During the three-month period ended June 30, 2007, results from stability testing performed on Zanaflex Capsules by our manufacturing partner, Elan, supported an increase in Zanaflex Capsules expiration dating from 36 months to 48 months.

### *Research and Development*

Research and development expenses for the year ended December 31, 2007 were \$22.4 million as compared to \$12.1 million for the year ended December 31, 2006, an increase of approximately \$10.3 million, or 86%. The increase in research and development expenses was primarily due the initiation of our second Phase 3 trial for Fampridine-SR and expenses related to our Thorough QT cardiac study and NDA preparation. Our MS clinical development program expense increased to \$10.8 million for the year ended December 31, 2007 from \$6.0 million for the year ended December 31, 2006, an increase of \$4.8 million or 80%, primarily due to the continuation of our second Phase 3 clinical trial of Fampridine-SR which began in June 2007 and the Thorough QT cardiac study which was conducted during the second half of 2007 and the results of which were announced in January 2008.

Operating expenses for clinical development, preclinical research and development and regulatory were \$9.5 million for the year ended December 31, 2007, compared to \$5.1 million for the year ended December 31, 2006, an increase of \$4.4 million, or 85%. This increase was primarily attributable to an increase in regulatory expenses of \$3.1 million for the preparation of an NDA for Fampridine-SR and related salaries, non-cash charges related to share-based compensation and benefits and consulting fees and approximately \$854,000 in increased salaries, non-cash charges related to share-based compensation and benefits in clinical and preclinical research and development.

Other contract expenses increased to \$2.0 million for the year ended December 31, 2007, from \$904,000 for the year ended December 31, 2006, an increase of \$1.1 million or 127%, including an increase of \$617,000 for manufacturing and stability fees related to Fampridine-SR and an increase of \$482,000 for preclinical programs related primarily to antibody development with the Mayo Clinic.

### *Sales and Marketing*

Sales and marketing expenses for the year ended December 31, 2007 were \$30.7 million compared to \$19.1 million for the year ended December 31, 2006, an increase of approximately

\$11.6 million, or 61%. This increase was primarily attributable to an increase in salaries and benefits of \$5.8 million, other selling related expenses of \$2.0 million resulting from the expansion of our Zanaflex Capsules specialty sales force, that was completed during the three-month period ended March 31, 2007, an increase in marketing expenses of \$2.3 million of which \$829,000 was related to pre-launch activities associated with the possible commercialization of Fampridine-SR, if approved and an increase of \$1.5 million in non-cash charges related to share-based compensation.

#### *General and Administrative*

General and administrative expenses for the year ended December 31, 2007 were \$17.4 million compared to \$12.6 million for the year ended December 31, 2006, an increase of approximately \$4.8 million, or 39%. This increase is primarily attributable to a \$1.8 million increase in non-cash charges related to share-based compensation, an increase in medical affairs expenses of \$791,000, an increase in general and administrative compensation expense of \$599,000 due to employee headcount and salary increases, an increase in other third party services of \$364,000 resulting from costs associated with compliance activities from being a publicly traded company, an increase in business development expenses of \$211,000, an increase of \$206,000 in patent prosecution and defense expenses, an increase in depreciation primarily related to the expansion of our Hawthorne facility of \$171,000 and an increase in the loss related to the PRF put/call valuation of \$163,000.

#### *Other Income (Expense)*

Other income (expense) was \$1.5 million in income for the year ended December 31, 2007 compared to an expense of \$1.0 million for the year ended December 31, 2006, an increase of approximately \$2.5 million, or 246%. This increase was largely due to an increase of \$2.6 million in interest income as a result of the investment of the net proceeds from our follow-on public offering completed in July 2007, offset by an increase in interest expense of \$110,000 principally related to the PRF revenue interest agreement.

#### *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, we changed our 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 for the twelve-months ending December 31, 2006 of \$454,000 compared to none for the year ended December 31, 2007. 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 decreased from \$36.0 million for the twelve-month period ended December 31, 2006 to no charge for the twelve-month period ended December 31, 2007, due to the recognition of the remaining unamortized portion of beneficial conversion charges and issuance costs and reversal of the cumulative preferred dividend upon the completion of our initial public offering of our common stock in February 2006. No further charges are necessary.

***Liquidity and Capital Resources***

We have incurred annual operating losses since inception and, as of December 31, 2008, we had an accumulated deficit of approximately \$344.4 million. We have financed our operations primarily through public offerings of our common stock, private placements of our securities, our financing arrangement with PRF and, to a lesser extent, from loans and government grants.

We completed a follow-on public offering in February 2008 in which approximately 3.7 million shares of our common stock were sold, resulting in proceeds of approximately \$74.6 million, net of issuance costs.

We completed a follow-on public offering in August 2008 in which approximately 4.6 million shares of our common stock were sold, resulting in proceeds of approximately \$126.6 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, Elan transferred these promissory notes to funds affiliated with Saints Capital. As of December 31, 2008, \$5.0 million of these promissory notes were outstanding. In January 2005, we entered into a \$6.0 million senior secured term loan which was repaid during the three-month period ended March 31, 2008.

On December 23, 2005, we entered into a revenue interest 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 interest 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 in February 2007 since our net revenues during the fiscal year 2006 exceeded \$25.0 million. 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 recorded a liability as of December 31, 2008, referred to as the revenue interest liability, of approximately \$18.7 million in accordance with EITF 88-18, *Sales of Future Revenues*. We impute interest expense associated with this liability using the effective interest rate method and 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 6.2%. 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.

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 \$337,500 as of December 31, 2008 related to the put/call option to reflect its current estimated fair value, in accordance with SFAS No. 133, *Accounting for Derivatives Instruments and Hedging Activities*. This liability is revalued on a semi-annual 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.

#### *Investment Activities*

At December 31, 2008, cash and cash equivalents and short-term investments were approximately \$246.0 million, as compared to \$95.1 million at December 31, 2007. 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 a Treasury money market fund and high-quality government 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, 2008, our cash and cash equivalents were \$29.6 million, as compared to

\$16.8 million as of December 31, 2007. Our short-term investments consist of US Treasury bonds, and commercial paper securities with original maturities greater than three months and less than one year. The balance of these investments was \$216.4 million as of December 31, 2008, as compared to \$78.3 million as of December 31, 2007.

#### *Net Cash Used in Operations*

Net cash used in operations was \$49.2 million and \$25.7 million for the years ended December 31, 2008 and 2007, respectively. Cash used in operations for the year ended December 31, 2008 was primarily attributable to a net loss of \$74.3 million, amortization of the discount on short-term investments of \$3.1 million, an increase in prepaid expenses and other current assets of \$1.3 million, an increase in inventory held by others of \$598,000, and an increase in accounts receivable of \$357,000. Cash used in operations for the year ended December 31, 2008 was partially offset by an increase in accounts payable, accrued expenses, and other current liabilities of \$8.8 million, a non-cash share-based compensation expense of \$9.8 million, depreciation and amortization of \$3.5 million, a non-cash expense for the acquisition of NRI assets of \$2.7 million, an increase in Zanaflex Capsules deferred product revenue of \$2.5 million and a decrease in inventory of \$3.3 million. Cash used in operations for the year ended December 31, 2007 was primarily attributable to a net loss of \$38.0 million, amortization of the discount on short-term investments of \$3.0 million, a decrease in Zanaflex tablets deferred product revenue of \$1.2 million and an increase in prepaid expenses and other current assets of \$970,000. Cash used in operations for the year ended December 31, 2007 was partially offset by a non-cash share-based compensation expense of \$7.8 million, an increase in accounts payable, accrued expenses, and other current liabilities of \$4.6 million, depreciation and amortization of \$2.3 million, and an increase in Zanaflex Capsules deferred product revenue of \$2.6 million.

#### *Net Cash Used in Investing*

Net cash used in investing activities for the year ended December 31, 2008 was \$141.3 million, primarily due to \$326.0 million in purchases of short-term investments, a \$5.0 million payment for the purchase of intangible assets due to the final Elan Zanaflex milestone, and purchases of property and equipment of \$1.8 million, offset by \$191.6 million in proceeds from maturities and sales of short-term investments.

#### *Net Cash Provided by Financing*

Net cash provided by financing activities for the year ended December 31, 2008 was \$203.2 million, primarily due to \$205.1 million in net proceeds from the issuance of common stock and exercise of stock options which was partially offset by \$1.6 million in repayments to PRF and \$188,000 for 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, revenue from Fampridine-SR, if approved, 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 support our sales and marketing infrastructure for the commercialization of Zanaflex Capsules, increase our efforts to support pre-launch activities for



Fampridine-SR and its commercialization, if approved, and continue our clinical development and advance our preclinical programs.

We believe our year-end 2009 cash, cash equivalents and investment balances will be in excess of \$150.0 million and that our current financial resources and sources of liquidity will be sufficient to fund operations and meet financial obligations through 2010 based on our current projected revenue and spending levels. To the extent our capital resources are insufficient to meet future operating requirements we will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund its 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 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 Saints 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 interest assignment arrangement with PRF.

In July 2004, we acquired all of Elan's research and development, distribution, and sales and marketing rights to Zanaflex Capsules and Zanaflex tablets in the United States. Under our Zanaflex purchase agreement with Elan, we were 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, 2008, we have made all of these milestone payments. The final \$5.0 million milestone was reached in January 2008 and was paid in the three-month period ended June 30, 2008. 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, 2008, the forecast requirement for the five-month period following December 31, 2008 amounted to approximately \$3.8 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. The first milestone

payment is due to Elan 90 days following the FDA's approval of a NDA for Fampridine-SR's use for the first indication and further milestone amounts are payable in connection with additional indications.

In December 2005, we entered into a revenue interest 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 million at signing. 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.

In November 2006, we entered into an amendment to the revenue interest 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 was met and the receivable was 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, 2008. This table does not include certain contingent payments as to which we cannot reasonably determine amount and timing 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. This table should be read in conjunction with the accompanying notes to our consolidated financial statements:

	Payments due by period			
	Total	Less than 1 year	1-3 years	3-5 years
PRF Payments(1) . . . . .	\$10,000	\$ 5,000	\$5,000	\$ —
Accrued Interest on Convertible Notes Payable(2) . . . . .	1,128	207	446	475
Operating Lease . . . . .	4,000	1,000	2,000	1,000
Inventory Purchase Commitment . . . . .	3,800	3,800	—	—
Total . . . . .	<u>\$18,928</u>	<u>\$10,007</u>	<u>\$7,446</u>	<u>\$1,475</u>

- (1) PRF payments represent the two \$5 million payments due to PRF on December 1, 2009 and December 1, 2010 and exclude principal and interest payments, due to uncertainty as to the amount and timing of such payments.
- (2) Represents accrued interest on the convertible note on the assumption that it remains outstanding during these periods. The table does not reflect the repayment of principal, due to the contingent nature of any such repayment and the timing thereof.

