

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For the fiscal year ended December 31, 2012**

**OR**

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

Commission File Number 000-50513

**ACORDA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation  
or organization)

**13-3831168**  
(I.R.S. Employer Identification Number)

**420 Saw Mill River Road  
Ardsley, New York 10502  
(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  No

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

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

Indicate by check mark 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  No

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.

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 the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

As of June 29, 2012, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was \$524,746,202. 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, 2012 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 15, 2013, the registrant had 40,280,070 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 2013 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2012. 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.**  
**2012 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.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products 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 or from our other research and development programs, including Diazepam Nasal Spray any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Diazepam Nasal Spray or other products under development; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; failure to protect our intellectual property, to defend against the intellectual property claims of others, or to obtain third party intellectual property licenses needed for the commercialization of our products; failure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. 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.*

## PART I

### Item 1. Business.

#### Company Overview

We are a commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis, or MS, spinal cord injury, or SCI, and other disorders of the nervous system. We have marketed as well as developmental stage products and are working to bring important new therapies to people with nervous system disorders. Our goal is to help patients to a better future, while building a leading neurology company with a portfolio of innovative products.

The first product for which we completed clinical development, Ampyra (dalfampridine) Extended Release Tablets, 10mg was approved by the U.S. Food and Drug Administration, or 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 \$266.1 million for the year ended December 31, 2012.

Approximately 400,000 people in the U.S. suffer from MS, and each year approximately 10,000 people in the U.S. are newly diagnosed. 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 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. More than 73,000 new patients have tried Ampyra therapy since the 2010 launch.

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec International GmbH, or Biogen Idec, under a license and collaboration agreement that we entered into in June 2009. Fampyra is commercially available in a number of European Union countries and in Canada, Australia, New Zealand and Israel, and Biogen Idec anticipates making Fampyra commercially available in additional markets in 2013, as well as filing for regulatory approval in other countries.

We also sell Zanaflex Capsules and Zanaflex tablets, which contain tizanidine hydrochloride, a short-acting drug approved by the FDA for the management of spasticity. In 2012, we launched tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules, under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), following the launch by Apotex, Inc. of its generic tizanidine hydrochloride capsules.

We are developing what we believe is an industry leading pipeline of novel neurological therapies. We are developing Diazepam Nasal Spray, which we acquired in December 2012, for the treatment of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS. We are also studying dalfampridine to improve a range of functional impairments, in addition to walking disability, caused by MS, as well as its potential use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, we are developing clinical stage compounds AC105 for acute treatment of SCI, GGF2 for treatment of heart failure, and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and

SCI. Chondroitinase, an enzyme that encourages nerve plasticity in SCI, is in preclinical development.

We are focused on continuing to grow as a fully-integrated biopharmaceutical company 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 by acquiring and inlicensing new assets, focusing on near-commercial or commercial stage assets that leverage our scientific and commercial expertise in the neurology space.

## Company Highlights

- *Ampyra*: Ampyra (dalfampridine) Extended Release Tablets, 10mg 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 \$266.1 million for the year ended December 31, 2012, with more than 73,000 new patients trying Ampyra therapy since the 2010 launch. As of December 31, 2012, approximately 70% of all people with MS who were prescribed Ampyra received a first refill, and approximately 40% of all people with MS who were prescribed Ampyra have been dispensed at least six months of the medicine through refills, consistent with previously reported trends. Three of the largest national health plans in the U.S. – Aetna, United Healthcare and Cigna – have listed Ampyra in the lowest branded co-pay tier of their commercial preferred drug list or formulary. This formulary status at all three health plans was renewed in 2012.
- *Ampyra Development Programs*: We are studying dalfampridine to improve a range of functional impairments, in addition to walking disability, caused by MS, as well as its potential use in other neurological conditions, including cerebral palsy, or CP, and post-stroke deficits. In December 2011, we initiated a Phase 2 proof-of-concept clinical study of dalfampridine in adults with CP. The first phase of this proof-of-concept study, which has been completed, was a single-dose phase primarily to evaluate safety and tolerability prior to proceeding to a multi-dose cohort. This 10-person, single dose phase of the study detected no safety signals that would prevent additional study of the drug in the treatment of CP. We completed enrollment for the second phase, a multi-dose study including 20 adults with CP, to evaluate both safety and efficacy. We expect to announce topline results of this phase of the study in the second quarter of 2013. Also, in June 2012, we enrolled the first patient in a Phase 2 proof-of-concept trial of dalfampridine in post-stroke deficits, and we expect to announce topline study results in the second quarter of 2013. This study is exploring the use of dalfampridine in patients who have experienced a stroke and who have stabilized with chronic neurologic deficits, which may include walking impairment and upper extremity function impairment, such as arm weakness. Over the first six months following a stroke, patients typically show some degree of spontaneous recovery of function, which may be enhanced by rehabilitation and physical therapy. This trial is targeting motor impairments that remain after such recovery. We also are providing grants for investigator-initiated studies exploring potential benefits on a range of functional deficits in MS and other neurological disorders.
- *Ampyra Patents*: We have two issued patents listed in the Orange Book for Ampyra. The first is U.S. Patent No. US 8,007,826 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the United States Patent and Trademark Office, or USPTO, this patent will extend into 2027. The second is U.S. Patent No. 5,540,938 (“the ‘938 patent”), the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In October 2012, the USPTO determined that the ‘938 patent is entitled to a full five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the ‘938 patent would expire in 2018.

On January 15, 2013, the USPTO issued U.S. Patent No. 8,354,437 (U.S. Patent Application No. 11/102,559) with claims relating to methods to improve walking, walking speed, lower extremity muscle tone and lower extremity muscle strength in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. In 2011, the European Patent Office, or EPO, granted the counterpart European patent with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging this granted European patent. We intend to vigorously defend the European patent, although the outcome of opposition proceedings is unpredictable.

- *Fampyra/Biogen*: Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec under a 2009 license and collaboration agreement. Fampyra is commercially available in a number of European Union countries and in Canada, Australia, New Zealand and Israel, and Biogen Idec anticipates making Fampyra commercially available in additional markets in 2013, as well as filing for regulatory approval in other countries. We recorded \$7.1 million of royalty revenue and \$9.1 million of amortized license revenue in 2012 related to Fampyra.
- *Zanaflex Capsules and Zanaflex tablets*: Our Zanaflex Capsules 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. We launched Zanaflex Capsules in April 2005 as part of our strategy to build a commercial platform for the potential market launch of Ampyra. In February 2012, Apotex Inc. commercially launched a generic version of tizanidine hydrochloride capsules, and we also launched our own authorized generic version, which is being marketed by Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.). Net revenues for our Zanaflex franchise including our own authorized generic version were \$23.5 million for the year ended December 31, 2012. The commercial launch of generic tizanidine hydrochloride capsules has caused a significant decline in net revenue of Zanaflex Capsules, and the launch of these generic versions and the potential launch of other generic versions are expected to cause our net revenues from Zanaflex Capsules to further decline in 2013 and beyond. In May 2012, we received a Paragraph IV Certification Notice from Mylan Laboratories Limited advising us that Mylan Laboratories has filed an Abbreviated New Drug Application for generic versions of the three dosage strengths of Zanaflex Capsules. The FDA approved Mylan's ANDA on November 9, 2012. Based upon our request, the FDA delisted from the Orange Book the patent against which Mylan Laboratories filed the Paragraph IV Certification Notice.
- *Research and Development Programs*: Our lead research and development programs include three distinct therapeutic approaches to restoring neurologic function— neuregulins, remyelinating antibodies and chondroitinase, our program to develop AC105 as an acute treatment for neurological trauma, and our recently acquired program to develop Diazepam Nasal Spray as a treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS.
  - *Neuregulins*: GGF2 is our lead product candidate for our neuregulins program. We have completed a Phase 1 clinical trial of GGF2 in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. We have completed analysis of the three-month data, and we plan to present findings in a platform presentation at the American College of Cardiology (ACC) annual meeting in March 2013. We will also discuss the data with the FDA before proceeding to a multiple dose study. 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 independently or we may decide to enter into a partnership, most likely with a cardiovascular-focused company. We also are continuing with research on potential neurology indications for GGF2.



