ACORDA THERAPEUTICS INC
Form 10-K
March 01, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2010

OR

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

Commission File Number 000-50513

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	13-3831168
(State or other jurisdiction of incorporation or organization)	(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:

Title of each class	Name of each exchange on which registered
Common Stock $0.001 par value	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. o

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.

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

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

As of June 30, 2010, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was $859,576,238. 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, 2010 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 17, 2011, the registrant had 39,101,223 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 for its 2011 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2010. 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.

2010 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, including our ability to successfully market and sell Ampyra in the U.S. and to successfully market Zanaflex Capsules, third party payors (including governmental agencies) may not reimburse for the use of Ampyra at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions, the risk of unfavorable results from future studies of Ampyra, the occurrence of adverse safety events with our products, delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith, competition, failure to protect our intellectual property or to defend against the intellectual property claims of others, the ability to obtain additional financing to support our operations, and unfavorable results from our preclinical programs. 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. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make, and investors should not place undue reliance on these statements. In addition to the risks and uncertainties described above, we have included important factors in the cautionary statements included in this Annual 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. Forward-looking statements in this report are made only as of the date hereof, and we do not assume any obligation to publicly update any forward-looking statements as a result of developments occurring after the date of this report.

We own several registered trademarks in the U.S. and in other countries. These registered trademarks include, in the U.S., the marks “Acorda Therapeutics,” our stylized Acorda Therapeutics logo, “Ampyra,” “Zanaflex,” and “Zanaflex Capsules.” Also, our mark “Fampyra” is a registered mark in the European Community Trademark Office and we have registrations or pending applications for this mark in other jurisdictions. Our trademark portfolio also includes several registered trademarks and pending trademark applications in the U.S. and worldwide for potential product names or for disease awareness activities. Third party trademarks, trade names, and service marks used in this report are the property of their respective owners.

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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 (MS), spinal cord injury (SCI), and other disorders of the nervous system. The first product for which we completed clinical development, Ampyra (dalfampridine) Extended Release Tablets, 10mg (Ampyra) was approved by the U.S. Food and Drug Administration (FDA) in January 2010 as a treatment to improve walking in patients with MS. This was demonstrated by an increase in walking speed. Ampyra is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), which was previously referred to as fampridine. Ampyra demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra was made commercially available in the U.S. in March 2010, and had net revenue of $133.1 million for the year ended December 31, 2010.

Approximately 400,000 people in the U.S. suffer from MS. Research indicates that 64% to 85% of those people experience walking disability and that 70% of people with MS who have difficulty walking report it to be the most challenging aspect of their MS. Within 15 years of an MS diagnosis, 50% of people with MS often require assistance walking and, in later stages, up to a one third are unable to walk. Even in early stages of the disease, walking can be a significant issue; one study found that 28% of people reported walking disabilities within two years of MS diagnosis. In the European Union (EU), approximately 600,000 people suffer from MS, and an additional 55,000 to 75,000 people in Canada are also diagnosed with this disease.

In June 2009, we entered into an exclusive collaboration and license agreement with Biogen Idec International GmbH (Biogen Idec) to develop and commercialize Ampyra in markets outside the U.S. (the Collaboration Agreement). In January 2010, Biogen Idec announced that it had submitted a centralized Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and a New Drug Submission (NDS) to Health Canada for Ampyra, known outside the U.S. as Fampyra (fampridine). In January 2011, the EMA's Committee for Medicinal Products for Human Use (CHMP) decided against approval of fampridine. Biogen Idec has appealed the decision.

We have another marketed product, Zanaflex Capsules, which is approved by the FDA as a short-acting drug for the management of spasticity. Zanaflex Capsules and Zanaflex tablets, which we also sell, had combined net revenue for the year ended December 31, 2010 of $48.5 million.

Our research and development programs target other aspects of MS, as well as SCI, stroke and other central nervous system (CNS) disorders, and may also have application beyond CNS diseases, such as peripheral nerve injury or heart failure. We filed an Investigational New Drug (IND) application for Glial Growth Factor 2 (GGF2), the lead product candidate of our neuregulins program, for heart failure in early 2010. The IND became effective in April 2010, and

we enrolled the first patient in a Phase 1 clinical trial for GGF2 in December 2010.

Our goal is to continue to grow as a fully-integrated biopharmaceutical company focused on innovative therapies in neurology by commercializing our FDA approved products, developing our product candidates and advancing our research and development programs for underserved markets. We will also look to build long-term value in the company by bringing in new clinical or commercial stage assets that leverage our scientific and commercial expertise in the neurology space.

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Company Highlights

- Ampyra: Ampyra was approved by the FDA in January 2010 for the improvement of walking in people with MS. This was demonstrated by an increase in walking speed. To our knowledge, Ampyra is the first and only product indicated to improve walking in people with MS. Ampyra was made commercially available in the U.S. in March 2010, using our own specialty sales force, and had net revenue of $133.1 million for the year ended December 31, 2010. Under our 2009 Collaboration Agreement, Biogen Idec has the right to develop and commercialize Ampyra in markets outside the U.S.

- Zanaflex Capsules and Zanaflex tablets: Our Zanaflex Capsules, which we launched in April 2005, and Zanaflex tablets, which we also sell, are FDA-approved as short-acting drugs for the management of spasticity, a symptom of many CNS disorders, including MS and SCI. These products contain tizanidine hydrochloride, one of the two leading drugs used to treat spasticity. Combined net revenue for the year ended December 31, 2010 was $48.5 million.

- Managed Markets and Sales Force: Ampyra is being marketed in the U.S. through our own field-based specialty sales force, and commercial infrastructure, which is also responsible for sales and marketing of Zanaflex Capsules. We completed expansion of our sales force in March 2010 and currently have approximately 100 sales representatives in the field calling on a priority list of approximately 10,000 physicians. These are primarily neurologists and other specialists and prescribers who treat patients with MS and other conditions that involve spasticity. We employ a separate, 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 (DOD). For Zanaflex Capsules, we also engage a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care physicians, specialty physicians and pharmacists.

- Research and Development Programs: We have three research and development programs focused on novel approaches to repair damaged components of the CNS. We believe all of our research and development programs – neuregulins, remyelinating antibodies and chondroitinase – have broad potential applicability and have the potential to be first-in-class therapies. While these programs were initially 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 systems, including in such fields as cardiology, oncology, orthopedics and ophthalmology. In March 2010, we filed an Investigational New Drug (IND) application for Glial Growth Factor 2 (GGF2), the lead product candidate for our neuregulins program, as a therapy for heart failure, and in April 2010 the IND became effective. We enrolled the first patient in a Phase 1 clinical trial for GGF2 in December 2010. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product either by entering into a partnership, most likely with a cardiovascular-focused company, or by developing it on our own. We also are continuing with research on potential neurology indications for GGF2. Our other research and development programs have not yet advanced to clinical trials.

Our Strategy

Our strategy is to continue to grow as a fully-integrated biopharmaceutical company and to become a leading neurology 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 nervous system markets, including stroke and traumatic brain injury. Key aspects of our strategy

are:
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- Build on strong 2010 Ampyra launch to continue to grow the business, with focus on sales and marketing programs that educate prescribers about the broad range of appropriate patients who could potentially benefit from Ampyra.
- Work to expand our Ampyra franchise through additional patent protection for Ampyra, new formulations and additional indications.
- Support the efforts of our collaboration partner, Biogen Idec, in seeking health authority approval for and commercializing Ampyra in the EU and other markets.
- Maximize Zanaflex Capsules sales and vigorously prosecute our pending litigation against Apotex Inc. and Apotex Corp. (collectively, Apotex).
- Advance our clinical product, GGF2, through its ongoing Phase 1 trial and our pipeline of other research and development programs into clinical trials.
- Expand our pipeline through the potential in-licensing and/or acquisition of select products and technologies in neurology, with our focus through 2011 on Phase 2 and Phase 3 product candidates.

Our Products and Product Pipeline

Commercial Products	Indication	Status	Marketing Rights
Ampyra	MS	FDA-approved	Acorda (U.S.)
Ampyra	MS	Regulatory applications filed by Biogen Idec in EU, Canada; EU application was not approved but Biogen Idec has appealed; Biogen Idec received a Notice of Deficiency in Canada and intends to respond	Biogen Idec (outside U.S.)
Zanaflex Capsules	Spasticity	FDA-approved	Acorda (U.S.)
Zanaflex tablets	Spasticity	FDA-approved	Acorda (U.S.)
Research and Development Programs	Proposed Therapeutic Area(s)	Stage of Development	Marketing Rights
Dalfampridine QD formulation	MS	Development work ongoing	Acorda (U.S.)
Neuregulin Program	Heart failure*	Phase 1	Acorda/Worldwide
Remyelinating Antibodies Program	MS	Preclinical	Acorda/Worldwide

Chondroitinase Program	SCI	Research	Acorda/Worldwide

*The company is also continuing with research on potential neurology indications.

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Ampyra

Ampyra is an oral drug approved by the FDA on January 22, 2010 as a treatment to improve walking in patients with MS. This was demonstrated by an increase in walking speed. Ampyra demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra can be used alone or with concurrent medications, including immunomodulatory drugs. The majority of patients in our two Phase 3 clinical trials for Ampyra (63%) were taking immunomodulatory drugs (interferons, glatiramer acetate, or natalizumab). Ampyra is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), which was previously referred to as fampridine. We have obtained Orphan Drug designation from the FDA for dalfampridine in MS, which will provide Ampyra with seven years of market exclusivity for this use. We also have patents and pending patent applications covering Ampyra. In March 2010, we filed applications for patent term extension for Ampyra under the Hatch-Waxman law that allows for up to five additional years of patent protection based on the development timeline of a drug. Although we applied to extend two Ampyra patents listed in the FDA Orange Book (the list of approved drug products and their therapeutic equivalents, if any), if both are granted potential extensions, we will need to select only one patent for extension. Without extension, these patents currently expire on December 6, 2011 and July 30, 2013. The U.S. Patent and Trademark Office (USPTO) has notified us that it has determined that both patents are eligible for extension under its criteria and has forwarded them to the FDA to determine how much, if any, extension should be granted.

On January 21, 2011, Biogen Idec announced that CHMP decided against approval of Fampyra® (prolonged-release fampridine 10 mg tablets) to improve walking ability in adult patients with MS. Biogen Idec has filed an appeal to request a re-examination of the decision by the CHMP. Biogen Idec received a Notice of Deficiency from Health Canada regarding its application for approval of Fampyra in Canada, to which it intends to respond. Health Canada will have approximately a year to reply to that response.

Background

MS is a chronic, usually progressive disease in which the immune system attacks and degrades the function of nerve fibers in the brain and spinal cord. These nerve fibers consist of long, thin fibers, or axons, surrounded by a myelin sheath, which facilitates the transmission of electrical impulses. In MS, the myelin sheath is damaged by the body's own immune system, causing areas of myelin sheath loss, also known as demyelination. 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. 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.

Dalfampridine is a potassium channel blocker. In animal studies, dalfampridine has been shown to increase conduction of nerve signals in demyelinated axons through blocking of potassium channels. The mechanism by which dalfampridine exerts its therapeutic effect has not been fully elucidated.

Clinical Studies and Safety Profile

Our New Drug Application (NDA) for Ampyra was based on data from a comprehensive development program assessing the safety and efficacy of Ampyra, including two Phase 3 trials that involved 540 people with MS. The

primary measure of efficacy in our two Phase 3 MS trials was walking speed (in feet per second) as measured by the Timed 25-foot Walk (T25FW), using a responder analysis. A responder was defined as a patient who showed faster walking speed for at least three visits out of a possible four during the double-blind period than the maximum speed achieved in the five non-double-blind, no treatment visits (four before the double-blind period and one after). A significantly greater proportion of patients taking Ampyra 10 mg twice daily were responders compared to patients taking placebo, as measured by the T25FW (Trial 1: 34.8% vs. 8.3%; Trial 2: 42.9% vs. 9.3%). The increased response rate in the Ampyra group was observed across all four major types of MS. During the double-blind treatment period, a significantly greater proportion of patients taking Ampyra 10 mg twice daily had increases in walking speed of at least 10%, 20%, or 30% from baseline, compared to placebo. In both trials, the consistent improvements in walking speed were shown to be associated with improvements on a patient self-assessment of ambulatory disability, the 12 item Multiple Sclerosis Walking Scale (MSWS-12), for both drug and placebo treated patients. However, a drug placebo difference was not established for that outcome measure.

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The FDA approved Ampyra with a risk evaluation and mitigation strategy (REMS) consisting of a medication guide and communication plan. The goals of the communication plan include informing patients and healthcare providers about the serious risks, including seizures, associated with Ampyra, the importance of proper dosing, and the change of the established name from fampridine to dalfampridine. A medication guide is dispensed to patients with each Ampyra prescription. We have implemented a communication plan to support implementation of the REMS, consisting of letters to prescribers and pharmacists. In addition, the REMS includes a timetable for our submission of periodic assessments to the FDA of the REMS and patient and healthcare professional understanding of Ampyra's risks.

The FDA's approval letter also included certain post-marketing study requirements and confirmed certain commitments made by us with respect to Ampyra. The post-marketing requirements include additional animal toxicology studies to evaluate certain impurities, in vitro receptor binding and abuse potential studies in animals, and an evaluation of clinical adverse events related to abuse potential. In addition, we are working with external parties on a potential once-daily formulation, and developing plans to explore new potential indications both within MS and other diseases. We also are providing grants for investigator-initiated studies in MS, looking at a range of neurological functions.

We have committed to the FDA that we will conduct a placebo-controlled trial to evaluate a 5 mg twice daily dosing regimen of Ampyra, as well as a pharmacokinetic evaluation of a 7.5 mg dosage strength in patients with mild or moderate renal impairment. We have also committed to report all post-marketing seizure events on an expedited basis to the FDA. We are proceeding with these studies, with the renal impairment study underway and preparations for the 5 mg efficacy study in progress.

In our two Phase 3 clinical studies of Ampyra in SCI, the results did not reach statistical significance on their primary endpoints. Based on the entire body of data in clinical trials of Ampyra in people with SCI, we may resume development of Ampyra for SCI in the future, but have no current plans to do so.

Zanaflex Products

Zanaflex Capsules and Zanaflex tablets contain tizanidine hydrochloride, one of the two leading active ingredients used for the management of spasticity. Tizanidine hydrochloride is approved by the FDA as a short-acting drug for the management of spasticity. We acquired from Elan Pharmaceuticals, Inc. (Elan) all of its U.S. sales, marketing and distribution rights to Zanaflex Capsules and Zanaflex tablets in July 2004. Zanaflex tablets were approved by the FDA in 1996 and lost compound patent protection in 2002. There are currently over 10 generic versions of tizanidine hydrochloride tablets on the market. Zanaflex Capsules were approved by the FDA in 2002, but were never marketed by Elan. We began marketing Zanaflex Capsules in April 2005.

Background

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 U.S. and over 12 million worldwide.

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Clinical Studies

Clinical trials conducted by Elan demonstrated that Zanaflex Capsules, when taken with food, produce average peak levels of tizanidine hydrochloride 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 hydrochloride 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 hydrochloride tablets, although some substitution does take place in practice.

Research and Development Programs

Our lead early-stage programs include three distinct biologic therapeutic approaches to restoring neurologic and cardiac function. The first is a neuregulin growth factor that has been shown to promote recovery after neurological injury as well as enhance heart function in animal models of heart failure. In December 2010, we enrolled the first patient in a Phase 1 clinical trial exploring the safety and tolerability of GGF2 in patients with heart failure, and we are continuing preclinical studies of potential neurology indications for GGF2. The second program comprises a series of IgM antibodies. We are developing the lead antibody (rHIgM22) as a potential therapeutic for MS. rHIgM22 requires completion of preclinical toxicology tests before moving into clinical development. We believe a therapy, such as this antibody, that could permanently repair myelin sheaths has the potential to restore substantial neurological function to those affected by demyelinating conditions. The third program is in the research stage and is focused on developing chontroitinase as a therapeutic to break down inhibitory factors in the scar tissue that develops as a result of an injury to the CNS. Published research has demonstrated that this scar tissue is partly responsible for limiting the regeneration of nerve fibers in the CNS and restricting their ability to modify existing neural connections.