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 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, 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 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, 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 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 share-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 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, clinical trial vendors, contract manufacturing for our preclinical program, and regulatory consulting to support our NDA filing. 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. All research and development costs are expensed as incurred except where EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* applies. In these cases, non-refundable advance payments for goods and services that will be used in future research and development activities are capitalized at the time of payment and expensed when the research and development activity has been performed.

#### *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, 2008 and 2007. We have provided a valuation allowance for the full amount of our gross 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, 2008.

As of December 31, 2008, we had available net operating loss carry-forwards of approximately \$262.2 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 2028 and research and development tax credit carry-forwards of approximately \$1.6 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.

#### **Share-Based Compensation**

We account for stock options and restricted stock granted to employees according to the provisions of SFAS No. 123R, *Share Based Payment*, 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 of January 1, 2006.

We estimate the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions for the expected term of the stock options, expected volatility of our common stock, prevailing interest rates, and an estimated forfeiture rate.

We have based our current assumptions on the following:

<u>Assumption</u>	<u>Method of estimating</u>
● Estimated expected term of options . . .	● Based on the 50 <sup>th</sup> percentile of our peer companies
● Expected volatility . . . . .	● Combination of historic volatility of our common stock since October 1, 2006 and the historic volatility of the stock of our peer companies
● Risk-free interest rate . . . . .	● Yields of U.S. Treasury securities corresponding with the expected life of option grants
● Forfeiture rates . . . . .	● Historical forfeiture data

Of these assumptions, the expected term of the option and expected volatility of our common stock are the most difficult to estimate since they are based on the exercise behavior of the employees and expected performance of our common stock. Increases in the term and the volatility of our common stock will generally cause an increase in compensation expense.

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, grants receivable, notes payable, convertible notes payable, accounts payable, and put/call liability. The estimated fair values of all of our financial instruments approximate their carrying amounts at December 31, 2008.

We have cash equivalents and short-term investments at December 31, 2008, 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, US Treasury bonds and corporate debt securities, the carrying value of our cash equivalents and short-term investments approximate their fair value at December 31, 2008.

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, 2008, 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, 2008 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.

***Management's Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) of the Exchange Act).

Under the supervision of and with the participation of our chief executive officer and our chief financial officer, our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework and criteria established in Internal Control—Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management has concluded that, as of December 31, 2008, our internal control over financial reporting was effective.

KPMG LLP, the independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on the Company's internal control over financial reporting as of December 31, 2008. This attestation report appears below.

## Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders  
Acorda Therapeutics, Inc.:

We have audited Acorda Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Acorda Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Acorda Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.



We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Acorda Therapeutics, Inc. and subsidiary as of December 31, 2008 and 2007, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2008, and our report dated March 2, 2009 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

KPMG LLP

Short Hills, New Jersey

March 2, 2009

**Item 9B. Other Information.**

None.

## PART III

### **Item 10. Directors and Executive Officers of the Registrant.**

The information required by this item will be contained in our 2009 Proxy Statement under the captions “Discussion of Proposals,” “Information About Corporate Governance,” “Information About Our Executive Officers” and “Other Information” and is incorporated herein by this reference.

We have adopted a code of business conduct and ethics applicable to all of our directors and employees, including our principal executive officer, principal financial officer and our controller. The code of business conduct and ethics is available on the corporate governance section of “Investor Relations” of our website, *www.acorda.com*.

Any waiver of the code of business conduct and ethics for directors or executive officers, or any amendment to the code that applies to directors or executive officers, may only be made by the board of directors. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics by posting such information on its website, at the address and location specified above. To date, no such waivers have been requested or granted.

### **Item 11. Director and Executive Compensation.**

The information required by this item will be contained in our 2009 Proxy Statement under the captions “Corporate Governance,” “Information About Our Executive Officers” and “Other Information” and is incorporated herein by this reference.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item will be contained in our 2009 Proxy Statement under the captions “Information About Our Executive Officers” and “Other Information” and is incorporated herein by this reference.

### **Item 13. Certain Relationships and Related Transactions.**

The information required by this item will be contained in our 2009 Proxy Statement under the caption “Information About Our Executive Officers” and is incorporated herein by this reference.

### **Item 14. Principal Accountant Fees and Services.**

The information required by this item will be contained in our 2009 Proxy Statement under the caption “Discussion of Proposals” and is incorporated herein by this reference.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules.

#### (a) The following documents are being filed as part of this report:

- (1) The following financial statements of the Company and the Report of Independent Registered Public Accounting Firm are included in this Annual Report on Form 10-K:

Financial Statements of Acorda Therapeutics, Inc. and Subsidiary:

Report of KPMG LLP, Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2008 and 2007

Statements of Operations for the years ended December 31, 2008, 2007 and 2006

Statements of Changes in Stockholders' Equity for the years ended December 31, 2008, 2007 and 2006

Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006

Notes to Financial Statements

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders  
Acorda Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Acorda Therapeutics, Inc. and subsidiary (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2008. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Acorda Therapeutics, Inc. and subsidiary as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 2, 2009 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

KPMG LLP

Short Hills, New Jersey  
March 2, 2009

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**Consolidated Balance Sheets**

	December 31,	
	2008	2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 29,612,916	\$ 16,810,415
Restricted cash . . . . .	297,655	288,194
Short-term investments . . . . .	216,435,416	78,310,241
Trade accounts receivable, net . . . . .	4,622,486	4,265,581
Prepaid expenses . . . . .	3,330,069	2,341,585
Finished goods inventory held by the Company . . . . .	3,670,949	5,849,929
Finished goods inventory held by others . . . . .	2,472,692	1,874,405
Other current assets . . . . .	1,605,572	1,293,496
Total current assets . . . . .	262,047,755	111,033,846
Property and equipment, net of accumulated depreciation . . . . .	2,348,147	1,651,739
Intangible assets, net of accumulated amortization . . . . .	16,565,456	13,943,888
Other assets . . . . .	539,328	676,993
Total assets . . . . .	\$ 281,500,686	\$ 127,306,466
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 10,124,840	\$ 6,675,894
Accrued expenses and other current liabilities . . . . .	13,993,753	8,777,645
Deferred product revenue—Zanaflex tablets . . . . .	7,867,046	7,913,776
Deferred product revenue—Zanaflex Capsules . . . . .	16,436,474	13,923,781
Current portion of notes payable . . . . .	—	187,645
Current portion of revenue interest liability . . . . .	6,181,100	1,785,018
Total current liabilities . . . . .	54,603,213	39,263,759
Put/call liability . . . . .	337,500	462,500
Non current portion of revenue interest liability . . . . .	12,497,745	17,444,324
Long-term convertible notes payable . . . . .	6,904,883	6,703,235
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at December 31, 2008 and 2007 respectively; issued and outstanding 37,613,356 and 28,574,678 shares as of December 31, 2008 and 2007, respectively . . . . .	37,614	28,575
Additional paid-in capital . . . . .	550,683,383	333,144,050
Accumulated deficit . . . . .	(344,376,410)	(270,035,770)
Accumulated other comprehensive income . . . . .	812,758	295,793
Total stockholders' equity . . . . .	207,157,345	63,432,648
Total liabilities and stockholders' equity . . . . .	\$ 281,500,686	\$ 127,306,466

See accompanying Notes to Consolidated Financial Statements

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**Consolidated Statements of Operations**

	<u>Year ended December 31, 2008</u>	<u>Year ended December 31, 2007</u>	<u>Year ended December 31, 2006</u>
Gross sales—Zanaflex . . . . .	\$ 53,397,999	\$ 43,586,367	\$ 26,548,264
Discounts and allowances . . . . .	(5,670,048)	(4,160,356)	395,517
Net sales . . . . .	<u>47,727,951</u>	<u>39,426,011</u>	<u>26,943,781</u>
Grant revenue . . . . .	98,846	59,880	407,165
Total net revenue . . . . .	<u>47,826,797</u>	<u>39,485,891</u>	<u>27,350,946</u>
Less: cost of sales . . . . .	<u>(11,354,912)</u>	<u>(8,355,858)</u>	<u>(7,122,833)</u>
Gross profit . . . . .	36,471,885	31,130,033	20,228,113
Operating expenses:			
Research and development . . . . .	36,604,478	22,410,279	12,054,780
Sales and marketing . . . . .	49,069,841	30,736,544	19,079,013
General and administrative . . . . .	24,236,920	17,430,561	12,561,245
Total operating expenses . . . . .	<u>109,911,239</u>	<u>70,577,384</u>	<u>43,695,038</u>
Operating loss . . . . .	(73,439,354)	(39,447,351)	(23,466,925)
Other income (expense):			
Interest and amortization of debt discount expense . . . . .	(5,591,426)	(2,664,390)	(2,553,443)
Interest income . . . . .	4,682,055	4,086,521	1,471,334
Other income . . . . .	8,085	50,753	75,437
Total other income (expense) . . . . .	<u>(901,286)</u>	<u>1,472,884</u>	<u>(1,006,672)</u>
Cumulative effect of change in accounting principle . . . . .	—	—	454,225
Net loss . . . . .	<u>(74,340,640)</u>	<u>(37,974,467)</u>	<u>(24,019,372)</u>
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders . . . . .	—	—	(36,007,456)
Net loss allocable to common stockholders . . . . .	<u>\$ (74,340,640)</u>	<u>\$ (37,974,467)</u>	<u>\$ (60,026,828)</u>
Net loss per share allocable to common stockholders—basic and diluted . . . . .	\$ (2.19)	\$ (1.45)	\$ (3.27)
Weighted average common shares outstanding used in computing net loss per share allocable to common stockholders—basic and diluted . . . . .	33,938,980	26,236,781	18,345,543