- *Remyelinating Antibodies:* rHIgM22 is the lead antibody in our remyelinating antibody program, and we are developing it as a potential therapeutic for MS. We believe a therapy, such as this antibody, that could repair myelin sheaths has the potential to restore substantial neurological function to those affected by demyelinating conditions. We have an open IND for rHIgM22 for the treatment of MS and plan to initiate enrollment in a Phase 1 safety study in MS patients in the first half of 2013.
- *AC105:* AC105 is a proprietary magnesium formulation that we are studying as an acute treatment for SCI. We licensed AC105 from Medtronic, Inc. and one of its affiliates in 2011. AC105 has been shown to reduce lesion size and enhance recovery in animal models of SCI. AC105 has been shown to be safe and tolerable in a small number of healthy normal subjects in Phase 1 human trials. We submitted a Phase 2 clinical trial protocol for AC105 for acute treatment of SCI to the FDA for review. The protocol has been reviewed by the FDA, and we are preparing to initiate the trial in the first half of 2013. The trial is designed primarily to assess the safety and tolerability of AC105 in people with acute SCI. In January 2013, we announced that the U.S. Department of Defense awarded us a \$2.67 million research contract to support this Phase 2 trial. The FDA granted Fast Track designation for AC105 to improve functional recovery of acute SCI.
- *Neuronex Acquisition:* In February 2012, we signed an agreement to acquire Neuronex, Inc., a privately-held pharmaceutical company developing a proprietary nasal spray formulation of diazepam as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS. We completed the acquisition of Neuronex in December 2012. Continuing with efforts commenced by Neuronex prior to the acquisition, pending additional clinical and manufacturing data, we plan to submit a 505(b)(2)-type New Drug Application, or NDA, for Diazepam Nasal Spray, to the FDA in 2013, with potential FDA approval and commercial launch in 2014. We anticipate that our current infrastructure can support sales and marketing of this product, and market planning is underway. A 505(b)(2) application allows for an NDA that references medical literature and the FDA's finding of safety and effectiveness for a previously approved drug product. We believe this is an important addition to our pipeline that aligns with our core strategy to develop and commercialize products that offer unique benefits to people with neurological diseases. This acquisition has provided a near-term commercial opportunity in neurology that leverages our existing sales, marketing and medical organizations. Financial terms of the acquisition are described below in the "Research and Development Programs" section of this report.
- *Corporate Headquarters:* In July 2012, we relocated our corporate headquarters, and all employees then based at our Hawthorne, N.Y. location, to a facility in Ardsley, New York consisting of an aggregate of approximately 138,000 square feet of office and laboratory space. We have grown substantially over the last several years, and the new facility provides state-of-the-art office and laboratory space that will accommodate our current needs and allow for future growth.
- *Corporate Update:* In October 2012, we named Jane Wasman, J.D., as President, International. Prior to her October 2012 promotion, Ms. Wasman served as our Chief, Strategic Development, General Counsel and Corporate Secretary. In her new role, Ms. Wasman leads our efforts to identify and launch inlicensing and commercial opportunities outside the United States. She is also responsible for managing our collaboration with Biogen Idec in their international development and commercialization of Fampyra (prolonged-release fampridine tablets). Ms. Wasman also continues to lead our global strategic development and has retained the titles of General Counsel and Secretary.

## **Our Strategy**

Our strategy is to continue to grow as a fully-integrated biopharmaceutical company and to be 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, TBI and epilepsy. For 2013, we are focused on making disciplined investments in growing Ampyra sales, expanding the Ampyra franchise, and advancing and expanding our pipeline. Key aspects of our strategy are:

- Continue to invest in growing Ampyra sales, with focus in 2013 on:
  - Implementing sales and marketing programs that increase awareness and use in patients with earlier stages of walking disability who can benefit from Ampyra, and that are aimed at increasing adherence to the prescribed therapy by patients who are benefitting from it. We expect that, for 2013, we will not be increasing our investment in Ampyra commercial activities above 2012 levels as a percentage of product sales.
  - Educating prescribers on the value of Ampyra for earlier-stage patients.
  - Expanding our reimbursement specialist programs, which provide assistance to physicians' offices in navigating managed care challenges.
- Work to expand our Ampyra franchise by assessing additional potential uses of dalfampridine in MS and possibly other neurological conditions such as cerebral palsy and post-stroke deficits.
- Support the efforts of our collaboration partner, Biogen Idec, in seeking health authority approval for and commercializing Fampyra in markets outside the U.S.
- Advance our pipeline of research and development programs, and for 2013 in particular achieving the milestones described above under "Company Highlights."
- Expand our pipeline through the potential inlicensing and/or acquisition of select products and technologies in neurology, with our focus through 2013 on commercial or near commercial opportunities.

## Our Products and Product Pipeline

<b>Commercial Products</b>	<b>Indication</b>	<b>Status</b>	<b>Marketing Rights</b>
Ampyra	MS	FDA-approved and marketed in the U.S.	Acorda (U.S.)
Fampyra	MS	Approved in the EU (conditional) and other countries; commercially available in a number of EU countries and in Canada, Australia, New Zealand and Israel.	Biogen Idec (outside U.S.)
Zanaflex Capsules and an authorized generic version of the capsules	Spasticity	FDA-approved	Acorda (U.S.); authorized generic marketed by Actavis/Watson Pharma
Zanaflex tablets	Spasticity	FDA-approved	Acorda (U.S.)
<b>Research and Development Programs</b>	<b>Proposed Therapeutic Area(s)</b>	<b>Stage of Development</b>	<b>Marketing Rights</b>
Diazepam Nasal Spray	Cluster/Acute Repetitive Seizures	NDA preparations ongoing; filing planned for 2013 pending additional clinical and manufacturing data	Acorda/Worldwide (excluding certain Asian countries)
Dalfampridine	Cerebral Palsy	Phase 2 proof-of-concept clinical trial	Acorda/Worldwide (Biogen ex-U.S. option)
Dalfampridine	Post-Stroke Deficits	Phase 2 proof-of-concept clinical trial	Acorda/Worldwide (Biogen ex-U.S. option)
AC105	SCI and TBI	Acute SCI Phase 2 clinical trial preparations ongoing; expect to initiate trial in H1 2013	Acorda/Worldwide
Neuregulin Program	Heart failure*	GGF2 Phase 1 clinical trial completed	Acorda/Worldwide
Remyelinating Antibodies Program	MS	Open IND for rHlgM22; Phase 1 clinical trial expected to begin H1 2013	Acorda/Worldwide
Chondroitinase Program	SCI	Research	Acorda/Worldwide

\*The company is also continuing with preclinical research on potential neurology indications such as stroke and SCI.

### ***Background on Neurological and Other Conditions***

We are dedicated to the identification, development and commercialization of novel therapies that

improve neurological function in people with disorders of the nervous system. Where our neurology programs may also show promise for disorders outside of the nervous system, we may elect to pursue these opportunistically as well. Currently, our products and product pipeline are targeted to the conditions described below. We believe there is significant unmet medical need for these conditions, which can severely impact the lives of those who suffer from them.

### *Multiple Sclerosis*

Multiple Sclerosis, or 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, much as insulation facilitates conduction in an electrical wire. 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. Patients with MS may suffer impairments in a wide range 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.

According to the National Multiple Sclerosis Society, or NMSS, in the U.S. approximately 400,000 people suffer from MS, and each year approximately 10,000 additional people are newly diagnosed. 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 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 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.