Neuregulins/GGF2

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 from 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, neuregulins offer us the potential for multiple CNS and cardiac indications, including MS, stroke and heart failure as well as protection from chemotherapy-induced damage.

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In March 2010 we filed an IND application for GGF2 as a therapy for the treatment of heart failure, and the IND became effective in April 2010. In December 2010, we enrolled the first patient in a Phase 1 clinical trial exploring the safety and tolerability of GGF2 in patients with heart failure. We selected heart failure as the initial indication because of the strength of the preclinical data, the availability of clear outcome measures, and the potential market size. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we believe that this may enable us to enter into a partnership with a cardiovascular-focused company, or we may decide to continue development on our own.

Antibodies/Remyelinating Antibodies Program

Our remyelinating antibodies program is based on our research collaboration with 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 nervous system 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, leading to increased remyelination activity. Some antibodies within this portfolio also stimulate the growth of neurons and may have applications beyond demyelinating disorders. First identified in mice, similar remyelinating antibodies were subsequently identified in human blood samples by Mayo Clinic and we have been able to produce a recombinant human antibody (rHIgM22) 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 began working with a contract manufacturer in 2009 to scale up manufacturing and purification processes for one of the remyelinating antibodies (rHIgM22) under current good manufacturing practices, or cGMP, in preparation for a future IND application. These manufacturing processes have been completed and we are now in formal preclinical safety and toxicity studies. If rHIgM22 proves to have a satisfactory preclinical safety profile, we expect to file an IND for the treatment of MS.

Chondroitinase Program

According to the National Spinal Cord Injury Statistical Center (NSCISC), approximately 262,000 people in the U.S. live with the long-term consequences of SCI and approximately 12,000 new spinal cord injuries occur each year, typically in young men. NSCISC estimates that the average lifetime costs directly attributable to SCI for an individual injured at age 25 varies from approximately $700,000 to $3.2 million depending on the severity of the injury.

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. There is no cure for SCI and no approved treatment available that is capable of improving neurological function. Methylprednisolone, a steroid given in a high dose, is often used to treat acute injuries in the U.S. Methylprednisolone is a treatment administered to the patient immediately following an injury to reduce secondary tissue damage, and there is some disagreement in the clinical community on the overall risk-benefit of this treatment. There are several treatments for the symptoms of SCI – which include spasticity,

persistent pain, loss of control of bowel and bladder functions, loss of sexual function, compromised breathing, loss of motor function and sensation, and unstable control of blood pressure, heart rate and body temperature – 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.

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.

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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.

At least six independent laboratories have published animal studies showing that application of chondroitinase results in improved 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 a recombinant version of naturally occurring Chondroitinase ABC-I in these same animal models.

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. Our research is currently focused on SCI but we are also looking at other neurotraumatic indications. The approaches we are developing 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, Marketing and Managed Markets

We have established our own specialty sales force and commercial infrastructure in the U.S. to market both Ampyra and Zanaflex Capsules. We completed an expansion of the sales force in March 2010, and currently have approximately 100 sales representatives in the field calling on a priority target list of approximately 10,000 physicians.

- Specialty Sales Force. We employ a field-based team of highly experienced sales professionals to call primarily on neurologists and on other specialists and prescribers treating patients with MS, as well as other conditions that involve spasticity.

- Managed Markets Team. We employ a field-based team responsible for payer strategy, as well as contracting and account management of managed care organizations, pharmacy benefit managers, Medicaid agencies, specialty pharmacies, wholesale drug distribution customers, the Veterans Affairs institutions and the DOD.

- Contract Pharmaceutical Telesales Organization. To supplement our marketing efforts for Zanaflex Capsules, we engage TMS Professional Markets Group, LLC to provide a small, dedicated telesales force to contact primary care physicians, specialty physicians and pharmacies.

We have contracted with a third-party organization with extensive experience in coordinating patient benefits to run Ampyra Patient Support Services, a resource of support services for healthcare providers, people with MS and

insurance carriers. Prescriptions for Ampyra are processed through the Ampyra Patient Support Services center, where dedicated and experienced customer care agents are available to help healthcare professionals process prescriptions, work with insurance carriers to facilitate coverage, and direct patients to available copay and patient assistance programs. If insurance coverage is confirmed, the person with MS will be put in touch with the specialty pharmacy provider that has contracted with his or her insurance carrier. Those people with MS who meet income and other requirements, regardless of their insurance status, may receive Ampyra at no cost, where permitted by law. We have also established a program to assist individuals who have private insurance in managing their co-payment costs, where permitted by law.

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We believe that, in general, people with MS are knowledgeable about their conditions, actively seek new treatments, and are directly involved with their prescriber's evaluation of treatment options. We have existing relationships with the major advocacy groups that focus on MS. As an example of our commitment, since 2008, Acorda has been 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 impairment on their lives. Acorda has also developed the “I Walk Because” program to give a voice to the community that participates in the Walk MS events. Acorda takes its I Walk Because event booth to top Walk MS events across the country. Walkers are invited to decorate t-shirts with the reasons why they are walking for MS, and they are also invited to film a short video to share with friends and family. In addition to these efforts, we have implemented a comprehensive series of educational and promotional programs to support Ampyra as well as Zanaflex Capsules.

Pursuant to our REMS approved by the FDA, Ampyra is distributed exclusively through a limited network of specialty pharmacies and directly to Kaiser Permanente. Patients with insurance benefits through the Veterans Affairs Administration, Public Health Systems and DOD also can access Ampyra through the Ampyra Patient Support Services center and the Specialty Pharmacy Provider network. Distribution through specialty pharmacies is well established within the MS community, and physicians and patients are familiar with this model. This distribution process is intended to provide the best possible patient experience, improve patient adherence to the required drug regimen, including dosage, and assist in educating patients regarding the risks associated with Ampyra.

Zanaflex Capsules are principally distributed through wholesale pharmaceutical distributors. In addition to our educational, promotional and drug safety monitoring 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 Zanaflex Capsules and tizanidine hydrochloride tablets, including generic tizanidine hydrochloride tablets and Zanaflex tablets.

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. We also have consultants who are experts in heart failure, given our research in this area with GGF2. 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

Biogen Idec

On June 30, 2009, we entered into the Collaboration Agreement with Biogen Idec, pursuant to which we and Biogen Idec have agreed to collaborate on the development and commercialization of products containing aminopyridines, including Ampyra, initially directed to the treatment of MS (licensed products). The Collaboration Agreement includes a sublicense of our rights under an existing license agreement with Elan. We have also entered into a related supply agreement (Supply Agreement) pursuant to which we will supply Biogen Idec with its requirements for the licensed products through our existing supply agreement with Elan. Biogen Idec Inc., the parent of Biogen Idec, has guaranteed the performance of Biogen Idec's obligations under the Collaboration Agreement and the Supply

Agreement.

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Under the Collaboration Agreement, Biogen Idec, itself or through its affiliates, has the exclusive right to commercialize licensed products in all countries outside of the U.S., while we retain the exclusive right to commercialize licensed products in the U.S. Each party has the exclusive right to develop licensed products for its commercialization territory, although the parties may also decide to jointly carry out mutually agreed future development activities under a cost-sharing arrangement. If Biogen Idec does not participate in the development of licensed products for certain indications or forms of administration, it may lose the right to develop and commercialize the licensed products for such indication or form of administration. Biogen Idec may sublicense its rights to certain unaffiliated distributors. During the term of the Collaboration Agreement and for two years after the Collaboration Agreement terminates, neither party nor its affiliates may, other than pursuant to the Collaboration Agreement, research, develop, manufacture or commercialize any competing product, defined as one that contains aminopyridine or any other compound that acts at least in part through direct interaction with potassium channels to improve neurological function in MS, SCI or other demyelinating conditions, except that we may exploit the licensed products anywhere in the world following termination of the Collaboration Agreement.

In consideration for the rights granted to Biogen Idec under the Collaboration Agreement, we were entitled to a non-refundable upfront payment of $110.0 million as of June 30, 2009, which was received on July 1, 2009. Also, as a result of such payment to us, a payment of $7.7 million became payable by us to Elan. As of December 31, 2010 we estimated the revenue recognition period under the Collaboration Agreement for upfront and milestone payments to be approximately 12 years from the date of this agreement. The Company recognized $9.4 million in license revenue related to the $110.0 million received from Biogen Idec and $660,000 in cost of license revenue related to the $7.7 million paid to Elan during the year ended December 31, 2010. We are also eligible to receive up to $400 million from Biogen Idec if specified regulatory and sales milestones are met.

Under the Collaboration Agreement, we will also be entitled to receive double-digit tiered royalties on sales of licensed products by Biogen Idec, its affiliates or certain distributors outside of the U.S. Such royalties for products combining a licensed compound with at least one other clinically active therapeutic, prophylactic or diagnostic ingredient are determined based on the contribution of the licensed compound to the overall sales or value of the combination product. Biogen Idec may offset against the royalties payable to us a portion of certain royalties that it may need to pay to third parties.

Biogen Idec will exclusively purchase all of Biogen Idec's, its affiliates' and its sublicensees' requirements of the licensed products from us. The purchase price paid by Biogen Idec for licensed products under the Collaboration Agreement and Supply Agreement reflects the prices owed to our suppliers under our supply arrangements with Elan or other suppliers. In addition, Biogen Idec will pay us, in consideration for its purchase and sale of the licensed products, any amounts due to Elan for ex-U.S. sales, including royalties owed under the terms of our existing agreements with Elan.

The Collaboration Agreement will terminate upon the expiration of Biogen Idec's royalty payment obligations, which occurs, on a licensed product-by-licensed product and country-by-country basis, upon the latest of expiration of the last-to-expire patent covering a licensed product, fifteen years following first commercial sale of such licensed product, the expiration of regulatory exclusivity and the existence of certain levels of sales by competing products. The Collaboration Agreement and the Supply Agreement will automatically terminate upon the termination of our license agreement with Elan in its entirety or with respect to all countries outside of the U.S. We cannot terminate our license agreement with Elan without Biogen Idec's prior written consent under certain circumstances. Biogen Idec may terminate the Collaboration Agreement in its entirety or on a country-by-country basis at any time upon 180 days' prior written notice, subject to our right to accelerate such termination. The Collaboration Agreement may also be terminated by either party if the other party fails to cure a material breach under the agreement, which termination will be limited to a particular country or region under certain circumstances. However, if Biogen Idec has the right to terminate the Collaboration Agreement due to our material uncured breach, Biogen Idec may instead elect to keep the

agreement in effect, but decrease the royalty rates they pay us by a specified percentage. We may also terminate the Collaboration Agreement if Biogen Idec does not commercially launch a licensed product within a specified time period after receiving regulatory approval for such licensed product or otherwise fails to meet certain commercialization obligations. In addition, we may terminate the Collaboration Agreement under certain circumstances if (i) Biogen Idec, its affiliates or its sublicensees challenge certain of our patents or (ii) there is a change in control of Biogen Idec or its parent company or certain dispositions of assets by Biogen Idec, its parent or its affiliated companies, followed by a change in the sales and marketing personnel responsible for the licensed products in Biogen Idec's territory of more than a specified percentage within a certain period of time after such change in control or disposition. The Supply Agreement may be terminated by either party if the other party fails to cure a material breach under the Supply Agreement. In addition, the Supply Agreement will terminate automatically upon termination of the Collaboration Agreement, and the Collaboration Agreement will terminate automatically if the Supply Agreement is terminated for any reason other than for a material breach that we are responsible for. To the extent permitted by law, each party may terminate the Collaboration Agreement and the Supply Agreement if the other party is subject to bankruptcy proceedings.

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If the Supply Agreement is terminated by Biogen Idec for an uncured material breach, we will waive our right for Elan to exclusively supply the licensed products to us solely to permit Biogen Idec to negotiate terms with Elan for the supply of licensed products to Biogen Idec. If the Supply Agreement is otherwise terminated, Biogen Idec will not have any future obligations to purchase licensed products from us and we will not have any future obligations to supply Biogen Idec with licensed products. If the Collaboration Agreement is terminated, Biogen Idec will assign to us all regulatory documentation and other information necessary or useful to exploit the licensed products in the terminated countries and will grant us a license under Biogen Idec's and its affiliates' relevant patent rights, know-how and trademarks to exploit the licensed products in the terminated countries. Such assignment and license will be at no cost to us unless the Collaboration Agreement is terminated by Biogen Idec for a material uncured breach that we are responsible for, in which case the parties will negotiate a payment to Biogen Idec to reflect the net value of such assigned and licensed rights.

Neither party may assign the agreements without the prior written consent of the other, except to an affiliate or, in certain cases, to a third party acquirer of the party.

In connection with the entry into the Collaboration Agreement, Biogen Idec and Elan entered into a consent agreement (the Consent Agreement) with us. Under the Consent Agreement, Elan consented to our sublicense of rights to Biogen Idec, and the three parties agreed to set up a committee to coordinate activities under our agreements with Elan with respect to the development, supply and commercialization of the licensed products for Biogen Idec's territory. The Consent Agreement also amended our agreements with Elan by, among other things, permitting us to allow Biogen Idec to grant sublicenses to certain unaffiliated distributors; permitting us to allow Biogen Idec to package the licensed products and to work directly with Elan with respect to certain supply-related activities; and, requiring Elan to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

Elan Corporation plc

Ampyra

In September 2003, we entered into an amended and restated license agreement with Elan that replaced two prior license agreements for Ampyra in oral sustained release dosage form. Under this agreement, Elan granted us exclusive worldwide rights to Ampyra 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 products with dalfampridine as the active ingredient. We also agreed to pay Elan 7% of any upfront and milestone payments that we receive from the sublicensing of rights to Ampyra or other aminopyridine products, and in the third quarter 2009, as a result of our Collaboration Agreement with Biogen Idec, we paid Elan $7.7 million. The FDA approval of Ampyra triggered a milestone of $2.5 million to Elan that was paid during the three-month period ended June 30, 2010.

Elan is also obligated under this agreement to supply us with our commercial requirements for Ampyra in the U.S., as well as to supply Biogen Idec under the Supply Agreement and Consent Agreement with Ampyra for Biogen Idec’s clinical trials and for Biogen Idec’s commercial requirements.

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Elan may terminate our license 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 related 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 the expiration of 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 (2018), 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 were paid prior to our 2010 fiscal year, 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. For more information refer to "—Manufacturing."

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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. For more information, refer to "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 dalfampridine 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 dalfampridine for the treatment of MS. Rush has also assigned to us its Orphan Drug Designation for dalfampridine 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 or accrued an aggregate of $850,000 in milestone payments and $2.7 million in royalties under this agreement through December 31, 2010. The FDA approval of Ampyra triggered the final milestone of $750,000 which was paid during the quarter ended March 31, 2010. 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 (2018).

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 dalfampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject.

The agreement as amended and restated in 2003 required the Company to pay to CSRO royalties based on a percentage of net sales of any product incorporating the licensed rights, including certain royalties relating to Ampyra and dalfampridine. During the three-month period ended March 31, 2010, we paid CSRO $3.0 million as full and complete satisfaction of our royalty obligations under the agreement. This payment was recorded as an intangible asset in the consolidated financial statements. We had not made any other royalty payments to CSRO prior to making this payment.

Our agreement with CSRO remains in effect although we have fully satisfied our royalty payment obligations. 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. This expiration is based on when royalty payments would have been payable, which is the earlier of the expiration of the last to expire licensed patent in a country or ten years from the date of the first commercial sale of the product in a country. We expect the agreement to terminate in Canada in 2012, and in the U.S. and certain foreign countries other than Canada in 2013, when the respective patents covered by the agreement expire.