See accompanying Notes to Consolidated Financial Statements



**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**Consolidated Statements of Changes in Stockholders' Equity**

	Stockholders' equity														Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series F convertible preferred stock		Series H convertible preferred stock		Common Stock		Additional paid-in capital	Accumulated Deficit		
	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value				
Balance at December 31, 2005 . . . . .	1,306,068	\$ 1,306	900,000	\$ 900	333,333	\$ 333	2,300,000	\$ 2,300	1,575,229	\$ 1,575	208,732	\$ 209	\$ 91,501,190	\$ (208,041,931)	\$ (1,560)	\$ (116,535,678)
Research and development expense for issuance of stock options to nonemployees . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	1,444	—	—	1,444
Compensation expense for issuance of stock options to employees . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	2,087,602	—	—	2,087,602
Compensation expense for issuance of restricted stock to employees . . . . .	—	—	—	—	—	—	—	—	—	—	340,760	341	1,755,167	—	—	1,755,508
Exercise of stock options . . . . .	—	—	—	—	—	—	—	—	—	—	220,105	220	669,452	—	—	669,672
Accretion of issuance costs related to mandatorily redeemable convertible preferred stock . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	(270,725)	—	—	(270,725)
Accrual of preferred dividends of Series J mandatorily redeemable convertible preferred stock . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	12,734,009	—	—	12,734,009
Deemed dividends on preferred stock for issuance of preferred stock with beneficial conversion feature . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	(48,470,740)	—	—	(48,470,740)
Conversion convertible preferred stock to common stock . . . . .	(1,306,068)	(1,306)	(900,000)	(900)	(333,333)	(333)	(2,300,000)	(2,300)	(1,575,229)	(1,575)	13,338,278	13,337	127,212,872	—	—	127,219,795
Common stock issued pursuant to IPO, net of offering costs of \$4,994,373 . . . . .	—	—	—	—	—	—	—	—	—	—	6,075,614	6,076	31,453,233	—	—	31,459,309
Common stock issued pursuant to private placement, net of offering costs of \$1,718,584 . . . . .	—	—	—	—	—	—	—	—	—	—	3,230,769	3,231	29,778,183	—	—	29,781,414
Common stock issued pursuant to cashless exercise of warrants . . . . .	—	—	—	—	—	—	—	—	—	—	32,634	33	195,773	—	—	195,806
Common stock issued pursuant to conversion of convertible note . . . . .	—	—	—	—	—	—	—	—	—	—	210,863	211	2,499,789	—	—	2,500,000
Cumulative effect of change in accounting principle . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	(454,225)	—	—	(454,225)
<i>Comprehensive loss</i>	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Unrealized gain on investment securities . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	14,900	14,900
Net loss . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	(24,019,372)	—	(24,019,372)
<i>Total comprehensive loss</i> . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(24,004,472)
<b>Balance at December 31, 2006</b> . . . . .	—	—	—	—	—	—	—	—	—	—	<b>23,657,755</b>	<b>\$23,658</b>	<b>\$250,693,024</b>	<b>\$(232,061,303)</b>	<b>\$13,340</b>	<b>\$ 18,668,719</b>

See accompanying Notes to Consolidated Financial Statements.

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**Consolidated Statements of Changes in Stockholders' Equity (Continued)**

	Stockholders' equity														Additional paid-in capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series F convertible preferred stock		Series H convertible preferred stock		Common Stock							
	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value						
Research and development expense for issuance of stock options to nonemployees . . .	—	—	—	—	—	—	—	—	—	—	—	—	\$	357	—	—	\$	357
Compensation expense for issuance of stock options to employees . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	5,890,879	—	—	—	5,890,879	
Compensation expense for issuance of restricted stock to employees . . . . .	—	—	—	—	—	—	—	—	—	342,682	343	1,904,897	—	—	—	—	1,905,240	
Exercise of stock options . . . . .	—	—	—	—	—	—	—	—	—	367,912	368	2,325,666	—	—	—	—	2,326,034	
Common stock issued pursuant to follow-on offering, net of offering costs of \$5,290,961 . . .	—	—	—	—	—	—	—	—	—	4,189,460	4,189	72,209,859	—	—	—	—	72,214,048	
Expense related to private placement . . . . .	—	—	—	—	—	—	—	—	—	—	—	(80,615)	—	—	—	—	(80,615)	
Common stock issued pursuant to exercise of warrants . . . . .	—	—	—	—	—	—	—	—	—	16,869	17	199,983	—	—	—	—	200,000	
<i>Comprehensive loss</i>																		
Unrealized gain on investment securities . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	282,453	—	282,453
Net loss . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(37,974,467)	—	—	(37,974,467)
<i>Total comprehensive loss</i> . . . . .																		(37,692,014)
<b>Balance at December 31, 2007</b> . . . . .	—	—	—	—	—	—	—	—	—	<b>28,574,678</b>	<b>\$28,575</b>	<b>\$333,144,050</b>	<b>\$(270,035,770)</b>	<b>\$295,793</b>	<b>\$63,432,648</b>			

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**Consolidated Statements of Changes in Stockholders' Equity (Continued)**

	Stockholders' equity															
	Series A convertible preferred stock		Series B convertible preferred stock		Series C convertible preferred stock		Series F convertible preferred stock		Series H convertible preferred stock		Common Stock		Additional paid-in capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value	Number of shares	Par value				
Research and development expense for issuance of stock options to nonemployees . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	\$ 252,754	—	—	\$ 252,754
Compensation expense for issuance of stock options to employees . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	8,046,376	—	—	8,046,376
Compensation expense for issuance of restricted stock to employees . . . . .	—	—	—	—	—	—	—	—	—	—	102,886	103	1,505,753	—	—	1,505,856
Exercise of stock options . . . . .	—	—	—	—	—	—	—	—	—	—	523,792	524	3,835,461	—	—	3,835,985
Common stock issued pursuant to follow-on offerings, net of offering costs of \$9,686,600 . . . . .	—	—	—	—	—	—	—	—	—	—	8,312,000	8,312	201,213,089	—	—	201,221,401
Stock issued pursuant to NRI asset acquisition . . . . .	—	—	—	—	—	—	—	—	—	—	100,000	100	2,685,900	—	—	2,686,000
<i>Comprehensive loss</i>																
Unrealized gain on investment securities . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	516,965	516,965
Net loss . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	(74,340,640)	—	(74,340,640)
<i>Total comprehensive loss</i> . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(73,823,674)
<b>Balance at December 31, 2008</b> . . . . .	—	—	—	—	—	—	—	—	—	—	<b>37,613,356</b>	<b>\$37,614</b>	<b>\$550,683,383</b>	<b>\$(344,376,410)</b>	<b>\$812,758</b>	<b>\$207,157,345</b>

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**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**Consolidated Statements of Cash Flows**

	<u>Year ended December 31, 2008</u>	<u>Year ended December 31, 2007</u>	<u>Year ended December 31 2006</u>
Cash flows from operating activities:			
Net loss . . . . .	\$ (74,340,640)	\$ (37,974,467)	\$(24,019,372)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock compensation expense . . . . .	9,804,986	7,796,476	3,844,554
NRI asset acquisition . . . . .	2,686,000	—	—
Amortization of note discount . . . . .	—	—	55,944
Amortization of discount on short-term investments . . . . .	(3,124,056)	(2,973,325)	(332,069)
Cumulative effect of change in accounting principle . . . . .	—	—	(454,225)
Amortization of revenue interest issuance cost . . . . .	89,235	65,861	72,741
Accretion of discount . . . . .	—	—	47,282
Realized/unrealized gain/loss on warrants . . . . .	—	—	46,782
Depreciation and amortization expense . . . . .	3,480,768	2,252,462	1,785,941
Gain (loss) on put/call liability . . . . .	(125,000)	112,500	(50,000)
(Gain) loss on disposal of property and equipment . . . . .	—	(23,750)	587
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable . . . . .	(356,905)	50,518	(3,726,847)
(Increase) decrease in prepaid expenses and other current assets . . . . .	(1,300,560)	(969,651)	1,426,341
(Increase) decrease in inventory held by the Company . . . . .	3,330,916	343,180	1,165,466
Increase in inventory held by others . . . . .	(598,287)	(354,341)	(349,461)
Decrease (increase) in other assets . . . . .	48,430	(8,536)	(18,528)
Increase (decrease) in accounts payable, accrued expenses, other liabilities . . . . .	8,793,339	4,623,743	(4,817,846)
Decrease in returns liability . . . . .	—	—	(1,831,211)
Decrease in deferred product revenue—Zanaflex tablets . . . . .	(46,730)	(1,203,199)	(2,392,623)
Increase in deferred product revenue—Zanaflex Capsules . . . . .	2,512,693	2,599,620	6,098,054
Restricted cash . . . . .	(9,461)	(13,813)	(11,388)
Net cash used in operating activities . . . . .	<u>(49,155,272)</u>	<u>(25,676,722)</u>	<u>(23,459,878)</u>
Cash flows from investing activities:			
Purchases of property and equipment . . . . .	(1,806,443)	(1,336,068)	(527,458)
Purchases of intangible assets . . . . .	(5,000,000)	(10,000,000)	—
Purchases of short-term investments . . . . .	(326,034,154)	(147,148,940)	(46,293,380)
Proceeds from maturities of short-term investments . . . . .	191,550,000	107,750,000	12,986,000
Net cash used in investing activities . . . . .	<u>(141,290,597)</u>	<u>(50,735,008)</u>	<u>(33,834,838)</u>
Cash flows from financing activities:			
Net proceeds from issuance of common stock and option and warrant exercises . . . . .	205,057,386	74,659,467	61,910,395
Proceeds from sale of revenue interest . . . . .	—	5,000,000	5,000,000
Repayments of revenue interest liability . . . . .	(1,621,371)	(3,494,281)	(2,245,012)
Repayments of notes payable . . . . .	(187,645)	(1,043,949)	(1,031,058)
Net cash provided by financing activities . . . . .	<u>203,248,370</u>	<u>75,121,237</u>	<u>63,634,325</u>
Net increase (decrease) in cash and cash equivalents . . . . .	12,802,501	(1,290,493)	6,339,609
Cash and cash equivalents at beginning of period . . . . .	16,810,415	18,100,908	11,761,299
Cash and cash equivalents at end of period . . . . .	<u>\$ 29,612,916</u>	<u>\$ 16,810,415</u>	<u>\$ 18,100,908</u>
Supplemental disclosure:			
Cash paid for interest . . . . .	\$ 3,874,525	\$ 2,312,453	\$ 1,950,420
Non-cash charges related to convertible preferred stock:			
Beneficial conversion feature . . . . .	—	—	48,470,740
Accretion of issuance costs . . . . .	—	—	270,725
Preferred dividend . . . . .	—	—	(12,734,009)
Non-cash activities:			
Conversion of preferred stock to common stock . . . . .	—	—	127,219,795
Accrued inventory . . . . .	1,151,936	1,492,084	279,649
Accrued Zanaflex milestone payments . . . . .	—	—	5,000,000
Conversion of note payable into common stock . . . . .	—	—	2,500,000
Conversion of warrant payable into common stock . . . . .	—	—	207,501

See accompanying Notes to Consolidated Financial Statements.

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**Notes to Consolidated Financial Statements**

**(1) Organization and Business Activities**

Acorda Therapeutics, Inc. (“Acorda” or the “Company”) 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 (MS), spinal cord injury and other disorders of the central nervous system.

The Company completed an initial public offering in February 2006. As part of that offering, 6,075,614 shares of the Company’s common stock were sold, resulting in net proceeds of approximately \$31.5 million after deducting the underwriting discount and offering expenses payable by the Company.

The Company completed a private placement in October 2006. As part of that offering, 3,230,769 shares of the Company’s common stock were sold, resulting in proceeds to the Company of approximately \$29.8 million, net of issuance costs.

The Company completed a follow-on public offering of its common stock in July 2007. As part of that offering, 4,189,460 shares of the Company’s common stock were sold, resulting in proceeds of approximately \$72.2 million, net of issuance costs.

The Company completed a follow-on public offering of its common stock in February 2008. As part of that offering, 3,712,000 shares of the Company’s common stock were sold, resulting in proceeds of approximately \$74.6 million, net of issuance costs.