### *Spinal Cord Injury*

A spinal cord injury, or SCI, usually refers to a traumatic blow to the spine that fractures or dislocates vertebrae and causes damage to the surrounding spinal cord tissue. SCI is caused by traumas such as a motor vehicle accident, a fall, or a sports injury. Depending on the location and severity of the injury, people with SCI can experience a number of disabilities, including partial or complete paralysis, muscle weakness, spasticity, loss or distortion of sensation, impaired bowel and/or bladder function, or sexual dysfunction. SCI often results in severe, lifelong disability, leading to long-term care and quality of life issues for the person with 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 may lose their myelin sheaths. There is no cure for SCI and no approved treatment available that is capable of significantly improving outcome from injury or improving long-term neurological function. Methylprednisolone, a steroid given in a high dose, is often used to treat acute injuries in the U.S. Methylprednisolone is administered to the patient immediately following an injury with the goal of reducing secondary tissue damage, but there is disagreement in the clinical community regarding the overall risk-benefit ratio of this treatment. The only other available medical therapies are limited treatments that target some of the symptoms of SCI, including spasticity and persistent pain, the same treatments used to address these symptoms in MS. We believe that an acute treatment that offers even an incremental improvement in outcome from injury could have a meaningful impact on the quality of life for people with SCI.

According to the National Spinal Cord Injury Statistical Center, or NSCISC, approximately 270,000 people in the U.S. live with the SCI and approximately 12,000 new spinal cord injuries occur each year, the majority of which are male. SCI primarily affect young people, with 50-70% occurring in those aged 15-35. Average annual medical cost for an SCI patient ranges from \$40,000 to \$178,000 depending on the extent of the

injury. 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.

### *Cerebral Palsy*

Cerebral Palsy, or CP, refers to a range of neurological disorders caused by damage to one or more specific areas of the brain, usually occurring during development, before, during or shortly after birth. CP may also occur during infancy or early childhood. These disorders permanently affect body movement and muscle coordination, and are often associated with poor myelination of nerve tracts in the brain. The early signs of CP usually appear before an individual reaches 3 years of age. The most common symptoms are a lack of muscle coordination when performing voluntary movements (ataxia); stiff or tight muscles and exaggerated reflexes (spasticity); walking with one foot or leg dragging; walking on the toes, a crouched gait, or a “scissored” gait; and muscle tone that is either too stiff or too floppy. Symptoms differ in type and severity from one person to the next, and may change in an individual over time. As with SCI, the available medical therapies for CP generally target specific symptoms, such as spasticity. Physical and occupational therapy are often employed to enable people with CP to live as independently as possible.

According to the National Center for Biotechnology Information, or NCBI, approximately 400,000 adults in the U.S. live with CP. The Centers for Disease Control and Prevention, or CDC, estimates that each year about 10,000 babies born in the United States will develop cerebral palsy.

### *Stroke*

A stroke occurs when the blood supply to part of the brain is interrupted or severely reduced, depriving brain tissue of oxygen and food, and causing the death of brain cells. Stroke may also be associated with damage to the myelin sheath of various nerve tracts in the brain. Over the first few months following a stroke, patients typically show some degree of spontaneous recovery of function, which may be enhanced by rehabilitation and physical therapy. After this initial recovery, patients may stabilize with chronic neurologic deficits. According to the American Stroke Association, or ASA, 795,000 people in the U.S. experience a stroke every year and approximately 7,000,000 people in the U.S. are living with the long term effects of stroke, or post-stroke deficits. Current treatments for post-stroke deficits include physical and occupational therapy, but there are no pharmacologic therapies indicated specifically to improve function. A majority of those living with post-stroke deficits experience walking or other lower limb disability and/or arm or other upper body deficits. Estimated stroke-related medical and disability costs were \$73.7 billion in the U.S. for 2010.

### *Heart Failure*

Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood through the heart to meet the body's need for blood and oxygen. Heart failure results from damage to heart, caused by trauma such as heart attack or coronary artery disease, viral infections, alcohol or chemotherapy-related toxicity, or added stress to the heart from other health conditions, such as diabetes or high blood pressure. Common symptoms of heart failure include shortness of breath (dyspnea), persistent coughing or wheezing, build up of excessive fluid in body tissue that may cause swelling of the feet, ankles, legs and abdomen (edema), and fatigue. Healthcare professionals typically classify heart failure based on the severity of symptoms and how those symptoms limit physical activity. Heart failure can range from no symptoms and no limitations on ordinary physical activity (Class 1) through severe physical limitations with patients experiencing symptoms even while at rest (Class 4).

Existing medications for heart failure aim to compensate for the heart's diminished blood pumping ability. There is evidence that such medications, together with dietary changes, may have a modest indirect impact on the heart, but do not directly repair the heart muscle.

The CDC estimates that approximately 5.8 million Americans have heart failure, and roughly 670,000 are

newly diagnosed each year.

### *Epilepsy*

Epilepsy is a neurological condition that produces seizures affecting a variety of mental and physical functions. Epilepsy is a brain disorder in which clusters of nerve cells, or neurons, in the brain sometimes signal abnormally, possibly resulting in convulsions, muscle spasms, and loss of consciousness. Epilepsy has many possible causes - an abnormality in brain wiring, an imbalance of nerve signaling chemicals called neurotransmitters, or some combination of these factors. When a person has had two or more seizures he or she is considered to have epilepsy. EEGs and brain scans are common diagnostic test for epilepsy.

The CDC estimates that approximately 2.3 million adults in the US have active epilepsy. Active epilepsy is defined as those who take medication or have had at least one seizure in the past year. Seizures are generally classified as either partial onset, or focal, seizures, or generalized onset seizures. Approximately one third of epilepsy patients are refractory to treatment, meaning that they may still experience one or more breakthrough seizures despite an existing regimen of anti-epileptic drug (AED) therapy. It is estimated that approximately 175,000 people in the U.S. have acute repetitive seizures, or ARS, which are characterized by recognizable, recurring episodes of seizure clusters.

### *Spasticity*

Spasticity refers to the often painful involuntary tensing, stiffening or contracting of muscles. Spasticity is not a disease but a symptom of other conditions, such as MS, SCI, stroke, TBI and CP, 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.

### *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 obtained Orphan Drug designation from the FDA for dalfampridine in MS, which will provide Ampyra with seven years of market exclusivity for this use, to January 2017.

We have two issued patents listed in the Orange Book for Ampyra, as follows:

- The first is U.S. Patent No. US 8,007,826 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the United States Patent and Trademark Office, or USPTO, this patent will extend into 2027.
- The second is U.S. Patent No. 5,540,938 (“the ‘938 patent”), the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking

in people with MS. In October 2012, the USPTO determined that the '938 patent is entitled to a full five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the '938 patent would expire in 2018. We have an exclusive license to this patent from Alkermes (originally with Elan, but transferred to Alkermes as part of its acquisition of Elan's Drug Technologies business).

On January 15, 2013, the USPTO issued U.S. Patent No. 8,354,437 (U.S. Patent Application No. 11/102,559) with claims relating to methods to improve walking, walking speed, lower extremity muscle tone and lower extremity muscle strength in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. In 2011, the European Patent Office, or EPO, granted the counterpart European patent with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging this granted European patent. We intend to vigorously defend the European patent, although the outcome of opposition proceedings is unpredictable.

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec under a 2009 license and collaboration agreement. In July 2011 Biogen Idec received conditional approval from the European Commission for Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). Fampyra is commercially available in a number of European Union countries and in Canada, Australia, New Zealand and Israel, and Biogen Idec anticipates making Fampyra commercially available in additional markets in 2013, as well as filing for regulatory approval in other countries.

### *Background*

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, or 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 vs. placebo difference was not established for that outcome measure.