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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 dalfampridine 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 Ampyra in amyotrophic lateral sclerosis. We made an aggregate of $50,000 in payments under this agreement through December 31, 2009 and did not make any payments in 2010. We are also obligated to pay Cornell an annual royalty on certain sales of Ampyra, 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 licensed patent, which will expire in 2016.

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 (now named Cambridge Enterprise 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 $2.2 million upon the achievement of certain milestones. We made an aggregate of $45,000 in payments under this agreement through December 31, 2009 and did not make any payments in 2010. 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.

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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 certain antibodies. Under this agreement, we have the right to develop, make, use and sell those antibodies for nervous system disorders or injuries. 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 certain antibodies, specifically myelination and remyelination in MS and SCI. Mayo Clinic has the right to continue internal research on the antibodies and, in the event it develops other applications that are related to our license, it must offer Acorda certain rights to this new subject matter before rights can be offered to a third party.

Under the Mayo Clinic agreement, we are obligated to make milestone payments of up to $1.9 million and to pay royalties based on net sales. During the quarter ended September 30, 2010, we reached our first milestone under this agreement. This milestone triggered a milestone payment of $45,000, which was paid during that quarter. 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 our 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 or fragments thereof 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. The completion of animal toxicology studies and the filing of an IND triggered milestone payment during the year ended December 31, 2010. We made milestone payments aggregating $1.0 million through December 31, 2010. We are obligated to make minimum royalty payments commencing in 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, or fragments thereof, 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.

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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 $5.9 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, 2009 and did not make any payments in 2010.

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.

In 2008, CeNeS was acquired by Paion AG.

The Brigham and Women’s Hospital, Inc.

In February 2008, we entered into a license agreement with Brigham and Women’s Hospital, Inc., or Brigham, acting on its own behalf and on behalf of Beth Israel Deaconess Medical Center, or Beth Israel. Pursuant to the license agreement, we were granted a co-exclusive license in the U.S., and an exclusive license outside the U.S., to their patent rights relating to the use of GGF2 in the treatment of congestive heart failure. Under this agreement, we have the right to develop, make, use and sell products covered by valid claims under the patent rights, with certain sublicensing rights. Brigham and Beth Israel have retained the right to use the subject matter of the license for internal research, clinical and educational purposes. If the other co-exclusive U.S. license to these patent rights (held by a third party) is terminated or expires, we have an option to negotiate an exclusive U.S. license to the patents, and Brigham and Beth Israel cannot license the patent rights to a third party unless we fail to reach agreement on an exclusive U.S. license.

Under this agreement, we paid a license fee of $25,000 in 2008 and we are obligated to make milestone payments of up to $1.4 million and to pay royalties based on net sales. Our IND for GGF2 filed during the quarter ended March 31, 2010, triggered our first milestone payment of $150,000, which was paid during that quarter. We have agreed to a timeline to achieve certain milestones relating to the research, development, clinical testing, and filing of regulatory approvals for a product covered by the agreement. If we fail to timely meet these milestones, Brigham and Beth Israel could, in certain cases, terminate the agreement subject to our right to present a plan to achieve the missed milestone within a reasonable period of time.

The agreement may be terminated by us at will upon prior written notice to Brigham and Beth Israel. In addition, the agreement may be terminated by Brigham and Beth Israel following our uncured material breach or upon our failure to maintain agreed upon insurance, our failure to remain solvent, the filing of a bankruptcy petition against us, or an

the assignment of our assets for the benefit of creditors. Subject to early termination provisions, this license agreement will terminate on a country by country basis upon the expiration of the last to expire licensed patent in a country. Based on current U.S. patents, termination in the U.S. is expected to be in 2021, and based on the current non-U.S. patent portfolio, termination is expected to be in 2020 in each country other than the U.S.

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Manufacturing

Ampyra

In September 2003, we entered into an agreement with Elan for our clinical and commercial supply of Ampyra. Under that agreement, we are required to purchase at least 75% of our annual requirements of Ampyra 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 second manufacturing source of Ampyra. 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 Ampyra if Elan is unable or unwilling to meet our requirements.

Under the Consent Agreement entered into among Elan, Biogen Idec and us, Elan consented to our sublicense of our rights under our agreements with Elan to Biogen Idec. The three parties agreed to set up a committee to coordinate activities under these agreements with respect to the development, supply and commercialization of the licensed products for Biogen Idec's territory. The Consent Agreement also amended our agreements with Elan by, among other things, permitting us to allow Biogen Idec to grant sublicenses to certain unaffiliated distributors, permitting us to allow Biogen Idec to package the licensed products and to work directly with Elan with respect to certain supply-related activities, and requiring Elan to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

Zanaflex

We currently rely on Elan to supply us with Zanaflex Capsules under our 2004 Supply Agreement. The initial term of the agreement expired in 2009, but is subject to 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 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 supply of tizanidine hydrochloride, the active pharmaceutical ingredient (API) in Zanaflex tablets. Novartis discontinued production of tizanidine hydrochloride and will no longer supply it. Therefore, we are required to obtain FDA approval for a new supplier of the tizanidine hydrochloride needed for the production of Zanaflex tablets. We have identified a potential new supplier

and we are seeking the required FDA approval. We expect to complete this process during the second quarter of 2011. Elan has supplied us with some Novartis-manufactured tizanidine hydrochloride, and based on current sales forecasts we believe we will have qualified our new supplier before our current inventory is depleted. However, we cannot obtain any more tizanidine hydrochloride for Zanaflex tablets from Elan. If we fail to gain FDA approval of our new tizanidine hydrochloride supplier, or if there is an unexpected delay in obtaining that approval, we may run out of inventory of tizanidine hydrochloride for Zanaflex tablets. We could also run out of inventory if, prior to qualifying our new supplier, sales of Zanaflex tablets are higher than our current forecasts. If we cannot manufacture enough Zanaflex tablets to meet demand, our sales of Zanaflex tablets would suffer.

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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.

Products in Development

We have established the internal capability to manufacture research quantities of antibody and protein product candidates.

GGF2

We contracted with CMC ICOS Biologics in 2008 to produce and purify GGF2 bulk material under cGMPs. Acorda and CMC ICOS have jointly developed analytical and characterization assays to support the manufacture of GGF2. The details of the manufacturing and purification processes and data from the analytical assays were provided to FDA in an IND application in March 2010. This drug substance was generated to support GLP safety and toxicology and is now being evaluated in our GGF2 Phase 1 clinical trial.

The final drug product for GGF2 for clinical studies was produced at Althea Technologies under a Product Development and Clinical Supply Agreement signed in 2009. The filling process and testing of the filled product was submitted to FDA in an IND application in March 2010.

rHIgM22

We have contracted for testing and manufacturing development activities for rHIgM22 to be performed by outside contractors. In 2009, we signed a Master Vendor Agreement with Biovest International Inc. to produce rHIgM22 under cGMPs. In 2009, we also contracted with CMC ICOS Biologics to develop methods and purify under cGMPs the rHIgM22 produced at Biovest. Acorda, CMC ICOS and Mayo are working to develop analytical and characterization assays to support the manufacture of rHIgM22. cGMP material produced at Biovest and CMC ICOS has been used in GLP safety and toxicology studies. If the safety profile is satisfactory, Acorda expects to file an IND for clearance to initiate human clinical studies.

Intellectual Property

As of January 2011, our intellectual property portfolio included intellectual property rights to over 45 U.S. patents, over 115 foreign patents and over 255 pending patent applications world-wide. There are five major families of subject matter in our patent portfolio: Ampyra, Zanaflex Capsules, neuregulins, remyelinating antibodies, and chondroitinase. Our intellectual property also includes copyrights, confidential and trade secret information as well as

a portfolio of trademarks.

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Ampyra/aminopyridines

We have a patent portfolio with multifaceted coverage on aminopyridine-related subject matter. Our aminopyridine intellectual property estate includes over 120 patent applications, six of which relate to responder analysis. Fifty-seven dalfampridine-related patents are issued and are being maintained world-wide (six in the U.S., 51 internationally).

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 dalfampridine, and methods of treatment directed to classes of relevant neurological conditions. In March 2010, on two of these U.S. patents (Patent Numbers 5,370,879 and 5,540,938), we filed patent term extension requests with the U.S. Patent and Trademark Office (USPTO) under the Hatch Waxman law to extend the expiration date of each patent. The length of the extension can be up to five years and depends on factors such as the amount of time taken by the FDA to review the first marketing approval application of the drug covered by the patent. We have requested extensions for the full five year period for both patents. If both requests are granted, we will need to designate one patent to which the extension shall apply, as only one patent can be extended. At present, Patent Number 5,370,879 expires December 6, 2011, and Patent Number 5,540,938 expires July 30, 2013.

We have been prosecuting applications covering methods of using aminopyridines, such as Ampyra, for a period of time. These include two pending U.S. patent applications and corresponding foreign applications. If granted, a patent resulting from any of these applications would be expected to remain in force at least through 2024. In November 2010, we received a Communication of Intention to Grant from the European Patent Office on the European counterpart of one of these U.S. Patents; following grant, any patent resulting from this case would be expected to expire in 2025. In 2009, we filed three pending U.S. patent applications covering aminopyridine formulations, such as Ampyra. If granted, a patent resulting from any of these formulation applications could remain in force at least through 2024.

In addition, during 2010, more than 60 patent applications were filed in the U.S. and world-wide that focus on various methods for using aminopyridines, such as Ampyra. If these applications issue as patents, they could remain in force at least through 2030.

We hold an exclusive license from Cornell University for an issued U.S. patent that relates to the use of aminopyridine compositions, including dalfampridine, for the treatment of diseases of anterior horn cells, including amyotrophic lateral sclerosis, which is also known as Lou Gehrig's disease. This patent is expected to expire 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 dalfampridine in the treatment of spasticity and chronic pain in patients with SCI. This U.S. patent is expected to expire in 2013.

In February 2008, we acquired certain assets of Neurorecovery, Inc. (NRI). This acquisition enabled us to broaden our intellectual property portfolio on dalfampridine and explore additional therapeutic indications for Ampyra, 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. In 2009, we evaluated the technologies acquired from NRI and identified certain non-aminopyridine technologies and devices that were not sufficiently relevant to our goals or business interests. We returned the corresponding intellectual property relating to those technologies to their original licensor, the University of Alabama. We continue to retain the intellectual property assets related to aminopyridines, including an issued U.S. patent and corresponding foreign patents covering the use of mono-aminopyridines, such as dalfampridine, to treat GBS.

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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. We also purchased the Zanaflex trademarks in the U.S. from Elan.

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.

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 response to the filing of the ANDA, in October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) in the U.S. 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 lawsuit is ongoing, and a trial date of April 25, 2011 has been set by the Court. Refer to the description of Legal Proceedings in Item 3 of this report for more information.

Neuregulins

Our neuregulin patent portfolio contains over 25 pending applications and over 80 neuregulin-related issued patents as of January 2011.

We are the exclusive licensee under a license agreement with CeNeS Pharmaceuticals, plc, of its 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 2009, we received a U.S. patent directed to using specified neuregulin sequences to treat a central or peripheral nervous system injury associated with demyelination. In February 2010, we received a U.S. patent directed to using specified neuregulin sequences to treat congestive heart failure.

Antibodies Related to Nervous System Disorders

Acorda is the exclusive licensee of a portfolio of patents and patent applications related to a series of remyelinating antibodies with respect to nervous system diseases and injuries discovered by scientists at the Mayo Clinic In this portfolio, we now have over 25 patent applications and 19 corresponding issued patents (6 in the U.S. and 13 foreign)

directed to technologies involving such antibodies and their uses. This includes five additional patent families obtained in 2010 under the existing license with Mayo Clinic that contain subject matter directed to antibodies understood to induce growth and/or development of neurons.

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In October 2010, a U.S. patent issued covering methods of stimulating remyelination in a mammal, and methods of stimulating proliferation of glial cells in a mammal, in each instance comprising administering the antibody sHIgM22 (or recombinant antibodies, monomers, or active fragments thereof). Thus, we now have three U.S. patents directed to antibody compositions that can induce remyelination, as well as several issued related foreign counterparts.

Chondroitinase

We have four chondroitinase-related U.S. patents, three issued foreign patents, and over 50 pending chondroitinase patent applications.

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 pending 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. In addition, we have a license from King's College and University of Cambridge to a U.S. application and its foreign counterparts directed to treatment of CNS damage.

Trademarks

In addition to patents, our intellectual property portfolio includes over 35 registered trademarks, along with over 140 pending trademarks. The registered marks include "Acorda Therapeutics" and our stylized Acorda Therapeutics logo, both of which are registered in the U.S. In addition, our Ampyra trademark was registered in the U.S. in June 2010. We have applied to register the Ampyra trademark internationally. We also own the rights to the registered marks "Zanaflex" and "Zanaflex Capsules" in the U.S. In addition, our trademark portfolio 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

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, Tysabri from Biogen-IDEC and Elan, and Gilenya from Novartis AG.

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To our knowledge, Ampyra is the first product that is approved as a treatment to improve walking in patients with MS. This was demonstrated by walking speed. Several biotechnology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, including MS. Other companies also have products in clinical development, including products approved for other indications in MS, to address improvement of walking ability in people with MS. BioMarin Pharmaceutical Inc. (BioMarin) acquired the rights formerly owned by EUSA Pharma to amifampridine phosphate, a 3,4-diaminopyridine compound, which in January 2010 received marketing authorization in the EU for use in Lambert Eaton Myasthenic Syndrome (LEMS). BioMarin has announced that it will be working to determine the regulatory path for approval in the U.S. for LEMS, as well as exploring developing the product for use in other indications, which may include MS. In the EU, and the U.S., if this product is successfully developed and approved, physicians might prescribe it instead of Ampyra 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, which is referred to as compounding. We are aware that at present compounded dalfampridine is used by some people with MS. Although we expect this use to decrease substantially because Ampyra is commercially available, we expect that some people will continue to use compounded dalfampridine. 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 Ampyra or our preclinical candidates in the future.

We believe that Ampyra may be complementary to both the relapse management and disease course management therapies that are commercially available. Nonetheless, Ampyra may compete for market acceptance with these current treatments because they have been accepted and regularly prescribed to people with MS by physicians, or because they are being promoted to improve walking or other neurological functions.

Spasticity

Tizanidine hydrochloride, the active pharmaceutical ingredient in Zanaflex Capsules, Zanaflex tablets and generic tizanidine hydrochloride 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. Ten generic manufacturers of tizanidine hydrochloride are distributing their own tablet formulations. As noted under “–Intellectual Property–Zanaflex” above, 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 hydrochloride. 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 hydrochloride. Due to the different pharmacokinetic profile of Zanaflex Capsules, Zanaflex tablets and generic tizanidine hydrochloride 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.

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In the U.S., Ampyra, Zanaflex Capsules and Zanaflex tablets and our product candidates, are regulated by the FDA as drugs. Other of our product candidates are potentially regulated both as drugs and as biological products. Drugs are subject to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations of the FDA, as well as to other federal, state, and local statutes and regulations. Biologics are 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 U.S. generally involves the following:

- preclinical laboratory and animal tests;
- submission to the FDA of an IND, an application which must become effective before human clinical trials may begin;
- completion of at least 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 each 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 proposed 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. Many studies also employ a data safety monitoring board, or DSMB, with experts who are otherwise independent of the conduct of the study and are given access to the unblinded study data periodically during the study to determine whether the study should be halted. For example, a DSMB might halt a study if an unacceptable safety issue emerges, or if the data showing the effectiveness of the study drug would make it unethical to continue giving patients placebo. Study subjects must provide informed consent before their participation in the research study.

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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 Phase 3 study, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment or SPA. SPAs 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.

Federal and state law requires the submission of registry and results information for most clinical trials. These requirements generally do not apply to Phase 1 clinical trials.

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, the Institutional Review Boards or the DSMB 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.

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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.