The Company completed a follow-on public offering of its common stock in August 2008. As part of that offering, 4,600,000 shares of the Company’s common stock were sold, resulting in proceeds of approximately \$126.6 million, net of issuance costs.

The Company finances its operations through a combination of issuance of equity securities, revenues from Zanaflex Capsules, loans and, to a lesser extent, grants. There are no assurances that the Company will be successful in obtaining an adequate level of financing needed to fund its development and commercialization efforts. The Company believes that its current financial resources and sources of liquidity will be sufficient to fund operations and meet financial obligations through 2010 based on the Company’s currently projected revenue and spending levels. To the extent the Company’s capital resources are insufficient to meet future operating requirements, the Company will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund its operations. The Company may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, the Company may be required to curtail its sales and marketing efforts, delay, reduce the scope of or eliminate some of its 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 it might otherwise seek to develop or commercialize independently.

**(2) Summary of Significant Accounting Policies**

***Principles of Consolidation***

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America and include the results of operations of the Company and its majority owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

### **Use of Estimates**

The preparation of the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include research and development (clinical trial accrual) and share-based compensation accounting, which are largely dependent on the fair value of the Company's equity securities. In addition, the Company recognizes revenue based on estimated prescriptions filled. The Company adjusts its inventory value based on an estimate of inventory that may be returned. Actual results could differ from those estimates.

### **Cash and Cash Equivalents**

The Company considers all highly liquid debt instruments with original maturities of three months or less from date of purchase to be cash equivalents. All cash and cash equivalents are held in highly rated securities including a Treasury money market fund and US Treasury bonds, which are unrestricted as to withdrawal or use. To date, the Company has not experienced any losses on its cash and cash equivalents. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term and liquid nature.

### **Restricted Cash**

Restricted cash represents a certificate of deposit placed by the Company with a bank for issuance of a letter of credit to the Company's lessor for office space.

### **Short-Term Investments**

Short-term investments consist of highly rated corporate securities including industrial issuers and US Treasury bonds with maturities greater than three months. In accordance with Statement of Financial Accounting Standards (SFAS) No. 115 (SFAS 115), *Accounting for Certain Investments in Debt and Equity Securities*, the Company classifies its short-term investments as available-for-sale. Available-for-sale securities are recorded at fair value of the investments based on quoted market prices. The Company considers all of these investments to be available-for-sale.

Unrealized holding gains and losses on available-for-sale securities, which are determined to be temporary, are excluded from earnings and are reported as a separate component of other comprehensive income.

Premiums and discounts on investments are amortized over the life of the related available-for-sale security as an adjustment to yield using the effective-interest method. Dividend and interest income are recognized when earned. Amortized premiums and discounts, dividend and interest income and realized gains and losses are included in interest income.

### **Inventory**

Inventory is stated at the lower of cost or market value and includes amounts for both Zanaflex tablet and Zanaflex Capsule inventories. Inventories consist of finished goods. Cost is determined using the first-in, first-out method (FIFO) for all inventories. The Company adjusts its inventory value based on an estimate of inventory that may be returned or not sold based on sales projections and has established reserves for obsolescence and excess inventory.

### **Property and Equipment**

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful lives of the assets, which range from three to seven years. Leasehold improvements are recorded at cost, less accumulated amortization, which is computed on the straight-line basis over the shorter of the useful lives of the assets or the remaining lease term. Expenditures for maintenance and repairs are charged to expense as incurred.

### **Intangible Assets**

The Company has recorded intangible assets related to its Zanaflex acquisition. These intangible assets are amortized on a straight line basis over the period in which the Company expects to receive economic benefit and are reviewed for impairment when facts and circumstances indicate that the carrying value of the asset may not be recoverable. The determination of the expected life will be dependent upon the use and underlying characteristics of the intangible asset. In the Company's evaluation of the intangible assets, it considers the term of the underlying patent life and the expected life of the product line. If the carrying value is not recoverable, impairment is measured as the amount by which the carrying value exceeds its estimated fair value. Fair value is generally estimated based on either appraised value or other valuation techniques.

### **Impairment of Long-Lived Assets**

In accordance with the Financial Accounting Standards Board (FASB) SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired. The Company evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related assets. Any write-downs are treated as permanent reductions in the carrying amount of the assets. Based on this evaluation, the Company believes that, as of each of the balance sheet dates presented, none of the Company's long-lived assets was impaired.

### **Patent Costs**

Patent application and maintenance costs are expensed as incurred.

### **Research and Development**

Research and development expenses include the clinical development costs associated with the Company's product candidates and research and development costs associated with the Company's preclinical programs. These expenses include internal research and development costs and the costs of research and development conducted on behalf of the Company by third parties, including sponsored university-based research agreements, clinical study vendors and preclinical contract manufacturers. All research and development costs are expensed as incurred except where Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* applies. In these cases, non-refundable advance payments for goods and services that will be used in future research and development activities are capitalized at the time of payment and expensed when the research and development activity has been performed. Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

## **Accounting for Income Taxes**

Income taxes are accounted for under the asset and liability method with deferred tax assets and liabilities recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be reversed or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance for the amounts of any tax benefits which, more likely than not, will not be realized.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, An Interpretation of FASB Statement No. 109*, Accounting for Income Taxes. In addition, in May 2007, the FASB issued FASB Staff Position FIN 48-1 which provided guidance on how an enterprise should determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits. The Interpretation and Staff Position establishes criteria for recognizing and measuring the financial statement tax effects of positions taken on a company's tax returns. A two-step process is prescribed whereby the threshold for recognition is a more likely-than-not test that the tax position will be sustained upon examination and the tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. The Company adopted FIN 48 as of January 1, 2007. The adoption of this Interpretation had no impact on the Company's results of operations or financial position. The Company has no reserves for uncertain tax positions.

## **Revenue Recognition**

The Company applies 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. The amount of future tablet returns is uncertain due to generic competition and customer conversion to Zanaflex Capsules. Zanaflex Capsules has limited historical return data. Due to the uncertainty of returns for both products, the Company is accounting for these product shipments using a deferred revenue recognition model. Under the deferred revenue model, the Company does not recognize revenue upon product shipment. For these product shipments, the Company invoices the wholesaler, records deferred revenue at gross invoice sales price, and classifies the cost basis of the product held by the wholesaler as a component of inventory. The Company recognizes revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized is based on (1) the estimated prescription demand-based on pharmacy sales for its products, and (2) the Company's analysis of third-party information, including third-party market research data. The Company's estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations. The Company's sales and revenue recognition reflects the Company's estimates of actual product prescribed to the end-user. The Company expects to be able to apply a more traditional revenue recognition policy such that revenue is recognized upon shipment to the customer when it believes it has sufficient data to develop reasonable estimates of expected returns based upon historical returns.

The Company's net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. Product shipping and handling costs are included in cost of sales. These reserves are recorded in accordance with EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer*, which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor's



products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement. At the time product is shipped to wholesalers, an adjustment is recorded for estimated chargebacks, rebates, and discounts. These reserves are established by management as its best estimate based on available information and are adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates and discounts are established based on the contractual terms with customers, analysis of historical levels of discounts, chargebacks and rebates, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for each product and anticipated introduction of competitive products. In addition, the Company records a charge to cost of goods sold for the cost basis of the estimated product returns the Company believes may ultimately be realized at the time of product shipment to wholesalers. The Company has recognized this charge at the date of shipment since it is probable that it will receive a level of returned products; upon the return of such product it will be unable to resell the product considering its expiration dating; and it can reasonably estimate a range of returns. This charge represents the cost basis for the low end of the range of the Company's estimated returns.

### ***Revenue Recognition—Grants***

Revenue related to research and development grants is recognized when the related research expenses are incurred and the Company's specific performance obligations under the terms of the respective contract are satisfied. To the extent expended, grant funding related to purchases of equipment is deferred and amortized over the shorter of the equipment's useful life or the life of the related contract. Revenue recognized in the accompanying consolidated financial statements is not subject to repayment. Payments, if any, received in advance of performance under the contract are deferred and recognized as revenue when earned.

### ***Concentration of Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of investments in cash and cash equivalents, restricted cash, accounts receivable and debt securities. The Company maintains cash and cash equivalents, restricted cash and debt securities with approved financial institutions. The Company is exposed to credit risks and liquidity in the event of default by the financial institutions or issuers of investments in excess of FDIC insured limits. The Company performs periodic evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any institution.

The Company is substantially dependent upon Elan for several activities related to the development and commercialization of Fampridine-SR. The Company will rely on Elan to assist with the U.S. Food and Drug Administration (FDA) review of the New Drug Application (NDA) for Fampridine-SR in multiple sclerosis. If Elan fails to assist the Company in a complete and timely manner the Company could incur delays in approval and commercialization of Fampridine-SR in MS.

The Company relies 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 the Company in either producing Zanaflex Capsules itself 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 the Company to demonstrate through bioequivalence studies and laboratory testing that the product made by the new supplier is equivalent to the current Zanaflex Capsules before the Company could distribute products from that supplier.

Prior to March 2007, the Company relied on a single manufacturer, Novartis, for the manufacture of Zanaflex tablets and for the supply of tizanidine, the active pharmaceutical ingredient (API) 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 the Company for the production of Zanaflex tablets. The Company has recently received FDA approval to use the tizanidine manufactured by a new supplier, Farmak, as the active ingredient in the production of Zanaflex Capsules. However, the Company is still required to obtain FDA approval for a new supplier of the tizanidine needed for the production of Zanaflex tablets. Elan has agreed to supply the Company with Novartis-manufactured tizanidine for the manufacture of Zanaflex tablets to satisfy supply requirements through the first quarter of 2010. If the Company fails to gain FDA approval of a new tizanidine supplier for Zanaflex tablets prior to February 2010, the Company may experience an interruption in its supply.

The Company is currently in contract negotiations with Patheon regarding the manufacture of Zanaflex tablets, and Patheon has agreed to manufacture 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 the Company locates an alternate source of supply. The Company 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. The Company could experience substantial delays before it is able to qualify any new supplier and transfer the required manufacturing technology to that supplier.

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

Similar to other pharmaceutical companies, the Company's principal customers are wholesale pharmaceutical distributors. The Company periodically assesses the financial strength of these customers and establishes allowances for anticipated losses, if necessary. To date, such losses have been minimal. Sales to the Company's top three customers, McKesson, Cardinal and AmerisourceBergen, represent 94% of accounts receivable as of both December 31, 2008 and 2007.

#### ***Allowance for Doubtful Accounts***

A portion of the Company's accounts receivable may not be collected due principally to customer disputes and sales returns. The Company provides reserves for these situations based on the evaluation of the aging of its trade receivable portfolio and an analysis of high-risk customers. The Company has not recognized an allowance as of December 31, 2008 or 2007, as management believes all outstanding accounts receivable are fully collectible.

#### ***Fair Value of Financial Instruments***

The fair value of a financial instrument represents the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced sale or liquidation. Significant differences can arise between the fair value and carrying amounts of financial instruments that are recognized at historical cost amounts. Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework

for measuring fair value and expands required disclosures about fair value measurements. Under the standard, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. The standard clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability.