The FDA approved Ampyra with a risk evaluation and mitigation strategy, or 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 included 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. We completed these studies and timely submitted the results to the FDA. Also, we committed to the FDA that we would 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 also committed to report all post-marketing seizure events on an expedited basis to the FDA. We completed the renal impairment study and timely submitted the results to the FDA. In August 2012, we announced results of the 5mg efficacy study. The study failed to confirm efficacy of the 5mg dose. We believe that this study, together with Ampyra registration studies, continue to show that 10mg twice daily is the appropriate, safe, and effective dose. The study results were provided to the FDA and will be presented in peer-reviewed scientific forums. Study results that we have submitted to the FDA are subject to FDA review, and the FDA could require additional data and/or further studies before they confirm that we have satisfied the applicable requirement or commitment.

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 Alkermes plc (formerly 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 a number of 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 as part of our strategy to build a commercial platform for the potential market launch of Ampyra. On February 6, 2012, we launched an authorized generic version of tizanidine hydrochloride capsules under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), following the launch by Apotex of its generic tizanidine hydrochloride capsules.

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. However, they may be filled with generic tizanidine hydrochloride capsules or our authorized generic capsules.

### ***Research and Development Programs***

We are developing what we believe is an industry leading pipeline of novel neurological therapies. We are developing Diazepam Nasal Spray, which we acquired in December 2012, for the treatment of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS. Pending additional clinical and manufacturing data, we plan to submit an NDA to the FDA for Diazepam Nasal Spray in 2013. We are also studying dalfampridine to improve a range of functional impairments, in



addition to walking disability, caused by MS, as well as its potential use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, we have several research and development programs focused on distinct therapeutic approaches to restoring neurologic and/or cardiac function. We are developing clinical stage compounds AC105 for acute treatment of SCI, GGF2 for the treatment of heart failure, and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and SCI. Chondroitinase, an enzyme that encourages nerve plasticity in SCI, is in preclinical development. We believe these programs for restoring neurologic and/or cardiac function have the potential to be first-in-class therapies, and may be applicable across a number of CNS disorders, including stroke and TBI, because many of the mechanisms of tissue damage and repair are similar.

#### *Diazepam Nasal Spray; Neuronex Acquisition*

On December 20, 2012, we completed the acquisition of Neuronex, Inc., a privately-held pharmaceutical company developing Diazepam Nasal Spray. The acquisition was completed pursuant to a February 15, 2012, merger agreement among us, one of our wholly-owned subsidiaries, and Neuronex. Pursuant to the merger agreement, Neuronex merged with our wholly owned subsidiary and continued as the surviving corporation in the merger (the “Merger”).

Diazepam Nasal Spray is a proprietary formulation of diazepam that we are developing as a treatment for the management of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS. Currently, the only approved outpatient treatment option for people who experience this type of seizure activity is DIASTAT<sup>®</sup> AcuDial<sup>™</sup> (diazepam rectal gel), a rectally administered gel formulation of diazepam. Diazepam is currently available in other formulations, such as used for intramuscular and intravenous administration, for certain indications. The nasally administered formulation potentially offers patients and caregivers a more practical and socially acceptable treatment option. Continuing with efforts commenced by Neuronex prior to the acquisition, pending additional clinical and manufacturing data, we plan to submit a 505(b)(2)-type New Drug Application, or NDA, for Diazepam Nasal Spray to the FDA in 2013, with potential FDA approval and commercial launch in 2014. We anticipate that our current infrastructure can support sales and marketing of this product, and market planning is underway. A 505(b)(2) application allows for an NDA that references medical literature and the FDA’s finding of safety and effectiveness for a previously approved drug product.

In accordance with the terms and conditions of the merger agreement, upon its execution we made an initial payment of \$2 million to Neuronex. Also, prior to completion of the Merger, we provided Neuronex with \$1.5 million to support certain research and development activities conducted by Neuronex, including \$500,000 that we funded upon execution of the merger agreement. Upon closing of the Merger, we paid an additional \$6.8 million in cash consideration for the Merger, subject to a \$300,000 holdback in accordance with the provisions of the merger agreement. We used cash on hand to fund the initial \$2 million payment, the pre-closing research and development payments, and the closing consideration.

Under the terms of the merger agreement, the former equity holders of Neuronex will be entitled to receive from us up to an additional \$18 million in earnout payments upon the achievement of specified regulatory and manufacturing-related milestones with respect to the Diazepam Nasal Spray product, and up to \$105 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. There can be no guarantee that any such milestones will in fact be met. The former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments, ranging from the upper single digits to lower double digits, on worldwide net sales of Diazepam Nasal Spray products. These payments are payable on a country-by-country basis until the earlier to occur of ten (10) years after the first commercial sale of a product in such country and the entry of generic competition in such country as defined in the merger agreement.

Neuronex licenses patent other intellectual property and other rights relating to the Diazepam Nasal Spray product from SK Biopharmaceuticals Co., Ltd., or SK. Pursuant to the SK license, which grants worldwide rights

to Neuronex except certain specified Asian countries, Neuronex is obligated to pay SK up to \$8 million upon the achievement of specified development milestones with respect to the Diazepam Nasal Spray product (including a \$1 million payment upon the FDA's acceptance for review of the first NDA for the Diazepam Nasal Spray product), and up to \$3 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products.

The merger agreement contains customary representations, warranties and covenants of the parties and customary indemnification provisions.

Under the merger agreement, we are required to use diligent efforts, as defined in the merger agreement, to develop the Diazepam Nasal Spray product. However, we have the right, at any time after the Merger, to discontinue development and commercialization of the Diazepam Nasal Spray product and return the Diazepam Nasal Spray product assets. If this occurs, we will not have any further diligence obligations regarding the Diazepam Nasal Spray products but will not be entitled to recoup any of the payments previously made under the merger agreement.

Neuronex did not have any employees at the time we completed the acquisition.

#### *Ampyra/Dalfampridine Development Programs*

We are studying the potential for dalfampridine to be applied to other indications within MS and to other neurological conditions. In December 2011, we initiated a Phase 2 proof-of-concept clinical study of dalfampridine in adults with cerebral palsy, or CP. The first phase of this proof-of-concept study, which has been completed, was a single-dose phase primarily to evaluate safety and tolerability prior to proceeding to a multi-dose cohort. This 10-person, single dose phase of the study detected no safety signals that would prevent additional study of the drug in the treatment of CP. We completed enrollment for the second phase, a multi-dose study including 20 adults with CP, to evaluate both safety and efficacy. We expect to announce topline results of this phase of the study in the second quarter of 2013.

In June 2012, we enrolled the first patient in a Phase 2 proof-of-concept trial of dalfampridine in post-stroke deficits, and we expect to announce topline study results in the second quarter of 2013. This study is exploring the use of dalfampridine in patients who have experienced a stroke and who have stabilized with chronic neurologic deficits, which may include walking impairment and upper extremity function impairment, such as arm weakness. Over the first six months following a stroke, patients typically show some degree of spontaneous recovery of function, which may be enhanced by rehabilitation and physical therapy. This trial is targeting motor impairments that remain after such recovery.

We are providing grants for investigator-initiated studies exploring potential benefits on a range of functional deficits in MS and other neurological disorders.

Also, we are working with external parties on a potential once-daily formulation of dalfampridine.

#### *AC105*

In June 2011, we entered into a license agreement with Medtronic, Inc. and one of its affiliates pursuant to which we licensed from them worldwide development and commercialization rights to certain formulations of magnesium with a polymer such as polyethylene glycol, which we refer to as AC105. We are studying AC105 as a treatment for patients who have suffered acute SCI. Our development and commercialization rights are exclusive in all fields (including SCI, TBI and stroke) for certain formulations of the licensed compound. For other formulations, our rights are exclusive for indications of interest to us, including SCI, TBI, stroke and all other traumatic and ischemic central nervous system indications, while Medtronic and its affiliate have non-

exclusive (with us) development rights in specific areas, including certain areas of pain and musculoskeletal indications.