Once an NDA or BLA is submitted for FDA approval, the FDA will accept the NDA or BLA for filing if deemed complete, 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. 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 will limit the approved therapeutic uses for the product as described in the product labeling, may require that contraindications or warning statements be included in the product labeling, may 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 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 to patients and/or healthcare professionals or patient 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 after product approval. 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. 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 and maintain 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.

Post-Approval Regulation

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug and 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, the FDA may require 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 cGMPs, 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.

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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.

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. For example, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in that state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Any applicable state or local regulations may hinder our ability to market, or increase the cost of marketing, our products in those states or localities.

The FDA's policies may change and additional government regulations may be enacted which could impose additional burdens or limitations on our ability to market products after approval. Moreover, increased attention to the containment of health care costs in the U.S. 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 U.S. 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 Ampyra for the treatment of both MS and incomplete SCI. The number of people affected by MS has now exceeded 200,000. However, this should not affect Ampyra’s orphan drug designation, as it was granted prior to the increase in diagnoses above 200,000.

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, and 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 for that use. 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.

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Generic Drugs, AB Ratings and Pharmacy Substitution

Generic drugs are approved through an abbreviated regulatory 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 limited clinical data to demonstrate that the product covered by the ANDA is absorbed in the body at a rate and extent consistent with that of 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.

Special procedures apply when an ANDA contains certifications stating that a listed patent is invalid or not infringed. If the owner of the patent or the NDA for the reference listed drug brings a patent infringement suit within a specified time, an automatic stay bars FDA approval of the ANDA for 30 months pending resolution of the suit or other action by the court. If the 30-month stay is lifted or expires and the ANDA applicant is able otherwise to meet the FDA’s requirements for the approval of ANDAs, the generic manufacturer may begin selling its product even if patent litigation is pending. If the generic manufacturer launches before patent litigation is resolved, the launch is at the risk of the generic manufacturer being later held liable for patent infringement damages.

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 co-payments 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."

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Foreign Regulation and Product Approval

Outside the U.S., our ability or the ability of our collaboration partner Biogen Idec 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, 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, and are affected by 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. Under the Veterans Health Care Act (VHCA), we are required to offer certain drugs at a reduced price to a number of federal agencies including the Veterans Administration and DOD, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain DOD purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. In addition, our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Beginning in March 2013, pharmaceutical manufacturers will be subject to new federal reporting and disclosure requirements with regard to payments or other transfers of value made to health care providers. Reports submitted under these new requirements will be placed on a public database. Similarly, beginning in April 2012, pharmaceutical manufacturers will be required to report samples of prescription drugs requested by and distributed to health care providers. The new law does not state whether these disclosures will be made publicly available.

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.

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Reimbursement and Pricing Controls

In many of the markets where we or Biogen Idec, our collaboration partner for Ampyra, 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 U.S., 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 U.S., 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.

The Medicare Modernization Act (MAA), enacted in December 2003, altered federal reimbursement for physician-administered drugs covered by Medicare. Under the reimbursement methodology set forth in the MAA, physicians are reimbursed for such drugs based on a product's "average sales price," or ASP. This ASP-based reimbursement methodology has generally led to lower reimbursement levels. The MAA also established the Medicare Part D outpatient prescription drug benefit, which is provided primarily through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted in 2010, known as the Affordable Care Act, requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the “donut hole.”

The Deficit Reduction Act of 2005 resulted in changes to the way drug prices are reported to the government and the formula using such information to calculate the required Medicaid rebates. The Affordable Care Act increased the minimum basic Medicaid rebate for branded prescription drugs from 15.1% to 23.1% and requires pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, the Affordable Care Act increased the additional Medicaid rebate on “line extensions” (such as extended release formulations) of solid oral dosage forms of branded products, revised the definition of average manufacturer price by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted 340B pricing.

The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) will be based on the manufacturer’s market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U.S. government programs. The Affordable Care Act also contains a number of provisions, including provisions governing the way that health care is financed by both governmental and private insurers, enrollment in federal health care programs, reimbursement changes, the increased use of comparative effectiveness research in health care decision-making, and enhancements to fraud and abuse requirements and enforcement, that will affect existing government health care programs and will result in the development of new programs.

We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

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. Payers 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 Micromedix, DrugDex, or Clinical Pharmacology. Another commonly cited compendium, for example under Medicaid, is the DrugDex Information System.

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Different pricing and reimbursement schemes exist in other countries. For example, in the EU, 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 17, 2011, we had 305 employees. Of the 305 employees, 65 perform research and development activities, including preclinical programs, clinical trials, regulatory affairs, biostatistics, and drug safety, and 240 work in sales, marketing, managed markets, business development, manufacturing, medical affairs, communications, and general and administrative.

CORPORATE INFORMATION

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 15 Skyline Drive, Hawthorne, New York 10532. Our telephone number is (914) 347-4300. Our website is www.acorda.com. The information contained on our website is not incorporated by reference into this report and should not be considered to be a part of this report. References to our website address in this report have been included as, and are intended to be, inactive textual references only that do not hyperlink to our website.

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). Also, the SEC allows us to “incorporate by reference” some information from our proxy statement for our 2011 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2011 proxy statement within 120 days after the end of our 2010 fiscal year, in accordance with SEC rules and regulations, and we recommend that you refer to the information that we indicate will be contained in our 2011 proxy statement.

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Item 1A. Risk Factors.

You should carefully consider the risks described below, in addition to the other information contained in this Annual Report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks related to our business

We have a history of operating losses and we may continue to incur losses and may never reach or sustain profitability.

As of December 31, 2010, we had an accumulated deficit of approximately $440.1 million. We had net losses of $11.8 million, $83.9 million and $74.3 million for the years ended December 31, 2010, 2009 and 2008, respectively. We have had operating losses since inception as a result of our significant clinical development, research and development, general and administrative, sales, managed markets and marketing, medical affairs and business development expenses. We may incur losses for the next several years as we expand our sales, managed markets and marketing capabilities and conduct other activities in connection with the commercial launch of Ampyra, as we continue our product development and research and development activities, and as we potentially acquire new products or product candidates.

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

- commercialize Ampyra in the U.S. and have Biogen Idec obtain regulatory approval for Ampyra (as Fampridine Prolonged Release tablets) in the EU and other markets outside the U.S.;
- achieve planned sales levels for Zanaflex Capsules;
- continue to develop our preclinical product candidates and advance them into clinical trials; and
- evaluate and potentially expand our product development pipeline through the potential in-licensing and/or acquisition of additional products and technologies.

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

We will be highly dependent on the commercial success of Ampyra in the U.S. for the foreseeable future; we may be unable to meet our expectations with respect to Ampyra sales and/or attain profitability and positive cash flow from operations.

We currently derive substantially all of our revenue from the sale of Ampyra, Zanaflex Capsules and Zanaflex tablets, and we believe that sales of Ampyra will continue to constitute a significant portion of our total revenue for the foreseeable future. Sales of Zanaflex Capsules for 2010 declined compared to 2009, and it is possible that they will continue to decline in 2011 due to increasing managed care pressure, among other factors. Managed care organizations have increasingly established plans and programs to drive utilization of low-cost generic tizanidine hydrochloride tablets over higher-cost Zanaflex Capsules by making it more difficult for patients to obtain Zanaflex Capsules through restrictions and higher out-of-pocket (copay) costs.

On January 22, 2010, the FDA approved Ampyra as a treatment to improve walking in people with MS. This was demonstrated by an increase in walking speed. Ampyra became commercially available for the first time in March 2010. The commercial success of Ampyra will depend on a number of factors, including:

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- the effectiveness of our sales, managed markets and marketing efforts;
- the acceptance of Ampyra in the medical community, particularly with respect to whether physicians and patients view Ampyra as safe and effective for its labeled indication, and whether it has an acceptable benefit-to-risk profile;
- the availability of adequate reimbursement by third-party payers;
- the continued use of compounded dalfampridine available through pharmacies in the U.S. and elsewhere that engage in compounding;
- the occurrence of any side effects, adverse reactions or misuse (or any unfavorable publicity relating thereto) stemming from the use of Ampyra; and
- the development of competing products or therapies for the treatment of MS or its symptoms.

Forecasting revenue is difficult, especially when there is little commercial history, the product is the first product approved for a particular indication and the level of market acceptance of the product is uncertain. We may experience significant fluctuations in sales of Ampyra from period to period and, ultimately, we may never generate sufficient revenues from Ampyra and Zanaflex Capsules and Zanaflex tablets to reach or maintain profitability or sustain our projected levels of operations.

We have no manufacturing capabilities and are dependent upon Elan and other third party suppliers to manufacture Ampyra, Zanaflex Capsules and Zanaflex tablets.

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

We rely exclusively on Elan to supply us with our requirements for Ampyra. Under our supply agreement with Elan, we are obligated to purchase at least 75% of our yearly supply of Ampyra 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 second manufacturing source, with compensatory payment. We and Elan also rely on a single third-party manufacturer to supply dalfampridine, the active pharmaceutical ingredient in Ampyra.

Ampyra was initially manufactured at a smaller scale appropriate for clinical trial supply requirements. In 2009, both Elan and Patheon completed manufacturing scale-up appropriate to adequately supply our Ampyra commercial forecasts. There is always risk associated with the scale-up of production such that the drug product manufactured at the higher, commercial scale may not be equivalent to the drug product produced at the lower, clinical scale. In such case, we might not have adequate commercial supply or there might be issues with the quality of the drug product.

We also rely on a single manufacturer, Elan, for the supply of Zanaflex Capsules. Zanaflex Capsules are manufactured using Elan's proprietary 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 that 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.

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Under our supply agreement with Elan, we provide Elan with monthly written 18-month forecasts, and with annual written five-year forecasts for our supply requirements of Ampyra and two-year forecasts for our supply requirements of Zanaflex Capsules. In each of the five months for Zanaflex and three months for Ampyra 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 Ampyra and Zanaflex Capsules.

Prior to March 2007, we relied on a single manufacturer, Novartis, for the supply of tizanidine hydrochloride, the active pharmaceutical ingredient (API) in Zanaflex tablets. Novartis discontinued production of tizanidine hydrochloride and will no longer supply it. Therefore, we are required to obtain FDA approval for a new supplier of the tizanidine hydrochloride needed for the production of Zanaflex tablets. We have identified a potential new supplier and we are seeking the required FDA approval. We expect to complete this process during the second quarter of 2011. Elan has supplied us with some Novartis-manufactured tizanidine hydrochloride, and based on current sales forecasts we believe we will have qualified our new supplier before our current inventory is depleted. However, we cannot obtain any more tizanidine hydrochloride for Zanaflex tablets from Elan. If we fail to gain FDA approval of our new tizanidine hydrochloride supplier, or if there is an unexpected delay in obtaining that approval, we may run out of inventory of tizanidine hydrochloride for Zanaflex tablets. We could also run out of inventory if, prior to qualifying our new supplier, sales of Zanaflex tablets are higher than our current forecasts. If we cannot manufacture enough Zanaflex tablets to meet demand, our sales would suffer.

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

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. Any such failure may result in decreased product sales and lower product revenue, which would harm our business.

Even though we have obtained marketing approval for Ampyra, the approval is subject to a REMS and post-marketing commitments, which may affect the success of Ampyra.

The marketing approval we received for Ampyra is subject to risk mitigation activities we must undertake in accordance with a REMS, a commitment to report all seizures we learn about in post-approval use to the FDA on an expedited basis, and requirements for potentially costly follow-up animal and clinical studies and analyses. The post-approval requirements will impose burdens and costs on us. If the post-approval animal and clinical studies and analyses we must conduct identify new safety concerns, or if our REMS and other measures are not effective in preventing or minimizing the prevalence of seizures or other serious safety risks, the approval of Ampyra could be further limited or withdrawn, or we might be required to undertake additional burdensome post-approval activities. In addition, failure to complete the required studies and meet our other post-approval commitments could lead to negative regulatory action at the FDA, which could include withdrawal of regulatory approval.

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The FDA-approved product labeling for Ampyra is limited and may adversely affect market acceptance of Ampyra.

Ampyra was approved with an indicated use limited to improving walking. This was demonstrated by an increase in walking speed. The approved labeling also contains other limitations on use and warnings and contraindications for risks. If potential purchasers or those influencing purchasing decisions, such as physicians and pharmacists or payers, react negatively to Ampyra because of their perception of the limitations or safety risks in the approved product labeling, it may result in lower product acceptance and lower product revenues.

In addition, our promotion of Ampyra must reflect only the specific approved indication as well as other limitations on use, and disclose the safety risks associated with the use of Ampyra as set out in the approved product labeling. We must submit all promotional materials to the FDA at the time of their first use. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them and provide corrective information to healthcare practitioners, and we may face other adverse enforcement action.

If we or others identify previously unknown side effects of Ampyra, or known side effects are more frequent or severe than in the past, our business would be adversely affected and these events could lead to a significant decrease in sales of Ampyra or to the FDA's withdrawal of marketing approval.

Based on our clinical trials, the side effects of Ampyra include seizures, urinary tract infection, trouble sleeping (insomnia), dizziness, headache, nausea, weakness, back pain, and problems with balance. However, if we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for Ampyra or any products perceived to be similar to Ampyra, then in any of these circumstances:

- sales of Ampyra may be significantly decreased from projected sales;
- regulatory approvals for Ampyra may be restricted or withdrawn;
- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals;
- reformulation of the product, additional preclinical or clinical studies, changes in labeling or changes to or reapprovals of manufacturing facilities may be required;
- our reputation in the marketplace may suffer; and
- government investigations and lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of Ampyra, increase our expenses and impair our ability to successfully commercialize Ampyra.

Furthermore, now that Ampyra is commercially available, it is being used in a wider population and in a less rigorously controlled environment than in clinical studies. Some patients exposed to Ampyra have reportedly experienced serious adverse side effects, including seizures. As a result, regulatory authorities, healthcare practitioners, third party payers or patients may perceive or conclude that the use of Ampyra is associated with serious

adverse effects, which could mean that our ability to commercialize Ampyra could be adversely affected and our business could be impaired.

Under FDA regulations and our REMS for Ampyra, we are required to monitor the safety of Ampyra. We are required to document and investigate reports of adverse events, and to report them to the FDA in accordance with regulatory timelines based on their severity and expectedness. Failure to make timely safety reports and to establish and maintain related records could result in withdrawing of marketing authorization or other regulatory action, civil actions against us, or criminal penalties, any of which could harm our business.

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If the specialty pharmacies that we rely upon to sell Ampyra in the U.S. fail to perform, our business may be adversely affected.

Our success in commercializing Ampyra will depend on the continued customer support efforts of our network of specialty pharmacies. A specialty pharmacy is a pharmacy that specializes in the dispensing of injectable, infused or certain other medications typically for complex or chronic conditions, which often require a high level of patient education and ongoing management. Specialty pharmacies are commonly used to dispense MS drugs, many of which are injectable. The use of specialty pharmacies involves certain risks, including, but not limited to, risks that these specialty pharmacies will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using Ampyra, Ampyra adverse events, or Ampyra complaints;
- not effectively sell or support Ampyra;
- reduce their efforts or discontinue selling or supporting Ampyra;
- not devote the resources necessary to sell Ampyra in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others;
- not have the required licenses to distribute drugs; or
- cease operations.

In late 2010 and early 2011, we learned that two of the specialty pharmacies that dispense Ampyra failed timely to report to us some of the reports of adverse events that they received, which we believe was in violation of our contracts with them. Because the specialty pharmacies did not report these adverse events to us in a timely manner, while we reported them to the FDA, we did not report them in a timely manner. To our knowledge, no regulatory action has been taken, or is currently contemplated, against us or the specialty pharmacies involved by the FDA. However, if these specialty pharmacies continue to experience problems with adverse event reporting, and even if they do not, the FDA could take regulatory action against us and/or the specialty pharmacies. Even if the FDA takes regulatory action against a specialty pharmacy and not us, that could harm our business because, for example, the FDA could withdraw the pharmacy's authorization to dispense Ampyra, which could harm Ampyra sales.