The following methods are used to estimate the Company's financial instruments:

- (a) Cash equivalents, grants receivables, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these instruments;
- (b) Available-for-sale securities are recorded based primarily on quoted market prices;
- (c) Notes payable carrying value approximate fair value as the interest rates on these notes approximate market rate of interest; and

It is not practical for the Company to estimate the fair value of the convertible notes payable due to the specific provisions of these notes including the uncertainty of the timing of repayment which is dependent upon regulatory approval of certain products. The terms of these notes are disclosed at Note 10. See Note 16 for our discussion of fair value measurements.

### **Earnings per Share**

Net loss per share is computed in accordance with SFAS No. 128, *Earnings Per Share*, by dividing the net loss allocable to common stockholders by the weighted average number of shares of common stock outstanding. The Company has certain options, warrants, convertible preferred stock and mandatorily redeemable convertible preferred stock (see Notes 3 and 8), which have not been used in the calculation of diluted net loss per share because to do so would be anti-dilutive. As such, the numerator and the denominator used in computing both basic and diluted net loss per share allocable to common stockholders for each year are equal.

The following table shows dilutive common share equivalents outstanding, which are not included in earning per share calculations, as the effect of their inclusion is anti-dilutive during each period:

	Year Ended December 31,		
	2008	2007	2006
Convertible promissory note . . . . .	67,476	67,476	67,476
Options . . . . .	3,284,323	2,999,513	2,534,663
Warrants . . . . .	—	—	16,869
	<u>3,351,799</u>	<u>3,066,989</u>	<u>2,619,008</u>

The Company has reflected the beneficial conversion feature for Series E, Series I and Series J, accretion of issuance costs for Series E, Series I, Series J and Series K, and preferred dividend for Series J and Series K in the net loss allocable to common stockholders as set forth below.

	Beneficial conversion feature	Accretion of issuance costs	Preferred dividend
For the year ended December 31, 2008 . . . .	\$ —	\$ —	\$ —
For the year ended December 31, 2007 . . . .	—	—	—
For the year ended December 31, 2006 . . . .	48,470,740	270,725	(12,734,009)

### **Share-based Compensation**

The Company has various share-based employee and non-employee compensation plans, which are described more fully in Note 8.

On January 1, 2006, the Company adopted the provisions of SFAS 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. The Company 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 were not restated.

The Company accounts 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*.

### **Segment Information**

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product candidates or by location and does not have separately reportable segments as defined by SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

### **Comprehensive Income**

SFAS No. 130, *Reporting Comprehensive Income* (SFAS No. 130) establishes standards for the reporting and display of comprehensive income (loss) and its components in a full set of financial statements. SFAS No. 130 requires that unrealized gains (losses) from the Company's investment securities be included in other comprehensive income (loss).

### **Reclassification**

Certain prior period amounts have been reclassified to conform to current year presentation.

### **Recent Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which permits an entity to measure certain financial assets and financial liabilities at fair value on an instrument by instrument basis. Under SFAS 159, entities that elect the fair value option will report unrealized gains and losses in earnings at each subsequent reporting date. For the Company, SFAS 159 is effective as of January 1, 2008, but the Company did not elect to measure any additional financial instruments at fair value as a result of this statement. Therefore, the adoption of SFAS 159 did not have a material impact on our consolidated financial statements.

In June 2007, EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* was issued. EITF Issue No. 07-3 provides guidance concerning the accounting for non-refundable advance payments for goods and services that will be used in future R&D activities and requires that they be expensed when the research and development activity has been performed and not at the time of payment. The Company adopted EITF No. 07-3 as of January 1, 2008. The adoption has not had an impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*. This statement is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited, and generally applies to business acquisitions completed after December 31, 2008. Among other things, the new standard requires that all acquisition-related costs be expensed as incurred, that acquired in-process research and development be recorded at fair value as an indefinite-lived asset at the acquisition date and that all restructuring costs related to acquired operations be expensed as incurred. This new standard also addresses the current and subsequent accounting for assets and liabilities arising from contingencies acquired or assumed and, for acquisitions both prior and subsequent to December 31, 2008, requires the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly in contributed capital, depending on the circumstances. The Company does not expect the adoption of SFAS No. 141R to have a material impact on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 160 will change the accounting for minority interests, which will be recharacterized as noncontrolling interests and classified by the parent company as a component of equity. This statement is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited. Upon adoption, SFAS No. 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests and prospective adoption for all other requirements. The Company does not expect the adoption of SFAS No. 160 to have a material impact on its consolidated financial statements.

In April 2008, the FASB issued Final FASB Staff Position (FSP), FAS 142-3, *Determination of the Useful Life of Intangible Assets*, which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. This FSP shall be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company will ascertain its impact, if any, during the three-month period ending March 31, 2009.

In October 2008, the FASB issued FASB Staff Position (FSP), FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies the application of FASB SFAS No. 157, *Fair Value Measurements*, in a market that is not active and illustrates key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP does not currently have an impact on our financial statements.

### **(3) Equity**

#### ***Offerings of Common Stock***

The Company completed an initial public offering (IPO) on February 9, 2006. As part of that offering, 6,075,614 shares of the Company's common stock were sold, resulting in net proceeds of approximately \$31.5 million after deducting the underwriting discount and offering expenses payable by the Company.

Upon the closing of the IPO, all of the Company's convertible preferred stock and mandatorily redeemable convertible preferred stock was converted into 13,338,278 shares of common stock. This conversion resulting 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) net reversal of accrued preferred dividends on Series J and Series K preferred stock of \$12.7 million.

The Company completed a private placement of its common stock in October 2006. As part of that offering, 3,230,769 shares of the Company's common stock were sold, resulting in proceeds to the Company of approximately \$29.8 million net of issuance costs.

The Company completed a follow-on public offering in July 2007. As part of that offering, 4,189,460 shares of the Company's common stock were sold, resulting in proceeds of approximately \$72.2 million, net of issuance costs.

The Company completed a follow-on public offering in February 2008. As part of that offering, 3,712,000 shares of the Company's common stock were sold, resulting in proceeds of approximately \$74.6 million, net of issuance costs.

The Company completed a follow-on public offering in August 2008. As part of that offering, 4,600,000 shares of the Company's common stock were sold, resulting in proceeds of approximately \$126.6 million, net of issuance costs.

### **Warrants**

As part of the Elan Zanaflex purchase agreement, warrants to purchase 16,869 shares of common stock were issued for an aggregate exercise price of \$11.856. These warrants were transferred by Elan to Saints Capital IV, L.P. and Saints Capital V, L.P., together Saints Capital, in December 2005 and were exercised in January 2007 for an aggregate of \$200,000.

### **(4) Short-Term Investments**

The Company has accounted for its investments in accordance with SFAS No. 115 and determined that all of its short-term investments are classified as available-for-sale. Available-for-sale securities are carried at fair value with interest on these securities included in interest income. Available-for-sale securities consisted of the following:

	<u>Amortized Cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Estimated fair value</u>
2008				
Commercial paper . . . . .	\$119,302,891	\$585,564	\$ —	\$119,888,455
US Treasury bonds . . . . .	96,319,767	228,848	(1,654)	96,546,961
2007				
Commercial paper . . . . .	77,018,656	295,855	—	77,314,511
Corporate bonds . . . . .	995,792	—	(62)	995,730

The contractual maturities of available-for-sale debt securities at December 31, 2008 and 2007 are within one year.

A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value in accordance with FASB Staff Position (FSP) FAS No. 115-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. The impairment would be charged to earnings for the difference between the investment's cost and fair value at such date and a new cost basis for the security established. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the issuer; adverse changes in the general market condition in which the issuer operates; the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment; and, issues that raise concerns about the issuer's ability to continue as a going concern. The Company has determined that there were no

other-than-temporary declines in the fair values of its short term investments as of December 31, 2008.

Short-term investments with maturity of three months or less from date of purchase have been classified as cash and cash equivalents, and amounted to \$27,283,767 and \$15,766,935 as of December 31, 2008 and 2007, respectively.

## (5) Property and Equipment

Property and equipment consisted of the following:

	December 31, 2008	December 31, 2007	Estimated useful lives
Laboratory equipment . . . . .	\$ 1,746,163	\$ 2,299,170	5 years
Furniture and fixtures . . . . .	753,258	626,649	5 years
Computer equipment . . . . .	2,265,644	1,800,791	3 years
Websites(1) . . . . .	439,681	—	3 years
Capital in Progress(2) . . . . .	137,585	—	3 years
Leasehold improvements . . . . .	2,885,695	2,542,277	2 to 7 years
	<u>8,228,026</u>	<u>7,268,887</u>	
Less accumulated depreciation . . . . .	<u>(5,879,879)</u>	<u>(5,617,148)</u>	
	<u>\$ 2,348,147</u>	<u>\$ 1,651,739</u>	

(1) Website development has been capitalized in conformity with EITF 00-2, "Accounting for Web Site Development Costs".

(2) Capital in Progress represents website development for a site that is not complete and has not been launched as of December 31, 2008.

Depreciation and amortization expense on property and equipment was \$1,102,336 and \$1,018,758 for the years ended December 31, 2008 and 2007, respectively.

## (6) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2008	December 31, 2007
Accrued research and development expenses . . . . .	\$ 2,888,791	\$2,172,364
Bonus payable . . . . .	2,212,713	1,498,520
Sales force commissions and incentive payments payable . . . . .	2,287,211	1,044,881
Legal accruals . . . . .	1,321,882	173,413
Royalties payable . . . . .	906,695	962,831
Regulatory accruals . . . . .	895,810	—
Fees for distributor services payable . . . . .	621,000	1,084,932
Other accrued expenses . . . . .	2,859,651	1,840,704
	<u>\$13,993,753</u>	<u>\$8,777,645</u>

Accrued research and development expenses include amounts relating to the clinical trials as well as preclinical operating costs. Legal accruals are primarily comprised of expenses related to our Apotex litigation. Regulatory accruals include amounts for activities and consultants related to

the preparation of the NDA for Fampridine-SR. Other accrued expenses include payroll liabilities, vacation accruals, sales and marketing accruals, and other operating expense accruals.

### **(7) Notes Payable**

In 2005, the Company entered into a \$6 million senior secured term loan with General Electric Capital Corporation that bears an annual fixed interest rate of 9.93%. The Company was required to pay monthly installments until February 2008, with interest-only payments for the first six months starting March 2005 followed by principal and interest payments for the remaining 30 months. The loan was secured by all of the Company's personal property and fixtures owned at closing or subsequently acquired. The Company repaid \$3 million of the loan in December 2005. As of February 2008 this loan was paid in full.

For long-term convertible notes payable see Note 10.