During a traumatic neurological injury, depletion of magnesium at the site of injury has been shown to contribute to tissue injury and lesion development. AC105 addresses this issue by formulating magnesium in such a way that the magnesium is delivered to the CNS. Previous clinical studies that have delivered magnesium in the form of commonly-used salts (magnesium chloride or magnesium sulfate) have shown limited ability to significantly raise magnesium levels in the CNS and have failed to show benefit, for example in stroke or TBI. AC105 has been shown to reduce lesion size and enhance recovery in animal models of SCI. AC105 has been shown to be safe and tolerable in a small number of healthy normal subjects in Phase 1 human trials.

We submitted a Phase 2 clinical trial protocol for AC105 for acute treatment of SCI to the FDA for review. The protocol has been reviewed by the FDA, and we are preparing to initiate the trial in the first half of 2013. The trial is designed primarily to assess the safety and tolerability of AC105 in people with acute SCI. In January 2013, we announced that the U.S. Department of Defense awarded us a \$2.67 million research contract to support this Phase 2 trial. The FDA granted Fast Track designation for AC105 to improve functional recovery in SCI patients. We expect to apply for FDA orphan drug designation for the acute treatment of SCI and intend to explore orphan drug designations in Europe and in other parts of the world.

### *Neuregulins/GGF2*

This program is based on neuregulin growth factors that have been shown to promote recovery after neurological injury as well as enhance heart function in animal models of heart failure. Neuregulins form a family of growth factors related to epidermal growth factor. These molecules bind to erbB receptors, which translate the growth factor signal 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 Paion AG (formerly CeNeS Pharmaceuticals plc), or Paion, 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 Paion have a number of potential applications. Neuregulins and their erbB receptors are essential for cardiac development. They have been shown to protect cardiac muscle cells from stressors that can lead to congestive heart failure, and to enhance function in heart failure induced by 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.

We have completed a Phase 1 clinical trial of GGF2 in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. We have completed analysis of the three-month data, and we plan to present findings in a platform presentation at the American College of Cardiology (ACC) annual meeting in March 2013. We will also discuss the data with the FDA before proceeding to a multiple dose study. 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 may decide to develop the product independently or we may decide to enter into a partnership, most likely with a cardiovascular-focused company, or developing it on our own. We are also continuing with research on potential neurology indications for GGF2.

### *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 are developing the lead antibody (rHIgM22) as a potential therapeutic for MS. We believe a therapy, such as this antibody, that could repair myelin sheaths has the potential to restore substantial neurological function to those affected by demyelinating conditions. We have an open IND for rHIgM22 for the treatment of MS and plan to initiate enrollment in a Phase 1 safety study in MS patients in the first half of 2013.

### *Chondroitinase Program*

This pre-clinical program is focused on developing chondroitinase as a therapeutic to break down the matrix of scar tissue that develops as a result of an injury to the CNS. Published research has demonstrated that this scar matrix is partly responsible for limiting the regeneration of nerve fibers in the CNS. A similar matrix exists even in uninjured parts of the CNS tissue and restricts plasticity, the ability to modify or re-establish nerve connections. One or both forms of matrix may also inhibit repair of the myelin sheath by restricting the movements of the myelinating cells into the area of damage.

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

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 SCI. These studies were published in the *Journal of Neurotrauma* in February 2005. In these studies, rats that sustained an SCI 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 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. In 2003, we obtained an exclusive worldwide license to certain patents, patent applications, and technology from Cambridge University Technical Services Limited (now named Cambridge Enterprise 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 Ampyra. We currently have approximately 90 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Managed Markets account managers who work collaboratively with field teams and corporate personnel to assist in the execution of our strategic initiatives. We have contracted with a third-party organization with extensive experience in coordinating patient benefits to run Ampyra Patient Support Services, or APSS, a dedicated resource of support services that coordinates the prescription process among healthcare providers, people with MS and insurance carriers. Prescriptions for Ampyra are processed through the APSS center, where dedicated and experienced customer care agents are responsible for: helping healthcare professionals process prescriptions; working with insurance carriers to facilitate coverage; and working with a limited network of specialty pharmacy providers that deliver the medication directly to a patient's home. In addition, APSS assists in directing patients to available copay and patient assistance programs, where permitted by law. The process begins when a prescription is submitted by a physician to APSS through a Service Request Form, or SRF. If insurance coverage is confirmed, APSS will transmit the prescription information to the specialty pharmacy provider that has contracted with the patient's insurance carrier. The specialty pharmacy provider will then mail the prescription directly to the patient. In some cases, the specialty pharmacy provider will coordinate the insurance benefits investigation on behalf of the patient or will receive a prescription directly from a prescribing physician. Those people with MS who meet income and other requirements may receive Ampyra at no cost, where permitted by law, through Acorda's patient assistance program. We have also established a program to assist individuals who have private insurance in managing their co-payment costs through a co-pay mitigation program, where permitted by law.

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, each year Acorda sponsors numerous of the National Multiple Sclerosis Society's Walk MS events around the country. These sponsorships allow 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. In addition to these efforts, we have implemented a comprehensive series of educational and promotional programs to support Ampyra.

Ampyra is distributed exclusively through: a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which is the exclusive specialty pharmacy distributor for Ampyra to the U.S. Department of Veterans Affairs, or VA. The distribution process through specialty pharmacy providers 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. Our authorized generic version of tizanidine hydrochloride capsules is marketed under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.).

## **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, SCI, CP, epilepsy, stroke and cardiology. 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.

## Material and Other Collaborations and License Agreements

### *Biogen Idec*

In 2009, we entered into a 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 Alkermes (formerly Elan). We have also entered into a related Supply Agreement pursuant to which we will supply Biogen Idec with its requirements for the licensed products through our existing supply agreement with Alkermes. 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.

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. Under the Collaboration Agreement, we participate in overseeing the development and commercialization of Ampyra and other licensed products in markets outside the U.S. in part through our participation in joint committees with Biogen. 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.

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec. Fampyra is commercially available in a number of European Union countries and in Canada, Australia, New Zealand and Israel, and Biogen Idec anticipates making Fampyra commercially available in additional markets in 2013, as well as filing for regulatory approval in other countries.

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 in July 2009. Also, in August 2011, we received a \$25 million milestone payment from Biogen for approval of Fampyra in the EU. Under our separate license and supply agreements with Alkermes, in 2009 we paid Alkermes \$7.7 million of the \$110 million upfront Biogen payment and in 2011 we paid Alkermes \$1.8 million of the \$25 million Biogen milestone payment. We are entitled to receive additional payments from Biogen of up to \$10 million based on the successful achievement of future regulatory milestones and up to \$365 million based on the successful achievement of future sales milestones. The next expected milestone payment from Biogen Idec would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters.

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 Alkermes 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 Alkermes for ex-U.S. sales, including royalties owed under the terms of our existing agreements with Alkermes.

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 Alkermes in its entirety or with respect to all countries outside of the U.S. We cannot terminate our license agreement with Alkermes 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.

If the Supply Agreement is terminated by Biogen Idec for an uncured material breach, we will waive our right for Alkermes to exclusively supply the licensed products to us solely to permit Biogen Idec to negotiate terms with Alkermes 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 Alkermes entered into a Consent Agreement with us. Under the Consent Agreement, Alkermes 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 Alkermes 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 Alkermes 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 Alkermes with respect to certain supply-related activities; and, requiring Alkermes to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

### *Alkermes, formerly Elan Corporation plc*

We have entered into agreements with Elan Corporation plc, including those described immediately below and elsewhere in this report. In September 2011, Alkermes plc acquired Elan's Drug Technologies business and Elan transferred our agreements to Alkermes as part of that transaction. Throughout this report, references to "Alkermes" include Alkermes plc and also, as the context may require, Elan Corporation plc as the predecessor to Alkermes plc under our agreements.

### *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, of which we have reached and paid \$5.0 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. As a result of our Collaboration Agreement with Biogen Idec, described above, in 2009 we paid Elan \$7.7 million of a \$110 million upfront payment we received from Biogen, and in 2011 we paid Elan \$1.8 million of a \$25 million milestone payment we received from Biogen.