We may incur significant liability if it is determined that we are promoting the "off-label" use of Ampyra or any other marketed drug.

Physicians may prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies may not promote drugs for off-label uses. Accordingly, without FDA approval of Ampyra for use in any indications other than improving walking ability in people with MS, we may not promote Ampyra for these indications. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses

and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

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Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. Although we believe that all of our communications regarding our marketed products are in compliance with the relevant regulatory requirements, the FDA or another regulatory or enforcement authority may disagree. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

We are dependent on our collaboration with Biogen Idec to commercialize Ampyra outside of the U.S.

Pursuant to our Collaboration Agreement with Biogen Idec, entered into in June 2009, we granted Biogen Idec an exclusive license to develop and commercialize Ampyra and other products containing aminopyridines in all territories outside the U.S. We may enter into additional collaborations with third parties to develop and commercialize some of our product candidates in the future. Our dependence on Biogen Idec for the development and commercialization of Ampyra outside the U.S., and our dependence on future collaborators for development and commercialization of additional product candidates, will subject us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of product candidates or to their marketing and distribution;
- collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- the collaborations may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates; and
- collaborators may experience financial difficulties.

While the Company has negotiated certain terms in the Collaboration Agreement with Biogen Idec intended to assist in protecting the Company's rights in certain of the circumstances listed above, there can be no assurance that these terms will provide the Company with adequate rights and remedies, and actions required to enforce such rights could be costly and time consuming.

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Our collaboration partner, Biogen Idec, will need to obtain regulatory approval in foreign jurisdictions where we seek to market Ampyra.

In order to market our products in the EU and many other foreign jurisdictions, separate regulatory approvals must be obtained and numerous and varying regulatory requirements must be complied with. Approval procedures vary among countries and can involve additional clinical and nonclinical testing. The time required to obtain approval may differ from that required to obtain FDA approval. We and our partner may fail to obtain foreign regulatory approvals on a timely basis, if at all. In addition, individual countries, within the EU 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 the ability of us or our partner to market and sell products outside the U.S. 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. Inability to obtain necessary regulatory approvals to commercialize Ampyra or other product candidates in foreign markets could materially adversely affect our business prospects.

Under the Collaboration Agreement, Biogen Idec has the right to develop and commercialize Ampyra in the EU and other markets outside the U.S. In January 2010, Biogen Idec submitted a centralized Marketing Authorization Application, or MAA, to the European Medicines Agency (EMA) and a New Drug Submission, or NDS, to Health Canada for Ampyra, known outside the U.S. as Fampyra (fampridine). In January 2011 the EMA's Committee for Medicinal Products for Human Use (CHMP) decided against approval. Biogen Idec has appealed the decision, but we cannot provide any assurances regarding the outcome of that appeal. Biogen Idec received a Notice of Deficiency from Health Canada regarding its application for approval of Fampyra in Canada, to which it intends to respond. Health Canada will have approximately a year to reply to that response. The CHMP's decision against approval of Biogen Idec's application, and the similar decision by Health Canada, 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 and risks of development and approval. Additional or supplemental trials with respect to Ampyra or other product candidates 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 drug development programs are in early stages of development and may never be commercialized.

Two of our active research and development programs – remyelinating antibodies and chondroitinase – have not advanced to clinical trials. 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.

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

clinical testing or in obtaining regulatory approval, our long-term business prospects will be harmed.

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Our drug products in development 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 any 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, such as our neuregulin Glial Growth Factor 2, for which we commenced a Phase 1 clinical trial in the fourth quarter of 2010, 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
- change in our financial position.

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

If 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.

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The pharmaceutical industry is subject to stringent regulation and failure to obtain regulatory approval will prevent commercialization of our product candidates and, if we do not comply with FDA regulations if we obtain regulatory approval, approved products could be withdrawn from the market.

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. Any regulatory approvals may contain limitations on the indicated usage of a drug or, 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. Additional adverse events that could impact commercial success, or even continued regulatory approval, might emerge with more extensive post-approval patient use. Post-market evaluation of a product could result in marketing restrictions or withdrawal from the market.

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, or cGMPs, 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.

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 we 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.

We also are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to other regulatory requirements that apply to marketed drugs manufactured or distributed by us. If we receive a notice of inspectional observations or deficiencies from FDA, we may be required to undertake corrective and preventive actions in order to address the FDA's concerns, which could be expensive and time-consuming to complete and could impose additional burdens and expenses on how we conduct the affected activities. For example, the FDA conducted an inspection of our adverse event reporting in February 2009 that 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 have undertaken corrective and preventive actions in order to address the FDA's concerns cited in the Form FDA 483. However, the FDA might identify different or additional deficiencies in subsequent inspections. In addition, although Ampyra was approved by the FDA on January 22, 2010, the FDA has not inspected our third party suppliers' drug product manufacturing sites in connection with that approval. The process validation efforts and manufacturing process at these sites could be inspected at a later date and the FDA might find what it considers to be deficiencies in the manufacturing process or process validation efforts, which could negatively impact the availability of product supply.

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We and our third party suppliers are generally required to maintain compliance with cGMPs and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. In addition, the FDA must approve any significant changes to our suppliers or manufacturing methods. If we or our third party suppliers cannot demonstrate ongoing cGMP compliance, we may be required to withdraw or recall product and interrupt commercial supply of our products. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions. Non-compliance could increase our costs, cause us to lose revenue, and damage our reputation.

Even if our suppliers or manufacturing methods are in compliance with applicable requirements, we may encounter problems with the manufacture of our products. To investigate and/or resolve these problems, we may be required to withdraw or recall product and interrupt commercial supply of our products. We are required to submit field alert reports to the FDA if we learn of certain reported problems with our products, and we are required to investigate the causes of the reported problems. For example, in February 2011, we filed a field alert report with the FDA pertaining to two reports of empty Zanaflex Capsules that had been distributed to pharmacies and sold to patients. We are currently investigating the cause of the reported problems and, depending on the length of the investigation and other factors, we might have to interrupt the commercial supply of Zanaflex Capsules to allow for inspection of existing manufactured product. Depending on the outcome of our investigation, we expect to recall some Zanaflex Capsules, and are in discussions with the FDA about the level to which the recall should be conducted. It is also possible that the FDA might require additional recall or other actions. These events could increase our costs, cause us to lose revenue, and damage our reputation.

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 depends 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 hydrochloride tablets, or that the benefits of Ampyra are meaningful for patients.

Ampyra was approved with an indicated use limited to improving walking in patients with MS and specifies that this was demonstrated by an increase in walking speed. The approved labeling also contains other limitations on use and warnings and contraindications for risks. If potential purchasers or those influencing purchasing decisions, such as physicians and pharmacists or third-party payers react negatively to Ampyra because of their perception of the limitations or safety risks in the approved product labeling, it may result in lower product acceptance and lower product revenues. If Ampyra is not listed on the preferred drug lists of third-party payers, or Ampyra is on the preferred drug list but subject to unfavorable limitations or preconditions or in disadvantageous positions on tiered formularies, our sales may suffer.

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In the U.S., the federal government has provided significantly increased funding for comparative effectiveness research, which may compare our products with other treatments and may result in published findings that would, in turn, discourage use of our products by physicians and payments for our products by payers. Similar research is funded in other countries, including in Europe. 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.

If our products are approved in the EU, their success there will also depend largely on obtaining and maintaining government reimbursement because, in many European countries, patients will not use prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with governmental authorities can delay commercialization by one year or more. Even if reimbursement is available, reimbursement policies may adversely affect the ability of us or our partners, such as Biogen Idec, to sell our products on a profitable basis.

Several additional factors may limit the market acceptance of products, including:

- rate of adoption by healthcare practitioners;
- rate of a product's acceptance by the target population,
- timing of market entry relative to competitive products,
- availability of alternative therapies,
- perceived advantages of alternative therapies,
- price of product relative to alternative therapies,
- extent of marketing efforts,
- unavailability of adequate reimbursement by third parties, and
- side effects or unfavorable publicity concerning the products or similar products.

If our products do not achieve market acceptance in the U.S., we may not realize sufficient revenues from product sales, which may cause our stock price to decline.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate false claims laws or fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we may be subject to civil or criminal penalties or additional reimbursement requirements and sanctions, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include anti-kickback statutes and false claims statutes. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce or facilitate prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

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Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; and engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Sanctions under these federal and state laws may include requirements to make payments to correct for underpayments or repay overpayments, civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Service Act pharmaceutical pricing program, which requires us to sell our products to certain customers at prices lower than we otherwise might be able to charge. If products are made available to authorized users of the Federal Supply Schedule, additional pricing laws and requirements apply. Pharmaceutical companies have been prosecuted under federal and state false claims laws for manipulating information submitted to the Medicaid Rebate Program or for knowingly submitting or using allegedly inaccurate pricing information in connection with federal pricing and discount programs.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us or our contractors, governmental or regulatory agencies and the courts. Our methodologies for calculating these prices could be challenged under false claims laws or other laws. We or our contractors could make a mistake in calculating reported prices and required discounts, revisions to those prices and discounts, or determining whether a revision is necessary, which could result in retroactive rebates (and interest, if any). Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. If we make these mistakes or if governmental agencies make these changes, we could face, in addition to prosecution under federal and state false claims laws, substantial liability and civil monetary penalties, exclusion of our products from reimbursement under government programs, criminal fines or imprisonment or prosecutors may impose a Corporate Integrity Agreement, Deferred Prosecution Agreement, or similar arrangement.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In March 2010, Congress enacted legislation known as the Patient Protection and Affordable Care Act (Affordable Care Act), which substantially changes the way that health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. This new law contains a number of provisions, including provisions governing enrollment in federal health care programs, reimbursement changes, the increased use of comparative effectiveness research in health care decision-making, and enhancements to fraud and abuse requirements and enforcement, that will affect existing government health care programs and will result in the development of new programs.

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A number of provisions contained in the Affordable Care Act may adversely affect our net revenue for our marketed products and any future products. The new law, among other things, increased the minimum basic Medicaid rebate for branded prescription drugs from 15.1% to 23.1% and requires pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, the Affordable Care Act increased the additional Medicaid rebate on “line extensions” (such as extended release formulations) of solid oral dosage forms of branded products, revised the definition of average manufacturer price by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted 340B pricing.

Beginning in 2011, the new law requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the “donut hole.” At this time, although we have estimated a range of potential impact, we may not be able to accurately quantify what the potential impact will be for us. In addition, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) will be based on the manufacturer’s market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U.S. government programs.

The Affordable Care Act also includes substantial new provisions affecting compliance. For example, beginning in March 2013, pharmaceutical manufacturers will be required to report payments or other transfers of value made to health care providers during the preceding calendar year. These reports will be placed on a public database. Similarly, beginning in April 2012, pharmaceutical manufacturers will be required to report samples of prescription drugs requested by and distributed to health care providers during the preceding calendar year. The law does not state whether these disclosures will be made publicly available. If we fail to provide these reports, or if the reports we provide are not accurate, we could be subject to significant penalties. In addition, the federal government has been given additional enforcement authority.

The federal anti-kickback statute was also amended as a part of the Affordable Care Act to provide that a violation of the federal anti-kickback statute may serve as the basis for a false claim under the false claims act since claims for items or services “resulting from” a violation of the anti-kickback statute are “false” or fraudulent claims. The Affordable Care Act also permits the federal government to suspend payments to a supplier or provider pending an investigation of a "credible allegation" of fraud. The statute requires the Secretary of HHS to adopt regulations implementing this provision.

We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

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 or government-sponsored health administrative authorities, including Medicaid and Medicare Part D, 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 drug products. Third-party payers are increasingly challenging the pricing of medical products and services and their reimbursement practices may affect the price levels for Ampyra and Zanaflex Capsules. 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 or limit the circumstances under which our products will be reimbursed to a smaller set of circumstances we believe is appropriate.

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Third-party payers frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. We have agreed to provide these discounts and rebates to some third-party payers in relation to Ampyra. For both Ampyra and Zanaflex Capsules, we expect increasing pressure to offer larger discounts or discounts to a greater number of third-party payers to maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary. There is no guarantee that we would be able to negotiate agreements with third-party payers 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 Ampyra, and others may do so in the future. Similarly, a number of third-party payers require prior authorization for, or refuse to provide, reimbursement for Zanaflex Capsules, and other third-party payers may do so in the future. Patients who cannot meet the conditions of prior authorizations are often prevented from obtaining the prescribed medication, because they cannot afford to pay for the medication without reimbursement. If we are unsuccessful in maintaining reimbursement for our products at acceptable levels, or if reimbursement for our products by third-party payers is subject to overly-restrictive prior authorizations, 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.

The Medicare Part D outpatient prescription drug benefit has been in effect since 2006. 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 or increase rebate payments to offset price. 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. The Affordable Care Act requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the “donut hole.” At this time, although we have estimated a range of potential impact, we may not be able to accurately quantify what the potential impact will be for us. Legislative or regulatory revisions to the Medicare Part D outpatient prescription drug benefit, 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. For example, we are aware that BioMarin is developing a 3,4-diaminopyridine product that may compete with Ampyra. 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 dalfampridine is used by some people with MS and it is possible that some people will want to continue to use compounded formulations even though Ampyra is commercially available. 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 Ampyra or our preclinical candidates.

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Composition of matter patents on tizanidine, the active ingredient in Zanaflex Capsules and Zanaflex tablets, expired in 2002. As of January 1, 2011, there were ten companies with generic versions of tizanidine hydrochloride tablets on the market. To the extent that we are not able to differentiate Zanaflex Capsules from Zanaflex tablets and generic tizanidine hydrochloride tablets and/or pharmacists improperly substitute generic tizanidine hydrochloride tablets when filling prescriptions for Zanaflex Capsules, we may be unable to convert additional sales of Zanaflex tablets and generic tizanidine hydrochloride 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 hydrochloride exists, another company could develop a capsule or other formulation of tizanidine hydrochloride 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 another company, Zanaflex Capsules would face significant competition, which would likely cause significant declines in our revenue from this 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.

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 U.S. from Canada, Mexico and other countries where there are government price controls or other market dynamics that make the products lower priced.

We may expand our business through the acquisition of companies or businesses or in-licensing product candidates that could disrupt our business and harm our financial condition.

We may in the future seek to expand our products and capabilities by acquiring one or more companies or businesses or in-licensing one or more product candidates. Acquisitions and in-licenses involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- diverting our management’s attention away from other business concerns;

- entering markets in which we have limited or no direct experience; and

- potential loss of our key employees or key employees of the acquired companies or businesses.

We cannot assure you that any acquisition or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions and in-licenses. Any acquisition might distract resources from and otherwise negatively impact sales of Ampyra. We cannot assure you that we would be able to make the combination of our business with that of acquired businesses or companies or in-licensed product candidates work or be successful. Furthermore, the development or expansion of our business or any acquired business or company or in-licensed product candidate may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our stock, which could dilute our current shareholders' ownership interest, or securities convertible into our stock, which could dilute current shareholders' ownership interest upon conversion.

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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 Ampyra, Zanaflex Capsules, Zanaflex tablets 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 for our marketed products as well as for our clinical trials. The total insurance limit is $50 million per claim, and the aggregate amount of claims under the policy is also capped at $50 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.

Additionally, we have entered into various agreements where we indemnify third parties such as manufacturers and investigators for certain product liability claims related to our products. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

The approval of Zanaflex Capsules and Zanaflex tablets and any other products for which we may receive marketing approval in the future are subject to post-approval regulatory requirements, and we may be subject to penalties if we fail to comply with these 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.

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 report against the new standards set out in the 2007 FDA Amendments Act (FDAAA) and concluded that it did not satisfy the commitment. The FDA has informed us that a series of studies designed to further characterize the pharmacokinetics and demonstrate the efficacy and long-term safety of Zanaflex Capsules in children are required to fulfill the pediatric commitment for Zanaflex Capsules. We have initiated the first in a series of studies designed to fulfill our pediatric commitment. These studies could be more extensive and more costly than our prior studies and could result in new data that are not consistent with the current safety and efficacy profile of the drug. We also may be subject to penalties

for non-compliance with FDAAA, including a court-imposed injunction to conduct studies.