### **(8) Common Stock Options and Restricted Stock**

On June 18, 1999, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 1999 Employee Stock Option Plan (the 1999 Plan). All employees of the Company were eligible to participate in the 1999 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The 1999 Plan also covers the issuance of restricted stock. The 1999 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals to be granted options and stock appreciation rights, determines the time or times at which options and stock appreciation rights shall be granted under the 1999 Plan, determines the number of shares to be granted subject to any option or stock appreciation right under the 1999 Plan and the duration of each option and stock appreciation right, and makes any other determinations necessary, advisable, and/or appropriate to administer the 1999 Plan. Under the 1999 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. Compensation expense is calculated using a Black-Scholes calculation with the expense being recognized over the vesting period. The number of shares authorized for issuance under the 1999 Plan was 2,481,334.

On January 12, 2006, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 2006 Employee Incentive Plan (the 2006 Plan). This 2006 Plan serves as the successor to the Company's 1999 Plan, as amended, and no further option grants or stock issuances shall be made under the 1999 Plan after the effective date, as determined under Section 14 of the 2006 Plan. All employees of the Company are eligible to participate in the 2006 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The 2006 Plan also covers the issuance of restricted stock. The 2006 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals to be granted options and stock appreciation rights, determines the time or times at which options and stock appreciation rights shall be granted under the 2006 Plan, determines the number of shares to be granted subject to any option or stock appreciation right under the 2006 Plan and the duration of each option and stock appreciation right, and makes any other determinations necessary, advisable, and/or appropriate to administer the 2006 Plan. Under the 2006 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. The number of shares of common stock reserved for issuance pursuant to awards made under the 2006 Plan as of December 31, 2008 is 4,144,576 shares of stock. The total number of shares of common stock available for issuance under this 2006 Plan, including shares of common stock subject to the then outstanding awards, shall automatically increase on January 1 of each year during the term of this plan, beginning 2007, by a number of shares of common stock equal to 4% of the outstanding shares of common stock on that date, unless otherwise determined by the Board of Directors. The Board determined that the automatic increase should not take effect for 2007. The



Board determined that the automatic increase of 4% should take effect for 2008. Upon the exercise of options in the future, the Company intends to issue new shares.

The effects of applying SFAS No. 123R in a particular year may not be representative of the effects on reported net income or loss for future years. The fair value of each option granted is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Year ended December 31,		
	2008	2007	2006
Employees and directors:			
Estimated volatility . . . . .	80.17%	71.84%	71.49%
Expected life in years . . . . .	5.30	6.17	5.40
Risk free interest rate . . . . .	2.85%	4.66%	4.64%
Dividend yield . . . . .	—	—	—

The Company estimated volatility for purposes of computing compensation expense on its employee and non-employee options using a combination of the volatility of the Company's stock price since October 1, 2006 and the volatility of public companies that the Company considered comparable. The expected life used to estimate the fair value of employee options is 5.3 years. The Company based this assumption on the 50th percentile of 10 peer companies' choices for expected life for their valuations.

The weighted average fair value per share of options granted to employees and directors for the years ended December 31, 2008, 2007 and 2006 amounted to approximately \$14.20, \$13.00, \$5.00 and respectively. 15,000 options were granted to non-employees for the year ended December 31, 2008 and no options were granted to non-employees for the years ended December 31, 2007 and 2006.

During the year ended December 31, 2008, the Company granted 1,134,484 stock options and restricted stock awards to employees and directors under the 2006 Plan. These stock options were issued with a weighted average exercise price of \$21.31 per share. 1,100 of these options vested immediately, 95,000 of these options vest over a one-year vesting schedule and 813,384 will vest over a four-year vesting schedule. The 225,000 restricted stock awards granted in 2008 will vest over a three-year vesting schedule. As a result of these grants the total compensation charge to be recognized over the service period is \$15,992,480, of which \$4,035,988 was recognized during the year ended December 31, 2008.

Compensation costs for options and restricted stock granted to employees and directors amounted to \$9,552,236, \$7,796,118, and \$3,843,110 for the years ended December 31, 2008, 2007 and 2006, respectively. There were no compensation costs capitalized in our inventory balances. Compensation expense for options and restricted stock granted to employees and directors are classified between research and development, sales and marketing and general and administrative expense based on employee job function.

A summary of share-based compensation activity for the year ended December 31, 2008 is presented below:

**Stock Option Activity**

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value
Balance at January 1, 2008 . . . . .	2,999,513	\$10.17		
Granted . . . . .	924,484	21.29		
Forfeited . . . . .	(115,882)	16.21		
Exercised . . . . .	(523,792)	7.32		
Balance at December 31, 2008 . . . . .	<u>3,284,323</u>	<u>\$13.55</u>	<u>7.5</u>	<u>\$24,751,341</u>
Vested and expected to vest at December 31, 2008 . . . . .	<u>3,196,736</u>	<u>\$13.38</u>	<u>7.4</u>	<u>\$24,555,730</u>
Vested and exercisable at December 31, 2008 . . . . .	<u>1,735,910</u>	<u>\$ 9.42</u>	<u>6.5</u>	<u>\$19,512,382</u>

Range of exercise price	Options Outstanding			Options Exercisable	
	Outstanding as of December 31, 2008	Weighted- average remaining contractual life	Weighted- average exercise price	Exercisable as of December 31, 2008	Weighted- average exercise price
\$2.45-\$4.81 . . . . .	601,531	4.70	\$ 2.68	585,295	\$ 2.65
\$4.82-\$8.14 . . . . .	774,398	6.73	6.99	572,801	7.21
\$8.15-\$19.41 . . . . .	772,279	8.17	16.40	334,377	16.40
\$19.42-\$21.74 . . . . .	666,732	9.25	20.08	106,967	19.93
\$21.75-\$34.70 . . . . .	469,383	8.54	24.34	136,470	22.39
	<u>3,284,323</u>	<u>7.47</u>	<u>\$13.55</u>	<u>1,735,910</u>	<u>\$ 9.42</u>

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2008 totaled \$19.1 million and is expected to be recognized over a weighted average period of approximately 2.4 years.

**Restricted Stock Activity**

Restricted Stock	Number of Shares
Nonvested at January 1, 2008 . . . . .	39,722
Granted . . . . .	225,000
Vested . . . . .	(102,886)
Forfeited . . . . .	(11,673)
Nonvested at December 31, 2008 . . . . .	<u>150,163</u>

**(9) Income Taxes**

The Company had available net operating loss carry-forwards (NOL) of approximately \$262.2 million and \$179.9 million as of December 31, 2008 and 2007, 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 2028. The Company also has research and development tax credit carryforwards of approximately \$1.6 million and \$1.4 million as of December 31, 2008 and 2007, for

federal income tax reporting purposes that are available to reduce federal income taxes, if any, and expire in future years beginning in 2018.

The tax effect of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2008 and 2007 are presented below:

	December 31, 2008	December 31, 2007
Net operating loss carryforwards . . . . .	\$ 88,829,117	\$ 64,949,570
Research and development tax credit . . . . .	1,577,897	1,406,750
Property and equipment . . . . .	834,527	756,420
Intellectual property . . . . .	3,154,808	3,289,572
Stock options and warrants . . . . .	8,155,122	11,722,929
Deferred revenue . . . . .	7,724,122	7,342,693
Inventory reserve . . . . .	167,362	220,651
Revenue interest liability . . . . .	6,728,310	7,242,903
NRI acquisition . . . . .	892,276	—
Other temporary differences . . . . .	1,390,290	898,298
	<u>119,453,831</u>	<u>97,829,786</u>
Less valuation allowance . . . . .	<u>(119,453,831)</u>	<u>(97,829,786)</u>
Net deferred tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>

Changes in the valuation allowance for the years ended December 31, 2008 and 2007 amounted to approximately \$21.6 million and \$3.6 million, respectively. Since inception, the Company has incurred substantial losses and expects to incur substantial losses in future periods. The Tax Reform Act of 1986 (the Act) provides for a limitation of the annual use of NOL and research and development tax credit carryforwards (following certain ownership changes, as defined by the Act) that could significantly limit the Company's ability to utilize these carryforwards. The Company has experienced various ownership changes, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes. Because of the above mentioned factors, the Company has not recognized its gross deferred tax assets as of and for all periods presented. As of December 31, 2008, management believes that it is more likely than not that the net deferred tax assets will not be realized based on future operations and reversal of deferred tax liabilities. Accordingly, the Company has provided a full valuation allowance against its gross deferred tax assets and no tax benefit has been recognized relative to its pretax losses.

## **(10) License and Research Agreements**

### ***Elan***

In January 1997, the Company entered into several agreements with Elan, including a License and Supply Agreement (the Agreement) to develop Elan's sustained-release formulation of Fampridine-SR for treatment of spinal cord injury. The term of the agreement is equal to the greater of 20 years or the duration of relevant Fampridine-SR patent rights. The Company is responsible for all clinical trials and regulatory approvals. Elan has the right to manufacture, subject to certain exceptions, products for the Company upon regulatory approval at specified prices as a percentage of net selling price. In the event Elan does not manufacture the products, it is entitled to a royalty as a stated percentage of the products' net selling price.

### *Convertible Note*

Under the Agreement, Elan also loaned to the Company an aggregate of \$7.5 million pursuant to two convertible promissory notes. On December 23, 2005, Elan transferred these promissory notes to funds affiliated with Saints Capital. One promissory note in the amount of \$5.0 million bears interest at a rate of 3% beginning on the first anniversary of the issuance of the note. The unpaid principal 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 the Company receives certain regulatory approval for the products to be developed, subject to limitations related to gross margin on product sales. If it is determined by both parties that regulatory approval will not likely occur, the \$5.0 million promissory note will automatically convert into the underlying common stock. If the License and Supply Agreement is otherwise terminated, the principal and interest is repayable ratably over 15 years. The \$5.0 million promissory note restricts the Company's ability to incur indebtedness that is senior to the notes, subject to certain exceptions, including for the Company's revenue interest assignment arrangement (See Note 15).

The second promissory note was in the amount of \$2.5 million and was non-interest bearing. In December 2006, Saints Capital exercised the conversion of this note into 210,863 shares of common stock.

Interest on these convertible promissory notes has been imputed using 9% on 50% of the \$5 million note and 8% on the \$2.5 million note. In the case of the \$5 million note, the Company did not impute interest on 50% of the \$5 million note based on the provision in the License and Supply Agreement that provided for a recovery of up to \$2.5 million of the license fee paid, which was dependent upon regulatory approval of the product. If regulatory approval of the product is received, the convertible note would be repayable and the Company would be entitled to recovery of up to \$2.5 million based on the aforementioned provision. If the parties determine that regulatory approval will not likely occur, the note will not be repayable and the Company would not receive recovery of up to \$2.5 million of the license fee. Elan was considered to be a related party based on its ownership interest in the Company, significant license agreements entered into and involvement with research and development activities of the Company. The aggregate amount of the remaining \$5.0 million convertible note payable is convertible into 67,476 shares of common stock.