Alkermes (now the licensor under this agreement due to its 2011 acquisition of Elan's Drug Technologies business) 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.

Alkermes 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 and receipt of other needed regulatory approvals, or if we fail to fulfill our payment obligations under the license agreement. If Alkermes terminates our license in any applicable country, Alkermes 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 Alkermes license at any time by written notice. In addition, the Alkermes license may be immediately terminated by either party following an incurable breach of any term or provision by the other party. The Alkermes 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 Alkermes 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 Alkermes 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 2011 fiscal year, and royalties on sales of Zanaflex Capsules and Zanaflex tablets. We have no further Zanaflex milestone payment obligations to Elan or Alkermes (which has acquired Elan's Drug Technologies business). 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.

Alkermes manufactures Zanaflex Capsules for us (and the authorized generic version of Zanaflex capsules being marketed by Watson Pharma (a subsidiary of Actavis) and Patheon Inc. manufactures Zanaflex tablets for us. For more information refer to "*—Manufacturing.*"

In December 2005, we entered into a financing arrangement with Paul Royalty Fund, or PRF, pursuant to which we assigned PRF the right to receive a portion of our net revenues from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. This agreement was amended in November 2006 potentially to increase the total amount of royalty payments to which PRF is entitled and to provide for additional lump-sum payments both from us to PRF and from PRF to us. The arrangement covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the arrangement is terminated earlier. On August 3, 2012, we received a letter from PRF alleging that we breached specified covenants and representations in the PRF agreement and purporting to exercise the put option. The letter also includes an allegation that PRF has suffered injuries beyond what is covered by their purported exercise of the put option, although it does not specify or quantify those injuries. We believe that the allegations are without merit and that the put option has not been validly exercised. We cannot predict whether these allegations will lead to any legal actions or, if they are initiated, the outcome or impact on us of any such legal actions. For more information on our arrangement with PRF, 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 \$13.0 million in royalties under this agreement through December 31, 2012. The FDA approval of Ampyra triggered the final milestone of \$750,000, which was paid in 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).

### ***Medtronic***

In June 2011, we entered into a license agreement with Medtronic, Inc. and its affiliate Warsaw Orthopedic, Inc., collectively “Medtronic,” pursuant to which we licensed from Medtronic worldwide development and commercialization rights to certain formulations of magnesium with a polymer such as polyethylene glycol (licensed products), which we refer to as AC105. We are studying AC105 as an acute treatment for SCI. During a traumatic neurological injury, depletion of magnesium at the site of injury has been shown to contribute to tissue injury and lesion development. AC105 addresses this issue by formulating magnesium in such a way that the magnesium is delivered to the CNS. Previous clinical studies that have delivered magnesium in the form of commonly-used salts (magnesium chloride or magnesium sulfate) have shown limited ability to significantly raise magnesium levels in the CNS and have failed to show benefit, for example in stroke or TBI. AC105 has been shown to reduce lesion size and enhance recovery in animal models of SCI. AC105 has been shown to be safe and tolerable in a small number of healthy normal subjects in Phase 1 human trials.

Under the license agreement, we have a license to develop and commercialize the licensed products in all countries worldwide. Our rights are exclusive in all fields for certain formulations, and these are “exclusive products.” With respect to licensed products that are not exclusive products, we have non-exclusive rights in certain specified fields, including pain and musculoskeletal indications, and have exclusive rights in all other fields, including the treatment of TBI, stroke, and all other traumatic and ischemic central nervous system indications. Our license includes sublicensing rights, subject to Medtronic’s consent in certain cases. During the term of the license agreement and, except in certain circumstances for one year thereafter, neither Medtronic nor any of its affiliates may research, develop, manufacture or commercialize any exclusive product in any field or any other licensed product in the exclusive fields.

In consideration for the rights granted to us under the license agreement, in June 2011 we paid Medtronic an upfront \$3 million cash license fee. Medtronic is also eligible to receive up to \$32 million from us if specified regulatory and development milestones are met. There can be no guarantee that any such milestones will in fact be met. We will also pay to Medtronic a single-digit royalty on sales of licensed products by us or our affiliates. We may offset, against a portion of the royalties payable to Medtronic, a portion of any royalties we may pay under certain third party licenses.

We must use our commercially reasonable efforts to develop and commercialize a licensed product in at least one of the major markets specified in the license agreement. Prior to the launch of a licensed product in such a major market, Medtronic can terminate our exclusivity if we have failed to conduct material and good faith development and commercialization activities for a major market in the prior 6 months. However, Medtronic’s

right to terminate exclusivity is subject to our right to propose and implement a development and commercialization plan that satisfies the requirements of the license agreement.

The license agreement will terminate upon the expiration of our royalty payment obligations, which occurs, on a licensed product-by-licensed product and country-by-country basis, upon the latest of (a) the tenth anniversary of the first commercial sale of such licensed product, (b) expiration of the last-to-expire patent covering a licensed product, and (c) in the case of a licensed product that is not covered by a patent but that is subject to exclusivity under an orphan drug law for all indications for which regulatory approval has been received, the earlier of (i) the end of the regulatory exclusivity afforded by the orphan drug law for any indication for which the licensed product has received regulatory approval, and (ii) the date on which another drug receives regulatory approval for any indication for which the licensed product has received regulatory approval. Because the date of the first commercial sale of a licensed product is uncertain, and because a number of patent applications are pending that, if issued, would extend the term of the license agreement, the term of the license agreement in each country and with respect to each licensed product is uncertain. Upon termination of all royalty obligations for a licensed product in a country, the license becomes fully paid-up, irrevocable and perpetual for that product in that country.

The license agreement may be terminated by either party in the event of an uncured material breach by the other party. Also, Medtronic may terminate the license agreement if we fail to comply with applicable law in connection with the exploitation of any licensed product and such non-compliance remains uncured after notice by Medtronic. To the extent permitted by law, each party may terminate the license agreement if the other party is subject to bankruptcy or similar proceedings. Except in limited circumstances following a breach by Medtronic of the license agreement, Medtronic's liability to us is limited to amounts previously paid to Medtronic.

Neither party may assign the license agreement without the prior written consent of the other, except to an affiliate or to a third party acquirer of the party or its business relating to licensed products.

### ***SK Biopharmaceuticals Co., Ltd.***

In December 2012, we acquired Neuronex, Inc., a privately-held pharmaceutical company developing a proprietary nasal spray formulation of diazepam as a treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS. Currently, the only approved outpatient treatment option for people who experience this type of seizure activity is DIASTAT<sup>®</sup> AcuDial<sup>™</sup> (diazepam rectal gel), a rectally administered gel formulation of diazepam. Diazepam is currently available in other formulations, such as used for intramuscular and intravenous administration, for certain indications. The nasally administered formulation potentially offers patients and caregivers a more practical and socially acceptable treatment option.

Neuronex, now one of our wholly owned subsidiaries, licenses the patents, patent applications, and other intellectual property and other rights relating to the Diazepam Nasal Spray product from SK Biopharmaceuticals Co., Ltd., or SK. Under the SK license agreement, Neuronex has a license to develop and commercialize licensed products in all countries worldwide, except for specified Asian countries which are reserved for SK under the license agreement. The license is exclusive for all therapeutic, medical and in vivo uses in humans or animals.

Pursuant to the SK license, Neuronex is obligated to pay SK up to \$8 million upon the achievement of specified development milestones with respect to the Diazepam Nasal Spray product (including a \$1 million payment upon the FDA's acceptance for review of the first NDA for the Diazepam Nasal Spray product), and up to \$3 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. There can be no guarantee that any such milestones will in fact be met. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products. Neuronex may offset, against a portion of the royalties payable to SK, a portion of any royalties we may pay under certain third party licenses.