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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, the Federal Trade Commission, 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, and are affected by 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 (VHCA). If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the VHCA, we are required to offer certain drugs at a reduced price to a number of federal agencies including the Veterans Administration and the Department of Defense (DOD), the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain DOD purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. 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;

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

Many states have enacted laws governing the licensure of companies that distribute prescription drugs, although the scope of these laws varies, particularly where out-of-state distributors are concerned. In the past, we obtained licenses in all of the jurisdictions in which we believed we were required to be licensed. We were advised, however, that we needed to file license applications in certain additional jurisdictions and that some of our existing licenses needed to be amended. We filed amendments to certain licenses and obtained additional licenses. However, there can be no assurance that one or more of these states will not take action under these licensure laws.

In recent years, several states have also enacted legislation regarding promotional and other activities conducted by pharmaceutical companies. These laws require companies to establish marketing compliance programs; disclose various sales marketing expenses and pricing information; refrain from providing certain gifts or other payments to health care professionals; ensure that their sales representatives in that state are licensed; and/or restrict their use of prescriber data with respect to marketing activities in that state. 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 and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals. Similarly, some states, including California, Maine, Massachusetts, Minnesota, New Hampshire, Vermont and West Virginia, and the District of Columbia have passed laws of varying scope that ban or limit the provision of gifts, meals and certain other payments to healthcare professions or 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 requirements are new, and the manner in which they will be enforced going forward is uncertain. In some cases, the penalties for failure to comply with these requirements are unclear. We are continually updating our formal compliance infrastructure and standard operating procedures to comply with such laws, but we cannot eliminate the risk created by these uncertainties. Unless we are in full compliance with these laws, we could face enforcement action, fines and other penalties, including government orders to stop selling drugs into a state until properly licensed, and could receive adverse publicity.

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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, 2010, we had approximately $240.0 million in cash, cash equivalents and short-term investments. 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 may 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 Ampyra.

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.

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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 U.S. 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.

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

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

We currently maintain a general liability insurance policy that has a $1 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 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 and trademark 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.

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We have invented, in-licensed or are the assignee of over 45 U.S. patents, over 115 foreign patents and over 255 patent applications pending worldwide for technologies we invented or in-licensed. The process of obtaining patents and trademarks can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent or trademark 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 trademarks or the patents or trademarks of our licensors.

We may initiate actions to protect our intellectual property and in any litigation in which our intellectual property or our licensors' intellectual property is asserted, a court may determine that the intellectual property is invalid or unenforceable. Even if the validity or enforceability of that intellectual property is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by, for example, 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 advising that it had submitted an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. 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 U.S. 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.

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In November 2007, the defendants answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. We denied those counterclaims. Fact discovery in the case has been completed. On July 2, 2010, the U.S. District Court held a Markman hearing to determine the interpretation of certain terms in the Company's Zanaflex Capsules patent that is at issue in this litigation. The Court ruled favorably on a number of those terms, and the case is proceeding. A trial date of April 25, 2011 has been set by the Court. 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. 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.

In addition, Apotex could begin selling a generic tizanidine hydrochlorride capsule product while the patent litigation is pending. Our filing of a timely lawsuit against Apotex in October 2007 triggered an automatic stay on FDA approval of the Apotex ANDA for 30 months. That stay expired in March 2010. Consequently, Apotex will be able to receive FDA approval of its ANDA if Apotex is able otherwise to satisfy FDA's review requirements for ANDAs, at which time it could begin selling a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex tablets even if our patent litigation remains pending. If Apotex begins selling its product before it is successful in challenging the validity, infringement, or enforceability of our patent, Apotex would be selling at the risk of our ultimately prevailing on our patent infringement claims and its being held liable for damages for patent infringement. However, other generic manufacturers have launched products at risk in comparable circumstances.

Other third parties may bring similar claims to Apotex. 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. 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.

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;
- withdraw a product from the market;
- 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.

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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 Ampyra, Zanaflex and all of our research and development 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 dalfampridine 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 in markets outside the U.S. if we fail to launch a product within 180 days of NDA-equivalent approvals in those countries. Elan could also terminate our license agreement if we fail to make payments due under the license agreement. If we lose our rights to dalfampridine, 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 our collaborators or by our competitors;
- publicity regarding actual or potential clinical trial results or updates relating to products under development by us, our collaborators, 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;

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- litigation and other developments relating to our patents or other proprietary rights or those of our collaborators or competitors;
- governmental regulation and legislation in the U.S. 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
- changes in healthcare reimbursement policies.

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 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 17, 2011, we had outstanding 39,101,223 shares of voting common stock. Also, options to acquire 4,108,994 shares of common stock were outstanding as of February 17, 2011, exercisable at an average exercise price of $20.21 per share, and additional shares of common stock are authorized for issuance pursuant to options and other awards under our 2006 Employee Incentive Plan. 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, 2010, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 40.1% 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.

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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.

Not applicable.

Item 2. Properties.

Our principal executive offices are located in an approximately 52,785 square foot facility in Hawthorne, NY, which includes an expansion of 6,680 square feet of office space in February 2010. The current annual rent for this facility is approximately $1.1 million. We believe that our facility is currently adequate for our purposes; however, we expect we will need to rent additional space in the future based upon the possible growth of the company. The lease for this facility expires in December 2012.

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Item 3. Legal Proceedings.

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. 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 U.S. 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.

In November 2007, the defendants 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. Fact discovery in the case has been completed. On July 2, 2010, the U.S. District Court held a Markman hearing to determine the interpretation of certain terms contained in the Company's Zanaflex Capsules patent that is at issue in this litigation. The Court ruled favorably on a number of those terms, and the case is proceeding. A trial date of April 25, 2011 has been set by the Court.

Our filing of a timely lawsuit against Apotex in October 2007 triggered an automatic stay on FDA approval of the Apotex ANDA for 30 months. That stay expired in March 2010. Consequently, Apotex will be able to receive FDA approval of its ANDA, if Apotex is able otherwise to satisfy FDA's review requirements for ANDAs, at which time it could begin selling a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex tablets, even if our patent litigation remains pending. If Apotex begins selling its product before it is successful in challenging the validity, infringement, or enforceability of our patent, Apotex would be selling at the risk of our ultimately prevailing on our patent infringement claims and its being held liable for damages for patent infringement.

Item 4. (Removed and Reserved).

PART II

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

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

	High	Low
Fiscal Year Ended December 31, 2010		
Fourth Quarter	$33.39	$24.99
Third Quarter	$37.29	$28.53
Second Quarter	$40.48	$30.66

First Quarter	$36.83	$25.05

	High	Low
Fiscal Year Ended December 31, 2009		
Fourth Quarter	$26.00	$15.52
Third Quarter	$26.71	$21.12
Second Quarter	$28.62	$17.63
First Quarter	$29.27	$19.10

Registrar and Transfer Company is the transfer agent and registrar for our common stock. As of February 17, 2011, we had approximately 30 registered holders of record of our common stock.

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Stock Price Performance Graph

The following graph compares the cumulative 47-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 12/31/2010.

	2/06	2/06	3/06	4/06	5/06	6/06	7/06	8/06	9/06	10/06	11/06	12/06
Acorda Therapeutics, Inc	100.00	92.26	77.68	72.92	57.29	62.05	47.62	43.45	136.16	264.73	288.10	235.71
NASDAQ Composite	100.00	98.68	101.69	101.20	95.19	95.06	91.92	95.98	99.35	104.39	107.44	107.13
NASDAQ Biotechnology	100.00	103.56	102.22	96.41	92.60	91.14	93.57	93.81	95.99	101.62	100.43	98.17

1/07	2/07	3/07	4/07	5/07	6/07	7/07	8/07	9/07	10/07	11/07	12/07	1/08	2/08	3/08
257.29	323.07	288.99	368.75	296.13	253.87	249.70	267.71	273.07	301.64	278.42	326.79	377.38	304.17	267.11
109.51	107.51	107.70	112.27	115.68	116.24	113.62	115.92	121.64	128.95	119.67	119.52	107.50	102.21	102.30
101.54	98.42	95.75	104.17	102.64	100.16	99.22	100.57	106.74	111.31	108.04	101.49	99.57	98.37	98.51

4/08	5/08	6/08	7/08	8/08	9/08	10/08	11/08	12/08	1/09	2/09	3/09	4/09	5/09	6/09
313.24	320.83	488.54	488.24	418.90	354.91	303.57	269.64	305.21	365.03	327.38	294.79	295.09	367.41	419.49
108.61	113.57	103.44	103.49	104.92	92.16	76.29	68.47	70.73	66.43	62.30	68.68	76.73	79.72	82.56
99.33	101.48	99.89	113.42	110.43	103.68	94.74	88.34	94.85	93.52	84.73	87.89	86.41	89.06	94.53

7/09	8/09	9/09	10/09	11/09	12/09	1/10	2/10	3/10	4/10	5/10	6/10	7/10	8/10	9/10
375.89	336.61	346.43	323.36	358.33	375.00	416.37	449.11	508.93	576.64	511.61	462.95	481.25	448.21	491.37
89.13	90.80	95.63	92.67	97.31	102.71	97.19	101.41	108.52	110.97	101.74	95.62	102.22	96.29	107.85
102.58	101.22	104.04	95.25	101.59	104.84	107.50	109.81	114.19	111.71	100.54	97.26	101.34	98.95	107.59

10/10	11/10	12/10
402.38	393.12	405.65
114.10	113.62	120.74
111.46	107.69	113.02

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

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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.

Issuer Purchases of Equity Securities

This table provides information about our purchases of shares of Acorda stock during the three-month period ended December 31, 2010.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
October 1-31, 2010	-	-	-	-
November 1-30, 2010	-	-	-	-
December 1-31, 2010	12,420	$26.47	-	-
Total	12,420	$26.47	-	-

(1) Share repurchases reported in this column consist of shares tendered by employees in December 2010 to cover taxes relating to the vesting of restricted stock awards.

Item 6. Selected Financial Data.

The following unaudited selected consolidated financial data for each of the five years in the period ended December 31, 2010 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.

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	Year Ended December 31,				
	2010	2009	2008	2007	2006
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Gross product sales	$196,453	$58,267	$53,398	$43,586	$26,548
Less: discounts and allowances	(14,909)	(8,308)	(5,670)	(4,160)	396
Net sales	181,544	49,959	47,728	39,426	26,944
License revenue	9,461	4,714	—	—	—
Grant revenue	—	—	99	60	407
Total net revenue	191,005	54,673	47,827	39,486	27,351
Costs and expenses:					
Cost of Sales	35,518	11,059	11,355	8,356	7,123
Research and development	30,600	34,611	36,604	22,410	12,055
Selling, general and administrative	133,317	90,260	73,307	48,168	31,640
Total operating expenses	199,435	135,930	121,266	78,934	50,818
Operating loss	(8,430)	(81,257)	(73,439)	(39,448)	(23,467)
Other income (expense):					
Interest and amortization of debt discount expense	(3,923)	(4,415)	(5,591)	(2,664)	(2,553)
Interest income	575	1,750	4,682	4,087	1,471
Other income (expense)	8	(18)	8	51	76
Total other income (expense)	(3,340)	(2,683)	(901)	1,474	(1,006)
Cumulative effect of change in accounting principle(1)	—	—	—	—	454
Net loss	(11,770)	(83,940)	(74,340)	(37,974)	(24,019)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders	—	—	—	—	(36,008)
Net loss	$(11,770)	$(83,940)	$(74,340)	$(37,974)	$(60,027)
Net loss per share —basic & diluted	$(0.31)	$(2.22)	$(2.19)	$(1.45)	$(3.27)
Weighted average shares of common stock outstanding used in computing net loss per share —basic & diluted	38,355	37,735	33,939	26,237	18,346

(1) 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.

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	As of December 31,				
	2010	2009	2008	2007	2006
			(in thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$34,641	$47,314	$29,613	$16,810	$18,101
Short term investments	205,389	224,778	216,435	78,310	35,656
Working capital	216,919	220,380	207,445	71,770	33,324
Total assets	342,101	319,471	281,501	127,306	84,368
Deferred product revenue—Zanaflex tablets	9,526	9,215	7,867	7,914	9,117
Deferred product revenue—Zanaflex Capsules	21,770	21,489	16,436	13,924	11,324
Current portion of notes payable	—	—	—	188	1,044
Non-current portion of notes payable	—	—	—	—	187
Current portion of deferred license revenue	9,429	9,429	—	—	—
Non-current portion of deferred license revenue	86,429	95,857	—	—	—
Current portion of revenue interest liability—PRF transaction	1,297	6,179	6,181	1,785	3,392
Put/call option liability—PRF transaction	391	638	338	463	350
Non-current portion of revenue interest liability—PRF transaction	3,586	5,631	12,498	17,444	19,744
Long term convertible notes payable	6,186	7,112	6,905	6,703	6,508
Total stockholders' equity	151,261	137,333	207,157	63,433	18,669

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 and other neurological disorders. Ampyra, the first product for which we completed clinical development, was approved by the FDA in January 2010 for the improvement of walking in people with MS. This was demonstrated by an increase in walking speed. To our knowledge, Ampyra is the first and only product approved for this indication. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra was made commercially available in the U.S. in March 2010. Net revenue of Ampyra was $133.1 million for the year ended December 31, 2010.

Our other marketed drug, Zanaflex Capsules, which we began marketing in 2005, is FDA-approved as a short-acting drug for the management of spasticity. Combined net revenue of Zanaflex Capsules and Zanaflex tablets, which we also sell, were $48.5 and $50.0 million in the years ended December 31, 2010 and 2009 respectively. We expect that our gross sales of Zanaflex Capsules will continue to decline, principally due to increasing managed care pressure, among other factors. Managed care organizations have increasingly established plans and programs to drive utilization of low-cost generic tizanidine hydrochloride tablets over higher-cost Zanaflex Capsules by making it more difficult for patients to obtain Zanaflex Capsules through restrictions and higher out-of-pocket (copay) costs. There was a 15% price increase on Zanaflex Capsules effective February 1, 2010 and a 9% price increase on Zanaflex

Capsules and tablets effective November 1, 2010.

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Ampyra is being marketed in the U.S. through our own specialty sales force and commercial infrastructure, which is also responsible for sales and marketing of Zanaflex Capsules. We completed the expansion of our sales force in March 2010 and currently have approximately 100 sales representatives in the field calling on a priority target list of approximately 10,000 physicians. We also have established teams of Regional Scientific Managers and Managed Markets representatives who provide information on Ampyra to physicians and payors. As of December 31, 2010, approximately 7,000 healthcare professionals had written at least one prescription for Ampyra.

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail and Kaiser Permanente (Kaiser), and is supported by Ampyra Patient Support Services (APSS), a dedicated resource for healthcare providers and people with MS. This distribution process is well established within the MS community, and physicians and patients are familiar with this model. Prior to the launch of Ampyra, we contracted with a third party organization with extensive experience in coordinating patient benefits to run APSS. The customer care agents at Ampyra Patient Support Services are responsible for helping healthcare professionals process prescriptions, working with insurance carriers to facilitate coverage, and directing patients to available copay and patient assistance programs. The process begins when a prescription is submitted by a physician to APSS. Once this process is completed, the prescription is sent to a specialty pharmacy, which confirms the benefits and mails the prescription directly to the patient. In some cases, the specialty pharmacy rather than APSS performs the benefits investigation or receives a submitted prescription directly.