### *Amended and Restated License*

In September 2003, the Company entered into an amended and restated license agreement with Elan, which replaced two prior licenses for Fampridine-SR. Under this agreement, Elan granted the Company exclusive worldwide rights to Fampridine-SR, as well as Elan's formulation for any other mono- or di-aminopyridines, for all indications, including spinal cord injury and multiple sclerosis. The Company agreed to pay Elan milestone payments and royalties based on net sales of the product if and when approved.

Subject to early termination provisions, the Elan license terminates on a country by country basis on the latter 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.

### *Supply Agreement*

In September 2003, the Company entered into a supply agreement with Elan relating to the manufacture and supply of Fampridine-SR by Elan. The Company agreed to purchase at least 75% of its annual requirements of Fampridine from Elan, unless Elan is unable or unwilling to meet its requirements, for a purchase price based on a specified percentage of net sales. In those circumstances, where the Company elects to purchase less than 100% of its requirements from

Elan, the Company agreed to make certain compensatory payments to Elan. Elan agreed to assist the Company in qualifying a second manufacturer to manufacture and supply the Company with Fampridine-SR subject to its obligations to Elan.

**(11) Employee Benefit Plan**

Effective September 1, 1999, the Company adopted a defined contribution 401(k) savings plan (the 401(k) plan) covering all employees of the Company. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. Effective January 1, 2007, the Company amended the plan to include an employer match contribution to employee deferrals. For each dollar an employee invests up to 6% of his or her earnings, the Company will contribute an additional 50 cents into the funds. The Company's expense related to the plan was \$548,000, \$388,000 and \$0 for the years ended December 31, 2008, 2007 and 2006, respectively.

**(12) Commitments and Contingencies**

During 1998, the Company entered into a lease agreement for its facility. During November 2000, May 2001, February 2007, July 2008 and February 2009, the Company entered into amendments of the lease for its facility. Under the amendments, the Company increased the total leased space and extended the lease term for its original leased space. After the first six months of the February 2009 amendment the lease is subject to cancellation by us upon 12 months notice with no penalty. During 2008, the Company entered into a lease agreement through November 2009 for a corporate apartment. Future minimum commitments under all non-cancelable leases required subsequent to December 31, 2008 are as follows:

2009 . . . . .	\$1,021,000
2010 . . . . .	1,000,000
2011 . . . . .	1,000,000
2012 . . . . .	1,000,000
	<u>\$4,021,000</u>

Rent expense under these operating leases during the years ended December 31, 2008, 2007 and 2006 was \$882,378, \$799,006 and \$676,834, respectively.

Under our Zanaflex purchase agreement with Elan, the Company is 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, 2008, the Company has made all \$19.5 million of these milestone payments. Under its Zanaflex supply agreement with Elan, the Company is 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. The Company is bound to order one hundred percent of the forecast required quantities for each five month period immediately following each monthly forecast report. At December 31, 2008, the forecast requirement for the five month period following December 31, 2008 amounted to approximately \$3.8 million.

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

The Company is also party to employment agreements with its other executive officers, who are the Company's chief scientific officer, executive vice president and general counsel and chief financial officer that govern the terms and conditions of their employment. If any of the employment agreements are terminated by the Company or by the executives for reasons other than for cause, the Company must pay an amount equal to (i) the base salary the executive would have received during the nine month period immediately following the date of termination in the case of the chief scientific officer and a seven month period immediately following the date of termination in the case of the executive vice president and general counsel and chief financial officer, plus (ii) a bonus equal to the last annual bonus received by the executive multiplied by a fraction, the numerator of which shall be the number of days in the calendar year elapsed as of the termination date and the denominator of which shall be 365.

In August 2007, the Company received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an Abbreviated New Drug Application to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In October 2007, the Company filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) for patent infringement in relation to the filing of the ANDA by Apotex. The defendants have answered the Company's complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. The Company has denied those counterclaims. In March 2008, Apotex filed a motion, which the Company opposed, for partial judgment on the pleadings dismissing the Company's request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(4) or 285. The court ruled in the Company's favor and denied Apotex' motion in December 2008. The Company and Apotex are currently proceeding with discovery in the case. The Company accrues for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. As of December 31, 2008 there have been no accruals for legal matters.

### **(13) Product Returns**

As part of the terms of the Zanaflex asset purchase agreement, any product returned within six months of acquisition date was the obligation of Elan. Beginning in January 2005, such returns became a liability of the Company. Through June 30, 2006, the Company accepted \$4.7 million in total product returns, of which \$2.3 million was for product not sold by the Company. The Company accepts product returned up to twelve months subsequent to its expiration date. The Company recorded a charge to discounts and allowances of \$4.1 million in the year ending December 31, 2004 to record an estimated liability for returns of Zanaflex tablets sold by Elan. The Company continued to receive returns of the product sold by Elan through June 2006 at which point the right of return expired and the remaining \$1.8 million accrual balance was reversed through discounts and allowances.

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 received returns of the product sold by Elan through June 2006 at which point the right of return expired and the Company recognized the \$2.2 million deferred revenue balance as gross sales.

### **(14) Intangible Assets**

The Company acquired all of Elan's U.S. sales, marketing and distribution rights to Zanaflex Capsules and Zanaflex tablets in July 2004 for \$2.0 million plus \$675,000 for finished goods inventory. The Company is also responsible for up to \$19.5 million in future contingent milestone payments based on cumulative gross sales of Zanaflex tablets and Zanaflex Capsules. As of December 31, 2008, the Company has made \$19.5 million of these milestone payments which were

recorded as intangible assets in the consolidated financial statements. The final \$5.0 million milestone was reached in January 2008 and was paid during the three-month period ended June 30, 2008.

In connection with this transaction, the Company acquired the rights to the tradename “Zanaflex®”, one issued U.S. patent and two patent applications related to Zanaflex Capsules, and the remaining tablet inventory on hand with Elan. Additionally, the Company assumed Elan’s existing contract with Novartis to manufacture Zanaflex tablets and entered into a separate contract with Elan to manufacture Zanaflex Capsules. The Company separately launched Zanaflex Capsules in April 2005. The Company did not acquire any receivables, employees, facilities or fixed assets. The Company allocated, on a relative fair value basis, the initial and milestone payments made to Elan to the assets acquired, principally the Zanaflex tradename and the capsulation patent. There is no expected residual value of these intangible assets. The Company amortizes the allocated fair value of the tradename and patent over their estimated future economic benefit to be achieved.

Intangible assets consisted of the following:

	December 31, 2008	December 31, 2007	Estimated remaining useful lives as of December 31, 2008
Zanaflex patents . . . . .	\$19,350,000	\$14,850,000	13 years
Zanaflex tradename . . . . .	2,150,000	1,650,000	0 years
	<u>21,500,000</u>	<u>16,500,000</u>	
Less accumulated amortization . . . .	4,934,544	2,556,112	
	<u>\$16,565,456</u>	<u>\$13,943,888</u>	

The Company recorded \$2,378,431 and \$1,233,704 in amortization expense related to these intangible assets in the years ending December 31, 2008 and 2007, respectively.

Estimated future amortization expense for these intangible assets subsequent to December 31, 2008 for the next five years is as follows:

2009 . . . . .	\$1,282,696
2010 . . . . .	1,282,696
2011 . . . . .	1,282,696
2012 . . . . .	1,282,696
2013 . . . . .	1,282,696
	<u>\$6,413,480</u>

**(15) Sale of Revenue Interest**

On December 23, 2005, the Company entered into an agreement with an affiliate of Paul Royalty Fund (PRF), under which the Company received \$15 million in cash. In exchange the Company has assigned PRF revenue interest in 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. In November 2006, the Company entered into an amendment to the revenue interest assignment agreement with PRF. Under the terms of the amendment, PRF paid the Company \$5.0 million in November 2006. An additional \$5.0 million was due if the Company’s net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone was met and the receivable was reflected in the Company’s December 31, 2006 financial statements. Under

the terms of the amendment, the Company is required to pay PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010 since the net revenues milestone was met.

Under the agreement and the amendment to the agreement, PRF is entitled to the following portion of Zanaflex net revenues:

- with respect to Zanaflex net revenues up to and including \$30.0 million for each fiscal year during the term of the agreement, 15% of such net revenues;
- with respect to Zanaflex net revenues in excess of \$30.0 million but less than and including \$60.0 million for each fiscal year during the term of the agreement, 6% of such net revenues; and
- with respect to Zanaflex net revenues in excess of \$60.0 million for each fiscal year during the term of the agreement, 1% of such net revenues.

Notwithstanding the foregoing, once PRF has received and retained payments under the amended agreement that are at least 2.1 times the aggregate amount PRF has paid the Company under the agreement, PRF will only be entitled to 1% of Zanaflex net revenues. If PRF is entitled to 15% of net revenues as described above, the Company will remit 8% of cash payments received from wholesalers to PRF on a daily basis, with a quarterly reconciliation and settlement.

In connection with the transaction, the Company recorded a liability, referred to as the revenue interest liability, in accordance with EITF 88-18, *Sales of Future Revenues*. The Company imputes interest expense associated with this liability using the effective interest rate method and records 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. The Company currently estimates that the imputed interest rate associated with this liability will be approximately 6.2%. 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. The Company recorded approximately \$5.4 million, \$2.4 million and \$2.1 million in interest expense related to this agreement in 2008, 2007 and 2006, respectively. Interest expense in 2008 included a \$1.4 million out-of-period adjustment made during the second quarter of 2008 to correct an error identified in the previously recorded effective interest expense related to the November 2006 amended revenue interests assignment agreement with PRF. This out-of-period adjustment did not increase the total interest expense associated with this agreement. Through December 31, 2008, \$16.3 million in payments have been made to PRF as a result of Zanaflex sales levels.

The agreement also contains put and call options whereby the Company may repurchase the revenue interest at its option or can be required by PRF to repurchase the revenue interest, contingent upon certain events. If the Company experiences a change of control, undergoes certain bankruptcy events, transfers any of their interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfers all or substantially all of its assets, or breaches certain of the covenants, representations or warranties made under the agreement, PRF has the right, which the Company refers to as PRF's put option, to require the Company to repurchase the rights sold to PRF at the "put/call price" in effect on the date such right is exercised. If the Company experiences a change of control it has the right, which the Company refers to as the Company's call option, to repurchase the rights sold to PRF at the "put/call price" in effect on the date such right is exercised. If the Company's call option becomes exercisable as a result of this trigger, the Company will have a period of 180 days during which to exercise the option. The Company does not currently intend to



exercise its call option if it becomes exercisable as a result of such a transaction but may reevaluate whether it would exercise the option during the 180-day period. The put/call price on a given date is the greater of (i) 150% of all payments made by PRF as of such date, less all payments received by PRF 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 as of such date, taking into account the amount and timing of all payments received by PRF as of such date. The Company has determined that PRF's put option and the Company's call option meet the criteria to be considered an embedded derivative and should be accounted for as such. The Company recorded a net liability of \$337,500 as of December 31, 2008 related to the put/call option to reflect its current estimated fair value, in accordance with SFAS No. 133, *Accounting for Derivatives Instruments and Hedging Activities*. This liability is revalued on a semi-annual basis to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings. For the year ended December 31, 2008, a gain of \$125,000 has been recorded as a result of the change in the net put/call liability balance from December 31, 2007.