Under the license agreement, Neuronex must use commercially reasonable efforts to develop and market a Diazepam Nasal Spray product. Also, Neuronex is obligated to achieve specified development milestones within the timeframes specified in the SK license. SK is entitled to terminate the SK license if Neuronex fails to achieve the specified milestones, unless the failure is due to reasons beyond Neuronex's reasonable control.

The license agreement will terminate upon the expiration of Neuronex's royalty payment obligations, which occurs, on a country-by-country basis, upon the latest of (a) ten years after first commercial sale of Diazepam Nasal Spray product in a country, (b) expiration of regulatory exclusivity of Diazepam Nasal Spray product in a country, and (c) the expiration of the last-to expire licensed patent. Because the date of the first commercial sale of a licensed product is uncertain, and because patent applications are pending that, if issued, would extend the term of the SK license, the term of the SK license in each country is uncertain. Upon termination of all royalty obligations for a licensed product in a country, the license becomes fully paid-up and non-exclusive.

The SK license may be terminated by either party following an uncured material breach by the other party. Also, Neuronex may terminate the SK license at will upon prior written notice to SK.

Neither party may assign the SK license without the prior written consent of the other, except for assignments to affiliates that meet specified conditions.

### ***Other License Agreements***

In addition to the material license and collaboration agreements described above, we have entered into numerous other license agreements to support our research and development programs. These other license agreements include the following:

- We have an exclusive, worldwide license from the Canadian Spinal Research Organization for specified patents and know-how relating to the use of dalfampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject.
- We have an exclusive, worldwide license from Cambridge Enterprise Limited (formerly Cambridge University Technical Services Limited) and King's College London to specified patents and patent applications for products related to enzymatic methods, including chondroitinase, of treating CNS disorders. Under the same license, we also have non-exclusive rights to these patents and patent applications for products related to small molecule inhibitors for use in treating CNS disorders.
- We have an exclusive, worldwide license from the Mayo Foundation for Education and Research, or Mayo Clinic, to specified patents, patent applications, and other intellectual property on certain antibodies relating to our research on the therapeutic use of these antibodies, specifically myelination and remyelination in MS and SCI.
- We have an exclusive, worldwide sublicense from Paion AG (formerly CeNeS Pharmaceuticals plc) to certain patents, patent applications and know-how relating to 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 Paion by the Ludwig Institute for Cancer Research. We also have an exclusive, worldwide sublicense from Paion to certain Paion patents, patent applications, and know-how relating to the neuregulin growth factor gene NRG-2.
- We have a license from 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, to patent rights relating to the use of GGF2 in the treatment of congestive heart failure. Our rights in the U.S. are co-exclusive, with

Brigham and Beth Israel having retained rights for internal research, clinical, and education purposes, and our rights outside the U.S are exclusive.

## **Manufacturing**

### ***Ampyra***

We are party to a September 2003 agreement with Elan (now Alkermes, following Alkermes' 2011 acquisition of Elan's Drug Technologies business) for our clinical and commercial supply of Ampyra. Under that agreement, we are required to purchase at least 75% of our annual commercial requirements of Ampyra from Alkermes unless Alkermes 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 Alkermes.

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

Under a Consent Agreement among Elan (now Alkermes, following Alkermes' acquisition of Elan's Drug Technologies business), Biogen Idec and us, Alkermes consented to our sublicense of our rights under our agreements with Alkermes 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 Alkermes 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 Alkermes with respect to certain supply-related activities, and requiring Alkermes to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

Regis Technologies, Inc. is the sole supplier of 4-aminopyridine, the active pharmaceutical ingredient in Ampyra. If Regis experiences any disruption in their operations, a delay or interruption in the supply of our Ampyra product could result until the Regis 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.

### ***Zanaflex***

We currently rely on Alkermes to supply us under our 2004 Supply Agreement with Zanaflex Capsules (and for the supply of our authorized generic Zanaflex capsules being marketed by Watson Pharma, a subsidiary of Actavis). 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, Alkermes 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 Alkermes. If we need to transfer production, Alkermes 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 Alkermes. In the event of termination of the supply agreement due to a force majeure event that continues for more than three months, Alkermes 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. Patheon manufactures Zanaflex tablets for us.

Farmak a.s. is our supplier of tizanidine hydrochloride, the active pharmaceutical ingredient, or API, in Zanaflex Capsules and Zanaflex tablets. If Alkermes, Patheon, or Farmak 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 have completed a Phase 1 clinical trial of GGF2 in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. We have completed analysis of the three-month data, and we plan to present findings in a platform presentation at the American College of Cardiology (ACC) annual meeting in March 2013.

We contracted with CMC ICOS Biologics in 2008 to produce and purify GGF2 bulk material under cGMPs. Acorda and CMC Biologics (formerly 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 Good Laboratory Practices, or GLP, safety and toxicology.

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 as part of an IND application that was originally filed in March 2010.

#### ***rHlgM22***

We are developing rHlgM22 as a potential therapeutic for MS. We have contracted for testing and manufacturing development activities for rHlgM22 to be performed by outside contractors. In 2009, we signed a Master Vendor Agreement with Biovest International Inc. to produce rHlgM22 under cGMPs. In 2009, we also contracted with CMC Biologics to develop methods and purify under cGMPs the rHlgM22 produced at Biovest. Acorda and CMC Biologics are working to develop analytical and characterization assays to support the manufacture of rHlgM22. cGMP material produced at Biovest and CMC Biologics has been used in GLP safety and toxicology studies. We have an open IND for rHlgM22 for the treatment of MS and we plan to initiate enrollment in a Phase 1 safety study in MS patients in the first half of 2013. In preparation for an IND filing, we worked with Biovest and CMC Biologics to complete the scale up manufacturing and purification processes, and in 2011 we completed formal preclinical safety and toxicity studies.

#### ***Diazepam Nasal Spray***

On December 20, 2012, we completed the acquisition of Neuronex, Inc., a privately-held pharmaceutical company developing a proprietary nasal spray formulation of diazepam as a treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS.

Continuing with efforts commenced by Neuronex prior to the acquisition, pending additional clinical and manufacturing data, we plan to submit a 505(b)(2)-type New Drug Application, or NDA, for Diazepam Nasal Spray, to the FDA in 2013, with potential FDA approval and commercial launch in 2014. We anticipate that our current infrastructure can support sales and marketing of this product, and market planning is underway. A 505(b)(2) application allows for an NDA that references medical literature and the FDA's finding of safety and effectiveness for a previously approved drug product. We do not yet have manufacturing arrangements in place for this product, and we will rely on third parties for both the manufacturing of this product as well as the supply of the active pharmaceutical ingredient.

### ***AC105***

In June 2011, we entered into a license agreement with Medtronic, Inc. and one of its affiliates pursuant to which we licensed from them worldwide development and commercialization rights to certain formulations of magnesium with a polymer such as polyethylene glycol, which we refer to as AC105. We are studying AC105 as a treatment for patients who have suffered acute SCI. We submitted a Phase 2 clinical trial protocol for AC105 for acute treatment of SCI to the FDA for review. The protocol has been reviewed by the FDA, and we are preparing to initiate the trial in the first half of 2013. The trial is designed primarily to assess the safety and tolerability of AC105 in people with acute SCI. We are relying on a third party to manufacture and supply the clinical trial material.

### **Intellectual Property**

There are seven major families of subject matter in our patent portfolio: Ampyra, Zanaflex Capsules, neuregulins, remyelinating antibodies, chondroitinase, AC105, and Diazepam Nasal Spray. Our intellectual property also includes copyrights, confidential and trade secret information as well as a portfolio of trademarks.