A prescription request backlog was experienced at APSS early in the launch due to pent-up demand, and we worked to have APSS implement process improvements and staffing adjustments to address the backlog. The backlog continued to be filled during the quarter ended June 30, 2010, and it was eliminated by the end of that quarter. Third quarter 2010 sales were significantly impacted by the large backlog of prescription requests that were submitted earlier in the year and were not all filled until the third quarter. This backlog was eliminated in the third quarter. Processing of most incoming requests for prescriptions by APSS now begins within 24 hours of receipt. Patients will still experience a range of times to receive their first shipment based on their insurance requirements. As with any new prescription product, patients who are members of benefit plans that have restrictive prior authorizations may experience delays in receiving their prescription.

As of December 31, 2010, approximately 40,000 people with MS had filled a prescription for Ampyra, representing approximately 10% of all MS patients in the U.S. As of December 31, 2010, the rate of first refill was approximately 75%. Approximately 85% to 90% of total prescriptions written through December 31, 2010, were for a one month supply, with most of the balance being for three months. As of December 31, 2010, approximately 10% of shipped product is for no-cost use by patients enrolled in the Ampyra patient assistance program.

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Our managed markets representatives continue to meet with payors to provide information on Ampyra and discuss patient access. As of December 31, 2010, approximately 75% of commercially-insured individuals had no or limited prior authorizations (PAs) for Ampyra. We define limited PAs as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. As of December 31, 2010, approximately 20% of commercially-insured individuals were subject to more restrictive PAs, which may include requirements for multiple timed walk tests and/or EDSS (Expanded Disability Status Scale) score requirements to initiate therapy, and/or objective measures of ambulation improvement to reauthorize Ampyra therapy. We estimate that, as of December 31, 2010, approximately 5% of commercially-insured individuals were blocked from receiving reimbursement for Ampyra. Access figures were calculated based on the number of pharmacy lives reported by commercial healthcare plans.

As of December 31, 2010, inventory levels at the specialty pharmacy providers that distribute Ampyra (excluding Kaiser) were approximately two weeks. The specialty pharmacy providers and Kaiser are contractually obligated to hold no more than 30 days of inventory.

The FDA granted Ampyra orphan drug status, which provides seven years of market exclusivity for the drug. In addition, we have issued patents that cover the formulation and use of Ampyra. We filed for patent term extension for Ampyra pursuant to the provisions of the Hatch-Waxman Act that allows for up to five additional years of patent protection based on the development timeline of a drug. Although we have applied to extend both Ampyra patents listed in the FDA Orange Book, we will ultimately need to select only one patent for extension, if each is granted. In 2010, we received non-final rejection letters from the U.S. Patent and Trademark Office (USPTO) on two patent applications for Ampyra filed in late 2004 and early 2005. In November 2010, we timely responded to the letter regarding the 2005 application. We have until March17, 2011 to respond to the letter regarding the 2004 application, and we expect to file a timely response.

In November 2010, the European Patent Office (EPO) posted a Communication of Intention to Grant a Patent for a patent application we submitted with “composition for use” and other use claims directed to sustained release aminopyridine compositions for, among other things, increased walking speed, improving lower extremity muscle strength, or improving lower extremity muscle tone, in patients with MS. The grant fee for this application is due in March 2011, and we expect to timely file this fee. A corresponding patent is currently under review by the USPTO. The USPTO operates independently of the EPO, and the EPO’s decision should not be taken to indicate the outcome for the U.S. patent.

In June 2009, we entered into the Collaboration Agreement with Biogen Idec. In January 2010, Biogen Idec announced that it submitted a centralized Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and a New Drug Submission (NDS) to Health Canada for Ampyra, which is known outside the U.S. as fampridine. In January 2011 the EMA’s Committee for Medicinal Products for Human Use (CHMP) decided against approval. Biogen Idec has filed an appeal to request a re-examination of the decision by the CHMP. Biogen Idec received a Notice of Deficiency from Health Canada regarding its application for approval of Fampyra in Canada, to which it intends to respond. Health Canada will have approximately a year to reply to that response.

We have three research and development programs focused on novel approaches to repair damaged components of the CNS. We believe all of our research and development 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 spinal cord injury (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 March 2010, we filed an Investigational New Drug (IND) application for Glial Growth Factor 2 (GGF2), the lead product candidate for our neuregulins program, as a therapy for heart failure, and in April 2010 the IND became effective. In December 2010, the first patient was enrolled in the first clinical trial of GGF2. Acorda is collaborating with the Vanderbilt University Heart and Vascular Institute to conduct this Phase 1 single-dose trial in patients with heart failure. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product either by entering into a partnership, most likely with a cardiovascular-focused company, or developing it on our own. We and Vanderbilt University received a $1 million Cardiac Translational Research Implementation Program (C-TRIP) grant from the National Heart, Lung and Blood Institute (NHLBI) to support research on GGF2 separate from the Phase 1 clinical trial. If these studies are successful, Acorda and Vanderbilt will be eligible to apply for a second phase C-TRIP grant of at least $7.5 million.

We began work with a contract manufacturer in 2009 to scale up manufacturing and purification processes for one of the remyelinating antibodies, rHIgM22, under cGMP for preparation for a future IND application. These manufacturing processes have been completed and we are now in formal preclinical safety and toxicity studies. If rHIgM22 proves to have a satisfactory preclinical safety profile, we expect to file an IND for the treatment of MS. We also are continuing research on the potential use of chondroitinases for the treatment of injuries to the brain and spinal cord. The chondroitinase program is in the research and translational development phases and has not yet entered formal preclinical development.

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We have had significant operating losses since inception as a result of our focus on clinical and research and development activities and our goal of building an internal sales, managed markets and marketing organization in the U.S. We may incur losses for the next several years as we continue to support an expanded sales and marketing organization and other activities in connection with the commercialization of Ampyra and the advancement of our clinical and preclinical development programs. We currently expect Ampyra 2011 full year net revenue to increase to $205-$230 million. Selling, general and administrative (SG&A) expenses for the full year 2011 are currently expected to be $130-$140 million excluding share based compensation charges. SG&A will be primarily driven by commercial and administrative costs related to Ampyra. Research and development (R&D) expenses for the full year 2011 are currently expected to be $40-$45 million excluding share based compensation charges. R&D expenses in 2011 include post-marketing studies for Ampyra and continuing development expenses for our pipeline products, including Phase 1 clinical trials for GGF2. The projected amounts of SG&A and R&D for the full year 2011 in this paragraph and elsewhere in this report are non-GAAP financial measures. Non-GAAP financial measures are financial measures that exclude amounts, or which are subject to adjustments that have the effect of excluding amounts, that are included in the most directly comparable measure calculated in accordance with generally accepted accounting principles, or GAAP. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, we believe the presentation of these non-GAAP financial measures provides useful information to investors because they exclude non-cash charges that are substantially dependent on future changes in the market price of our common stock. Therefore, we believe that the use of these non-GAAP financial measures provides investors with a meaningful understanding of our projected operating performance. We have not provided corresponding forward-looking GAAP financial measures. Such forward-looking GAAP measures are not accessible to us because, among other reasons, we cannot predict the future market prices of our common stock.

We will also continue to explore opportunities to expand our pipeline through the potential in-licensing and/or acquisition of select products and technologies in neurology. We are interested in both clinical and commercial state products, with a particular focus on Phase 2 product candidates, although we are open to assessing compounds at other stages as well. We do not currently plan to acquire a marketed product for launch during the first year of Ampyra's commercial launch.

In August 2007, the Company received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an ANDA 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 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 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’s motion in December 2008. Fact discovery in the case has been completed. On July 2, 2010, the U.S. District Court held a Markman hearing to determine the interpretation of certain terms in the Company’s Zanaflex Capsules patent that is at issue in this litigation. The Court ruled favorably on a number of those terms, and the case is proceeding. A trial date of April 25, 2011 has been set by the Court.

Our timely filing of a lawsuit against Apotex in October 2007 triggered an automatic stay on FDA approval of the Apotex ANDA for 30 months. That stay expired in March 2010. Consequently, Apotex will be able to receive FDA approval of its ANDA, if Apotex is able otherwise to satisfy FDA's review requirements for ANDAs, at which time it could begin selling a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex tablets, even if our patent litigation remains pending. If Apotex begins selling its product before it is successful in challenging the validity, infringement, or enforceability of our patent, Apotex would be selling at the risk of our ultimately prevailing on our patent infringement claims and its being held liable for damages for patent infringement.

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The Company accrues for amounts related to loss contingencies if it is probable that a liability has been incurred and the amount is reasonably estimable. As of December 31, 2010, there have been no accruals for loss contingencies aside from payments related to the litigation itself.

Results of Operations

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

Net Revenue

Total net revenues are summarized in the following table:

	Year ended December 31, 2010	Year ended December 31, 2009
Gross product sales		
Ampyra	$141,389,196	$—
Zanaflex	55,063,901	58,267,284
Total gross product sales	196,453,097	58,267,284
Discounts and allowances		
Ampyra	(8,338,618)	—
Zanaflex	(6,569,979)	(8,307,936)
Total discounts and allowances	(14,908,597)	(8,307,936)
License and royalty revenue		
Ampyra	9,460,740	4,714,287
Zanaflex	—	—
Total license revenue	9,460,740	4,714,287
Total net revenue	$191,005,240	$54,673,635

We currently expect Ampyra 2011 full year net revenue to increase to $205-$230 million.

Gross Product Sales

Ampyra

We recognize product sales of Ampyra following shipment of product to a network of specialty pharmacy providers and Kaiser. We recognized gross revenue from the sale of Ampyra of $141.4 million for the year ended December 31, 2010.

Zanaflex

We recognize product sales of Zanaflex Capsules and Zanaflex tablets using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We recognized revenue from the sale of Zanaflex Capsules and Zanaflex tablets of $55.1 million for the year ended December 31, 2010, as compared to $58.3 million for the year ended December 31, 2009. The decrease was due to a decrease in both shipments and prescriptions due to increasing managed care pressure, among other factors, partially offset by a 15% price increase for Zanaflex Capsules effective February 1, 2010 and a 9% price increase for Zanaflex Capsules and tablets effective November 1, 2010. Sales of Zanaflex Capsules may decline in 2011.

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Discounts and Allowances

Ampyra

We recorded discounts and allowances of $8.3 million for the year ended December 31, 2010 which consists of allowances for customer credits, including estimated rebates, discounts and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers and Kaiser. Discounts and allowances consisted of $3.0 million for copay mitigation allowances, $2.6 million for cash discounts and allowances, $2.1 million for Government chargebacks and rebate allowances, $353,000 for product returns allowances, and $333,000 for managed care contract rebate allowances. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future and start to incur costs in 2011 related to new Healthcare Reform Medicare rebates described under the "Healthcare Reform" header below.

Zanaflex

We recorded discounts and allowances of $6.6 million for the year ended December 31, 2010 as compared to $8.3 million the year ended December 31, 2009. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances for the year ended December 31, 2010 consisted of $2.8 million in allowances for Government chargebacks and rebates, $2.5 million in fees for services payable to wholesalers, and $1.2 million in cash discounts and allowances. Discounts and allowances for the year ended December 31, 2009 consisted of $3.9 million in allowances for Government chargebacks and rebates, $2.9 million in fees for services payable to wholesalers and $1.6 million in cash discounts and allowances.

Healthcare Reform

In March 2010, healthcare reform legislation was enacted in the U.S. This legislation contains several provisions that will affect our business. Although many provisions of the new legislation do not take effect immediately, several provisions became effective in the first quarter of 2010. The 2010 changes did not have a material impact on our discounts and allowances.

Beginning in 2011, the new law requires drug manufacturers to provide a 50% discount to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the "donut hole"). At this time, although we have estimated a range of potential impact, we may not be able to accurately quantify what the potential impact will be for us.

Also, beginning in 2011, we will be assessed our share of a new fee (which will not be deductible for tax purposes) payable by all branded prescription drug manufacturers and importers. This fee will be based on each drug manufacturers' 2009 market share for certain drugs. We do not expect this fee to have a material impact on our financial statements in 2011.

License and Royalty Revenue

The Company recognized $9.4 million in license and royalty revenue related to the $110.0 million received from Biogen Idec in July 2009 for the year ended December 31, 2010 as compared to $4.7 million for the year ended December 31, 2009. The increase is due to recognition of a full year of revenue in 2010 versus a half year of recognition in 2009.

On January 21, 2011 Biogen Idec announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) decided against approval of fampridine to improve walking ability in adult patients

with multiple sclerosis. Biogen Idec has appealed this opinion and requested a re-examination of the decision by the CHMP. We are currently evaluating the impact on the period for the amortization of the deferred collaboration revenue and cost of license revenue, but it is likely to increase the amortization period and therefore decrease the amount of revenue recognized per period in the future.

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Cost of Sales

Ampyra

We recorded cost of sales of $26.1 million for the year ended December 31, 2010. Cost of sales for the year ended December 31, 2010 consisted primarily of $22.2 million in inventory costs related to recognized revenues. Our launch stock inventory was received in bulk form prior to regulatory approval; therefore, the manufacturing cost associated with this material was classified as research and development expense as there was no alternative future use prior to regulatory approval. This expensed bulk form material represented approximately 8% of the total cost basis of our launch stock inventory. The remaining packaged portion of the inventory cost was incurred after regulatory approval and thus capitalized. This reduction to our cost basis effectively reduced our cost of sales related to recognized revenues by approximately $1.3 million for the year ended December 31, 2010. Our reduced cost basis inventory was sold during the year ended December 31, 2010 and as of this date we are not carrying any launch inventory on our balance sheet with a reduced costs basis.

Cost of sales for the year ended December 31, 2010 also consisted of $2.8 million in royalty fees based on net sales, $789,000 in amortization of intangible assets, and $261,000 in period costs related to packaging, freight and stability testing.

Zanaflex

We recorded cost of sales of $9.5 million for the year ended December 31, 2010 as compared to $11.1 million for the year ended December 31, 2009. Cost of sales for the year ended December 31, 2010 consisted of $4.7 million in inventory costs primarily related to recognized revenues, $3.3 million in royalty fees based on net product shipments, $1.3 million in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $164,000 in period costs related to freight and stability testing. Cost of sales for the year ended December 31, 2009 consisted of $5.8 million in inventory costs primarily related to recognized revenues, $3.8 million in royalty fees based on net product shipments, $1.3 million in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $176,000 in period costs related to packaging, freight, and stability testing. Payments to and interest expense related to the PRF transaction discussed below in the section titled “Liquidity and Capital Resources” do not impact the Company’s cost of sales.

Research and Development

Research and development expenses for the year ended December 31, 2010 were $30.6 million as compared to $34.6 million for the year ended December 31, 2009, a decrease of approximately $4.0 million, or 12%. The decrease was primarily attributable to a decrease in regulatory expenses of $4.8 million which were incurred in 2009 related to NDA preparation and support for Ampyra. The decrease was also related to a reduction in expenses allocated to research and development of $1.4 million for Ampyra manufacturing and stability work that was classified as research and development for the year ended December 31, 2009 as it was incurred prior to FDA approval of the drug. Further, the decrease resulted from a decrease of $2.2 million and $690,000 in preclinical work on two of our pipeline products remyelinating antibodies rHIgM22 and GGF2, respectively. We initialized work with a contract manufacturer in 2009 on rHIgM22 to scale up manufacturing and purification processes under current good manufacturing practices, or cGMP, in preparation for a future IND application. These manufacturing processes have been completed and we are now working on formal preclinical safety and toxicity studies. In 2008, we began work with a contract manufacturer to develop production and purification methods for manufacturing GGF2 under cGMP. The bulk of this work was completed in 2009 culminating in our submission of an IND application in March 2010.

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The overall decrease in research and development expense was also partially offset by an increase in overall research and development staff and compensation of $2.0 million to support various pipeline initiatives as well as three milestone payments, totaling $1.2 million, paid during the year ended December 31, 2010 which were related to the filing of the IND for GGF2. Two milestone payments were for $500,000 each payable to Paion AG (formerly CeNeS) and one was for $150,000 payable to Brigham and Women's Hospital. The decrease in research and development expense was partially offset by an increase of $930,000 for clinical costs associated with the close-out of our MS extension study sites and overall increase in clinical staff and compensation to support the movement of one of our preclinical pipeline product candidates into the clinic, as well as an increase of $203,000 for the start-up of a Phase I GGF2 clinical trial. The decrease in research and development expense was further offset by an increase of $783,000 related to the start-up of a clinical trial and manufacturing and stability work for post-marketing studies of Ampyra.