### **(16) Fair Value Measurements**

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value and expands required disclosures about fair value measurements. Under the standard, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. The standard clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability. The impact of adopting SFAS No. 157 as of January 1, 2008 was not material to our consolidated financial statements.

FSP FAS No. 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13*, removed leasing transactions accounted for under SFAS No. 13, *Accounting for Leases*, and related guidance from the scope of SFAS No. 157. FSP FAS No. 157-2, *Effective Date of FASB Statement No. 157* deferred the effective date of SFAS No. 157 for the Company in relation to all nonfinancial assets and nonfinancial liabilities to January 1, 2009.

SFAS No. 157 establishes a fair value hierarchy which requires us to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company primarily applies the market approach for recurring fair value measurements. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table presents information about our assets and liabilities measured at fair value on a recurring basis as of December 31, 2008 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>Assets Carried at Fair Value:</b>			
Cash equivalents . . . . .	\$ 27,283,767	\$—	\$ —
Short-term investments . . . . .	216,435,415	—	—
<b>Liabilities Carried at Fair Value:</b>			
Put/call liability . . . . .	—	—	337,500

The following table presents additional information about assets and/or liabilities measured at fair value on a recurring basis and for which the Company utilizes Level 3 inputs to determine fair value.

	<u>Balance as of December 31, 2007</u>	<u>Realized gains included in net loss</u>	<u>Unrealized losses included in other comprehensive loss</u>	<u>Balance as of December 31, 2008</u>
<b>Liabilities Carried at Fair Value:</b>				
Put/call liability . . . . .	\$462,500	\$(125,000)	\$—	\$337,500

The Company evaluates the fair value of positions classified within the Level 3 category based on revenue projections, business, general economic and market conditions that could be reasonably evaluated as of the valuation date.

#### (17) Subsequent Events

On January 30, 2009, the Company submitted a New Drug Application to the U.S. Food and Drug Administration for Fampridine-SR.

#### (18) Quarterly Consolidated Financial Data (unaudited)

	2008			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Net sales . . . . .	11,487,326	11,359,021	12,442,431	12,439,173
Gross profit . . . . .	8,527,166	8,556,135	9,764,756	9,623,828
Net loss allocable to common stockholders—basic and diluted . . .	(16,430,875)	(18,822,458)	(18,855,762)	(20,231,545)
Net loss per share allocable to common stockholders—basic and diluted . . . . .	\$ (0.54)	\$ (0.58)	\$ (0.53)	\$ (0.54)
	2007			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Net sales . . . . .	8,310,772	9,484,250	10,439,028	11,191,961
Gross profit . . . . .	6,762,468	7,483,821	8,277,740	8,606,004
Net loss allocable to common stockholders—basic and diluted . . .	(7,548,740)	(8,163,712)	(8,532,440)	(13,729,575)
Net loss per share allocable to common stockholders—basic and diluted . . . . .	\$ (0.32)	\$ (0.33)	\$ (0.30)	\$ (0.48)

**(b) Exhibits.**

The following Exhibits are incorporated herein by reference or are filed with this Annual Report on Form 10-K as indicated below.

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on November 20, 2006.
3.2	Amended and Restated Bylaws of the Registrant. Incorporated herein by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on March 21, 2007.
4.1	Specimen Stock Certificate evidencing shares of common stock. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.1**	Acorda Therapeutics 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.2**	Amendment to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.3**	Amendment No. 2 to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.4**	Acorda Therapeutics 2006 Employee Incentive Plan. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.5**	Acorda Therapeutics 2006 Employee Incentive Plan, as amended as of January 13, 2005. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 18, 2006.
10.6	Sixth Amended and Restated Registration Rights Agreement, dated March 3, 2004, by and among the Registrant and certain stockholders named therein. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.7**	Employment Agreement, dated August 11, 2002, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.8**	Amendment to August 11, 2002 Employment Agreement, dated September 26, 2005, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.9**	Letter Agreement, dated November 30, 2004, by and between the Registrant and Mark Pinney. Incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.10**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

Exhibit No.	Description
10.11**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Mary Fisher. Incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.12**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.13**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.14*	Amended and Restated License Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.15*	Supply Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006
10.16*	License Agreement, dated September 26, 2003, by and between the Registrant and Rush-Presbyterian-St. Luke's Medical Center. Incorporated herein by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.17	Side Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.18*	Payment Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.19*	Amendment No. 1 to the Payment Agreement, dated as of October 27, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.20*	Amended and Restated License Agreement, dated August 1, 2003, by and between the Registrant and Canadian Spinal Research Organization. Incorporated herein by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006
10.21*	License Agreement, dated February 3, 2003, by and between the Registrant and Cornell Research Foundation, Inc. Incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Exhibit No.	Description
10.22*	License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.23*	License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.24*	License Agreement, dated September 8, 2000, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.25*	Side Letter Agreement, dated June 1, 2005, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.26*	Asset Purchase Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.27*	Zanaflex Supply Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.28*	Assignment and Assumption Agreement, dated as of July 21, 2004, by and among the Registrant, Elan Pharmaceuticals, Inc., and Novartis Pharma AG. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.29*	License Agreement, dated April 17, 1991, by and between Sandoz Pharma, now Novartis Pharma AG and Athena Neurosciences, Inc., now Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.30	Patent Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.31	Trademark License Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.32	Agreement Relating to Additional Trademark, dated as of July 2005, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.33	Domain Name Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Exhibit No.	Description
10.34	Bill of Sale and Assignment and Assumption Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.35	Limited Recourse Convertible Promissory Note issued to Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.36	Full Recourse Convertible Promissory Note issued to Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.37	Note Modification and Amendment, dated as of December 23, 2005, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.38*	Fampridine Tablet Technical Transfer Program Proposal for Commercial Registration, dated February 26, 2003, by and between the Registrant and Patheon, Inc. Incorporated herein by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.39	Securities Amendment Agreement, dated September 26, 2003, by and among the Registrant, Elan Corporation plc and Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.40*	Syndicated Sales Force Agreement, dated as of August 1, 2005, between the Registrant and Cardinal Health PTS, LLC. Incorporated herein by reference to Exhibit 10.40 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.41*	License Agreement, dated as of December 19, 2003, by and among the Registrant, Cambridge University Technical Services Limited, and King's College London. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.42	Promissory Note issued to General Electric Capital Corporation. Incorporated herein by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.43	Revenue Interests Assignment Agreement, dated as of December 23, 2005, between the Registrant and King George Holdings Luxembourg IIA S.à.r.l., an affiliate of Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.44	Securities Purchase Agreement, dated as of October 3, 2006, by and among the Registrant and the purchasers listed on Exhibit A thereto. Incorporated herein by reference to Exhibit 10.44 of the Registrant's Current Report on Form 8-K filed on October 5, 2006.
10.45	First Amendment to Revenue Interests Assignment Agreement and to Guaranty, dated November 28, 2006 by and among the Registrant, King George Holdings Luxembourg IIA S.à.r.l. and Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.45 to Registrant's Current Report on Form 8-K filed on November 29, 2006.
10.46**	Amendment to August 11, 2002 Employment Agreement, dated May 10, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.

Exhibit No.	Description
10.47**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.48**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Mary Fisher. Incorporated herein by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.49**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.50**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.51	Registration Rights Agreement, dated as of February 1, 2008, by and among the Registrant and Edward A. Labry III. Incorporated herein by reference to Exhibit 10.51 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.
10.52**	Amendment to August 11, 2002 Employment Agreement dated December 28, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.52 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.
10.53**	Employment Offer Letter, dated October 20, 2008, by and between the Registrant and Thomas C. Wessel.
21.1	List of Subsidiaries of the Registrant. Incorporated herein by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification Pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Confidential treatment granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission

\*\* Indicates management contract or compensatory plan or arrangement.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Acorda Therapeutics, Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the State of New York, on this 2<sup>nd</sup> day of March 2009.

### ACORDA THERAPEUTICS, INC.

By: /s/ RON COHEN

Ron Cohen  
*President and Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ RON COHEN, M.D.</u> Ron Cohen, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2009
<u>/s/ DAVID LAWRENCE, M.B.A.</u> David Lawrence, M.B.A.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 2, 2009
<u>/s/ BARRY GREENE</u> Barry Greene	Director	March 2, 2009
<u>/s/ JOHN P. KELLEY</u> John P. Kelley	Director	March 2, 2009
<u>/s/ SANDRA PANEM, PH.D.</u> Sandra Panem, Ph.D.	Director	March 2, 2009
<u>/s/ BARCLAY A. PHILLIPS</u> Barclay A. Phillips	Director	March 2, 2009
<u>/s/ LORIN J. RANDALL</u> Lorin J. Randall	Director	March 2, 2009
<u>/s/ STEVEN M. RAUSCHER, M.B.A.</u> Steven M. Rauscher, M.B.A.	Director	March 2, 2009
<u>/s/ IAN SMITH</u> Ian Smith	Director	March 2, 2009
<u>/s/ WISE YOUNG</u> Wise Young	Director	March 2, 2009



**Consent of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Acorda Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-131846 and 333-149726) on Form S-8 and in the registration statements (Nos. 333-143348, 333-147163, and 333-152826) on Form S-3 of Acorda Therapeutics, Inc. of our reports dated March 2, 2009, with respect to the consolidated balance sheets of Acorda Therapeutics, Inc. and subsidiary as of December 31, 2008 and 2007, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2008, and the effectiveness of internal control over financial reporting as of December 31, 2008, which reports appear in the December 31, 2008 Annual Report on Form 10-K of Acorda Therapeutics, Inc.

/s/ KPMG LLP  
KPMG LLP

Short Hills, New Jersey  
March 2, 2009

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**CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO  
RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934**

I, Ron Cohen, certify that:

1. I have reviewed this report on Form 10-K of Acorda Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2009

/s/ RON COHEN

Ron Cohen  
Chief Executive Officer

**CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO  
RULE 13A-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934**

I, David Lawrence, certify that:

1. I have reviewed this report on Form 10-K of Acorda Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2009

/s/ DAVID LAWRENCE

David Lawrence  
Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350  
ACORDA THERAPEUTICS, INC.  
CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of Acorda Therapeutics, Inc. (the “Company”) hereby certifies to his knowledge that the Company’s Annual Report on Form 10-K for the period ended December 31, 2008 (the “Report”), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ RON COHEN

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Ron Cohen  
*Chief Executive Officer*  
*(Principal Executive Officer)*  
March 2, 2009

/s/ DAVID LAWRENCE

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David Lawrence  
*Chief Financial Officer*  
*(Principal Accounting and Financial Officer)*  
March 2, 2009

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- \* A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Acorda Therapeutics, Inc and will be retained by Acorda Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This written statement accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and will not be incorporated by reference into any filing of Acorda Therapeutics, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, irrespective of any general incorporation language contained in such filing.

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