Research and development (R&D) expenses for the full year 2011 are currently expected to be $40-$45 million excluding share based compensation charges. R&D expenses in 2011 include post-marketing studies for Ampyra and continuing development expenses for our pipeline products, including Phase 1 clinical trials for GGF2.

Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2010 were $87.8 million compared to $58.0 million for the year ended December 31, 2009, an increase of approximately $29.8 million, or 51%. This increase was primarily attributable to an increase in staff and compensation of $20.7 million resulting from the expansion of our field sales staff and the overall commercial department in order to support the launch of Ampyra as well as an increase of $9.1 million in marketing, trade and distribution expenses, managed markets, and various launch activities associated with Ampyra.

General and administrative expenses for the year ended December 31, 2010 were $45.5 million compared to $32.2 million for the year ended December 31, 2009, an increase of approximately $12.9 million, or 40%. The increase was the result of an increase in general and administrative staff and compensation and other expenses of $5.3 million related to supporting the overall growth of the organization, an increase in medical affairs expenses including educational programs of $4.2 million, and an increase in costs related to Ampyra post-approval regulatory, safety and technical operations support expenses of $3.4 million.

Selling, general and administrative (SG&A) expenses for the full year 2011 are currently expected to be $130-$140 million excluding share based compensation charges. SG&A will be primarily driven by commercial and administrative costs related to Ampyra.

Other Expense

Other expense was $3.3 million for the year ended December 31, 2010 compared to $2.7 million for the year ended December 31, 2009, an increase of approximately $600,000, or 22%. The increase was primarily due to a decrease in interest income of $1.1 million resulting from a lower average interest rate and lower cash balances for the same period in 2009. The decrease in interest income was partially offset by a $492,000 decrease in interest expense principally related to the PRF revenue interest agreement.

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Gross Product Sales

We recognize product sales of Zanaflex Capsules and Zanaflex tablets sales using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when

end-user prescriptions of the product are reported. We recognized gross sales from the sale of Zanaflex Capsules and Zanaflex tablets of $58.3 million for the year ended December 31, 2009, as compared to $53.4 million for the year ended December 31, 2008, an increase of approximately $4.9 million, or 9%. The increase was due to a 10% price increase effective January 1, 2009, offset by a slight downward trend in dollarized prescriptions for Zanaflex Capsules observed beginning in the second quarter of 2009.

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Discounts and Allowances

We recorded discounts and allowances with respect to Zanaflex Capsules and Zanaflex tablets of $8.3 million for the year ended December 31, 2009 as compared to a $5.7 million for the year ended December 31, 2008, an increase of approximately $2.6 million or 47%. Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the year ended December 31, 2009 consisted of $3.9 million in allowances for Government chargebacks and rebates which included a rebate reserve of $1.1 million related to the U.S. military's Tricare program, of which $481,000 is related to 2009 and an adjustment of $639,000 is related to 2008. These rebates and adjustments resulted from a DOD regulation finalized during the three-month period ended March 31, 2009 which purports to require manufacturers to pay rebates to the DOD on utilization distributed to Tricare beneficiaries through retail pharmacies retroactive to January 28, 2008. The application of the regulation is currently being challenged in court by a coalition representing a number of manufacturers. We have not made any retroactive payments to the DOD to date.

Discounts and allowances for the year ended December 31, 2009 also included $2.9 million in fees for services payable to wholesalers and $1.6 million in cash discounts and allowances. Discounts and allowances for the year ended December 31, 2008 consisted of $2.3 million in fees for services payable to wholesalers, $1.9 million in allowances for Government chargebacks and rebates, and $1.5 million in cash discounts and allowances.

License Revenue

The Company recognized $4.7 million in license revenue related to the $110.0 million received from Biogen Idec in July 2009 for the year ended December 31, 2009.

Grant Revenue

We earned no grant revenue for the year ended December 31, 2009 compared to $99,000 for the year ended December 31, 2008. 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 related to Zanaflex Capsules and Zanaflex tablets of $11.1 million for the year ended December 31, 2009 as compared to $11.4 million for the year ended December 31, 2008, a decrease of approximately $300,000, or 3%. The decrease was principally due to the decrease in amortization of intangible assets resulting from having completed the amortization of the Zanaflex trademark portion of our intangible asset as of December 31, 2008. Cost of sales for the year ended December 31, 2009 consisted of $5.8 million in inventory costs, $3.8 million in royalty fees, $1.3 million in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and $176,000 in costs related to packaging, freight and stability testing. 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.

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Research and Development

Research and development expenses for the year ended December 31, 2009 were $34.6 million as compared to $36.6 million for the year ended December 31, 2008, a decrease of approximately $2.0 million, or 5%. The decrease was primarily attributable to the conclusion of our Phase 3 clinical trial of Ampyra in 2008, resulting in a decrease to MS clinical development program expense of $4.5 million or 51% to $4.4 million coupled with our acquisition of certain in-process research and development assets of Neurorecovery, Inc. (NRI) during the three-month period ended March 31, 2008, resulting in a one time non-cash expense of approximately $2.7 million. In addition, NDA preparation costs decreased $1.7 million or 25% to $4.9 million as the majority of the work for our submission to the FDA was completed in 2008.

These decreases were offset by an increase in preclinical research and development expense of $3.6 million or 38% to $13.0 million primarily related to work on two of our preclinical pipeline products, GGF2 (neuregulins) and remyelinating antibodies, including an increase in staff and compensation to support these initiatives. This overall increase in expense was primarily associated with animal toxicology expenses and the development of larger scale manufacturing and purification processes for GGF2, under cGMP, in preparation for a potential future IND application to support human clinical trials. The overall decrease in research and development expense was also offset by an increase in clinical and regulatory staff and compensation of $2.8 million or 40% to $9.7 million to support the overall growth of the organization and an increase in manufacturing and stability fees for Ampyra of $548,000, or 26% to $2.7 million. Research and development expenses are expected to increase in 2010 over 2009 due to the continued development of the Company’s pre-clinical programs, including expected initiation of a GGF2 Phase 1 study, and implementation of our post-marketing study commitments for Ampyra.

Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2009 were $58.0 million compared to $49.1 million for the year ended December 31, 2008, an increase of approximately $8.9 million, or 18%. This increase was primarily attributable to an increase of $9.0 million for pre-launch activities in anticipation of commercialization of Ampyra. In addition, we realized an increase in sales and marketing staff and compensation of $533,000 to support promotion of Zanaflex Capsules and Ampyra pre-launch activities and an increase in corporate communications costs of $275,000. These increases were offset by a decrease in other selling related expenses of $828,000, which primarily represents a reduction in field staff costs and a decrease in Zanaflex Capsules marketing expenses of $79,000.

General and administrative expenses for the year ended December 31, 2009 were $32.0 million compared to $24.2 million for the year ended December 31, 2008, an increase of approximately $7.8 million, or 32%. This increase was the result of an increase in staff and compensation and other expenses related to supporting the growth of the overall organization and our medical affairs program of $5.7 million, an increase in costs associated with medical affairs research and educational programs of $1.2 million, an increase in business development expenses of $600,000 related to our collaboration and licensing agreement efforts, and an increase in legal fees of approximately $200,000.

Other Expense

Other expense was $2.7 million for the year ended December 31, 2009 compared to $901,000 for the year ended December 31, 2008, an increase of approximately $1.8 million, or 198%. The increase was primarily due to a decrease in investment interest income of $2.9 million resulting from a lower average interest rate than for the same period in 2008. This decrease was offset by a decrease in interest expense of $1.2 million under the PRF revenue interest agreement as a result of 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.

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Liquidity and Capital Resources

We have incurred annual operating losses since inception and, as of December 31, 2010, we had an accumulated deficit of approximately $440.1 million. We have financed our operations primarily through private placements of our securities, public offerings of our common stock, our Collaboration and Licensing Agreement, sales of Zanaflex Capsules and Ampyra, and, to a lesser extent, from loans, government grants and our financing arrangement with PRF.

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, 2010, $5.0 million of these promissory notes plus $2.3 million of accrued interest was outstanding. The first of seven annual payments on this note was due and was paid on the one year anniversary after Ampyra approval on January 22, 2011.

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 were required to pay PRF $5.0 million on December 1, 2009 and an additional $5.0 million on December 1, 2010. These payments were made.

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, 2010, referred to as the revenue interest liability, of approximately $4.9 million. 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 5.7%. 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.

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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 $391,000 as of December 31, 2010 related to the put/call option to reflect its current estimated fair value. 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, 2010, cash and cash equivalents and short-term investments were approximately $240.0 million, as compared to $272.0 million at December 31, 2009. 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, 2010, our cash and cash equivalents were $34.6 million, as compared to $47.3 million as of December 31, 2009. Our short-term investments consist of US Treasury bonds with original maturities greater than three months and less than one year. The balance of these investments was $205.4 million as of December 31, 2010, as compared to $224.8 million as of December 31, 2009.

Net Cash Provided by/(Used in) Operations

Net cash used in operations was $19.2 million and $38.6 million for year ended December 31, 2010 and 2009, respectively. Cash used in operations for the year ended December 31, 2010 was primarily attributable to an increase in inventory held by the Company of $31.7 million due to the purchase of Ampyra launch stock and additional Ampyra inventory to meet demand which was launched in 2010, an increase in accounts receivable of $16.5 million resulting from an increase in gross product sales for Ampyra which was launched in 2010, a net loss of $11.8 million, and a decrease in the non-current portion of deferred license revenue of $9.4 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009. Cash used in operations for the year ended December 31, 2010 also included a net increase of $23.5 million due to changes in other working capital items. Cash used in operations was partially offset by a non-cash share-based compensation expense of $17.8 million, amortization of net premiums and discounts on short-term investments of $4.5 million, and

depreciation and amortization of $4.0 million.

Cash provided by operations for the year ended December 31, 2009 was primarily attributable to an increase in deferred license revenue of $105.3 million, a non-cash share-based compensation expense of $12.3 million, amortization of the discount on short-term investments of $4.9 million, depreciation and amortization of $2.8 million, and a loss on our put/call liability related to the Zanaflex revenue interest liability of $300,000. Cash provided by operations for the year ended December 31, 2009 also included a net increase of $3.7 million due to changes in other working capital items. Cash provided by operations for the year ended December 31, 2009 was partially offset by a net loss of $83.9 million and an increase in non current portion of deferred cost of license revenue of $6.7 million.

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Net Cash Provided by Investing

Net cash provided by investing activities for the year ended December 31, 2010 was $5.4 million, primarily due to $325.8 million in proceeds from maturities and sales of short-term investments partially offset by $311.0 million in purchases of short-term investments, purchases of intangible assets of $7.0 million, and purchases of property and equipment of $2.4 million.

Net Cash Provided by Financing

Net cash provided by financing activities for the year ended December 31, 2010 was $1.2 million, primarily due to $8.4 million in net proceeds from the issuance of common stock and exercise of stock options partially offset by $6.8 million in repayments to PRF and $0.3 million of purchases of treasury stock.

Future Capital Needs

We currently expect Ampyra 2011 full year net revenue to increase to $205-$230 million. Selling, general and administrative (SG&A) expenses for the full year 2011 are currently expected to be $130-$140 million excluding share based compensation charges. SG&A will be primarily driven by commercial and administrative costs related to Ampyra. Research and development (R&D) expenses for the full year 2011 are currently expected to be $40-$45 million excluding share based compensation charges. R&D expenses in 2011 include post-marketing studies for Ampyra and continuing development expenses for our pipeline products, including Phase 1 clinical trials for GGF2.

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

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

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. Under certain supply agreements and other agreements with manufacturers and suppliers, we are required to make payments for the manufacture and supply of our clinical and approved products. Our major outstanding contractual obligations are for payments related to our convertible notes, our facility leases and our commitments to purchase inventory. The following table summarizes our minimum significant contractual obligations at December 31, 2010 and the effect such obligations are expected to have on our liquidity and cash flow in future periods.

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		Payments due by period (1)		
(In thousands)	Total	Less than 1 year	1-3 years	4-5 years
Convertible note payable(2)	$6,865	$1,144	$3,433	$2,288
Operating leases	2,298	1,149	1,149	—
Inventory purchase commitments(3)	23,083	23,083	—	—
Total	$32,246	$25,376	$4,582	$2,288

(1) Excludes PRF principal and interest payments, due to uncertainty as to the amount and timing of such payments.

(2) Represents annual payments of principal and interest to be made on the convertible note payable to Saints Capital starting on January 22, 2011 (the first anniversary of Ampyra FDA approval).

(3) Represents Zanaflex and Ampyra inventory commitments. The Ampyra inventory commitment is an estimate as the price paid for Ampyra inventory is based on a percentage of the net product sales during the quarter Elan ships inventory to us. Under our supply agreement with Elan, we provide Elan with monthly written 18-month forecasts, and with annual written five-year forecasts for our supply requirements of Ampyra and two-year forecasts for our supply requirements of Zanaflex Capsules. In each of the five months for Zanaflex and three months for Ampyra 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. We have agreed to purchase at least 75% of our annual requirements of Ampyra from Elan, unless Elan is unable or unwilling to meet its requirements, for a percentage of net product sales and the quantity of product shipped by Elan to us.

Under certain license agreements, we are required to pay royalties for the use of technologies and products in our R&D activities and in the commercialization of products. The amount and timing of any of the foregoing payments are not known due to the uncertainty surrounding the successful research, development and commercialization of the products.

Under certain license agreements, we are also required to pay license fees and milestones for the use of technologies and products in our R&D activities and in the commercialization of products. We have committed to make potential future milestone payments to third parties of up to approximately $32.1 million as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2010, such contingencies have not been recorded in our financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory and commercial milestones. There is uncertainty regarding the various activities and outcomes needed to reach these milestones, and they may not be achieved.

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 document. 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.

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Revenue Recognition

Ampyra

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail and Kaiser Permanente (Kaiser). We recognize revenue by applying the guidance in Staff Accounting Bulletin (SAB) 104 which requires that we do not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, the Company has no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectability is reasonably assured. We recognize product sales of Ampyra following shipment of product to a network of specialty pharmacy providers and Kaiser. As of December 31, 2010, inventory levels at specialty pharmacy providers that distribute Ampyra (does not include Kaiser) represented approximately two weeks of their anticipated usage. The specialty pharmacy providers and Kaiser are contractually obligated to hold no more than 30 days of inventory.

Our net revenues represent total revenues less allowances for customer credits, including estimated rebates, discounts and returns. These allowances are recorded for cash consideration given by a vendor to a customer that is presumed to be a reduction of the selling prices of the vendor’s products or services and, therefore, are characterized as a reduction of revenue. At the time product is shipped to specialty pharmacies and Kaiser, an adjustment is recorded for estimated chargebacks, rebates, and returns. These allowances are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such reserves. In determining the amounts of certain allowances and accruals, we must make significant judgments and estimates. Allowances for rebates, discounts and returns are established based on the contractual terms with customers, 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. Product shipping and handling costs are included in cost of sales.

Based on our specialty distribution model where we sell to only 12 specialty pharmacy providers and Kaiser, the data we receive from these distributors, and returns experience of other specialty products with similar selling models, we have been able to make a reasonable estimate for product returns. At December 31, 2010, inventory levels at the specialty pharmacy providers (this does not include Kaiser) represented approximately two weeks of their anticipated usage. The specialty pharmacy providers and Kaiser have contractually agreed to hold no more than 30 days of inventory. We will accept returns of Ampyra for two months prior to and six months after its expiration date. We will provide a credit to customers with whom we have a direct relationship. Once our product is prescribed, it cannot be returned. We do not exchange product from inventory for the returned product.

Zanaflex