#### ***Ampyra/aminopyridines***

- We have a patent portfolio with multifaceted coverage on aminopyridine-related subject matter.
- We hold an exclusive, worldwide license from Alkermes (formerly Elan) to granted U.S. patents and the corresponding foreign patents. In March 2010 we filed a patent term extension request with the U.S. Patent and Trademark Office, or USPTO, under the Hatch Waxman law on U.S. Patent No. 5,540,938 ("the '938 patent"). The claims of the '938 patent relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In October 2012, the USPTO determined that the '938 patent is entitled to a full five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the '938 patent would expire in 2018. We have also applied for Supplementary Protection Certificates or "SPCs" in various European countries based on the corresponding European Patent, which was originally set to expire in November 2011.
- Also listed in the Orange Book is U.S. Patent No. US 8,007,826 (which is owned by Acorda) with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the United States Patent and Trademark Office, or USPTO, this patent will extend into 2027.

On January 15, 2013 the USPTO issued U.S. Patent No. 8,354,437 (U.S. Patent Application No. 11/102,559) with claims relating to methods to improve walking, walking speed, lower extremity muscle tone and lower extremity muscle strength in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent, which is eligible for listing in the FDA Orange Book, is expected to expire in 2025 plus any additional term determined by the final patent term adjustment calculation by the USPTO. In 2011, the European Patent Office, or EPO, granted the counterpart European patent with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to

increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging this granted European patent. We intend to vigorously defend the European patent, although the outcome of opposition proceedings is unpredictable. We have also applied for SPCs on this granted European Patent.

We have pending U.S. patent applications and corresponding foreign patent applications covering methods of using aminopyridines, such as 4-aminopyridine (dalfampridine). These include pending U.S. patent applications and corresponding foreign applications.

We have pending patent applications filed during the years 2010 through 2012 on various methods for using aminopyridines, such as 4-aminopyridine. If these applications issue as patents, they could remain in force at least through 2030 and 2032, respectively.

We hold an exclusive, worldwide license from the Canadian Spinal Research Organization, or CSRO, for a U.S. patent and 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., or NRI. This acquisition enabled us potentially 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 Ampyridin® (IR) for the treatment of chronic functional motor and sensory deficits resulting from Guillain-Barre Syndrome, or 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.

### *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. This agreement is now with Alkermes due to Alkermes' 2011 acquisition of Elan's Drug Technologies business. Under this agreement, Zanaflex Capsules are manufactured for us by Alkermes using Alkermes' proprietary SODAS® technology and proprietary information. This proprietary technology is owned by Alkermes and, in the event Alkermes ceases to manufacture Zanaflex Capsules, Alkermes 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 Alkermes.

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc., advising that it had submitted an Abbreviated New Drug Application, or 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 in the U.S. District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557. In September 2011, the Court ruled against us and, following our appeal, in June 2012 the U.S. Court of Appeals for the Federal Circuit affirmed the decision. We did not seek any further appeals of the decision. On September 6, 2011, we filed a citizen petition with the FDA requesting that the FDA not approve Apotex's ANDA because of public-safety concerns about Apotex's proposed drug. On December 2, 2011, Apotex filed suit against us in the U.S. District Court for the Southern District of New York. In that suit, Apotex alleged, among other claims, that we engaged in anticompetitive behavior and false advertising in connection with the development and marketing of Zanaflex Capsules, including that the citizen petition we filed with the FDA delayed FDA approval of Apotex's generic tizanidine capsules. On January 26, 2012, we moved to dismiss or stay Apotex's suit. On February 3, 2012, the FDA denied the citizen petition that we filed and approved Apotex's ANDA for a generic version of Zanaflex Capsules. On February 21, 2012, Apotex filed an amended complaint that incorporated the FDA action, but otherwise made allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits, recovery of litigation costs, and injunctive relief. Following our filing of a motion to dismiss the amended complaint, in 2013 the Court dismissed six of the seven counts in the amended complaint, including all of the antitrust claims, leaving only a claim under the Lanham Act relating to alleged product promotional activities. We have filed a motion for reconsideration of the decision regarding the Lanham Act claim. The Company intends to defend itself vigorously in the litigation.

### ***Neuregulins***

We are the exclusive licensee under a license agreement with Paion AG (formerly 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 2011, we returned some of the patent rights related to Neuregulin 2, which Paion sublicensed from the President and Fellows of Harvard College.

Our neuregulin portfolio includes a granted 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 and their use discovered by scientists at the Mayo Clinic. This portfolio also includes pending U.S. and foreign patent applications directed to additional antibodies and their use. With regard to remyelinating antibodies, the portfolio includes U.S. issued patents directed to antibody compositions that can induce remyelination, as well as several issued related foreign counterparts.

### ***Chondroitinase***

Our chondroitinase portfolio includes granted U.S. patents and granted foreign patent counterparts, as well as pending patent applications. The granted U.S. patents are directed to methods of using certain chondroitinase enzymes, including chondroitinase ABC-I, to reduce inflammation in patients with central nervous system diseases, spinal cord injury or multiple sclerosis and certain chondroitinase ABC-I mutant enzymes and related methods of use. The pending U.S. patent applications and their foreign counterparts are directed to chondroitinase enzymes, methods of use and formulations thereof. In particular, we have pending U.S. applications and foreign equivalents relating to chondroitinase enzymes, including fusion proteins of chondroitinase enzymes, chimeric proteins including chondroitinase enzymes, deletion mutants of chondroitinase enzymes and certain methods of use of the same.

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

### ***AC105***

In June 2011, we entered into a license agreement with Medtronic, Inc. and one of its affiliates pursuant to which we licensed from them worldwide development and commercialization rights to certain formulations of magnesium with a polymer such as polyethylene glycol, referred to as AC105. Under our license agreement with Medtronic, we have rights in pending patent applications relating to certain formulations of magnesium with a polymer (such as polyethylene glycol) and uses thereof. Our rights in these pending patent applications are exclusive as to certain formulations and certain fields.

### ***Diazepam Nasal Spray***

Our wholly-owned subsidiary Neuronex, Inc. has a license from SK Biopharmaceuticals Co., Ltd., or SK, for two patent families comprising pending U.S. and foreign patent applications relating to the clinical formulation for the Diazepam Nasal Spray clinical product. If granted, these patent applications would expire in 2029-2032. One patent family is owned by SK and one patent family is jointly owned by Neuronex and SK.

### ***Trademarks***

In addition to patents, our intellectual property portfolio includes registered trademarks, along with pending trademark applications. 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 also have trademark registrations for "Fampyra" and "Kampyra" and pending trademark applications therefore, in numerous foreign jurisdictions. We also own the rights to the registered marks "Zanaflex" and "Zanaflex Capsules" in the U.S. In addition, our trademark portfolio includes several trademark registrations and 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.

### ***Ampyra/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 and Extavia from Novartis AG.

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 an increase in 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. or 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, or LEMS. On October 31, 2012 BioMarin outlicensed the North American rights to Catalyst Pharmaceuticals. 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, and we expect that some people will continue to do this. Several companies are engaged in developing products that include novel immune system approaches and cell therapy 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 is 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.

### ***Zanaflex/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, among others, both MS and SCI patients. Zanaflex tablets were approved by the FDA in 1996 and lost compound patent protection in 2002. A number of generic manufacturers of tizanidine hydrochloride are distributing their own tablet formulations.

As noted under “–Intellectual Property–Zanaflex” above, on February 3, 2012, Apotex received FDA approval of its ANDA and on February 6, 2012, it launched generic tizanidine hydrochloride capsules. On February 6, 2012, we also launched an authorized generic version of Zanaflex Capsules under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.). Also, in May 2012, we received a Paragraph IV Certification Notice from Mylan Laboratories Limited advising us that Mylan Laboratories has filed an ANDA for generic versions of the three dosage strengths of Zanaflex Capsules. The FDA approved Mylan’s ANDA on November 9, 2012. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. In addition, several companies have reported that they are working on potential new delivery formulations of tizanidine hydrochloride. Our net revenue from Zanaflex Capsules has declined significantly due to competition from existing generic versions, and we expect it will continue to decline significantly in 2013 and beyond due to competition from existing and potentially other generic versions.

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 but Apotex’s generic tizanidine hydrochloride capsules are.

### ***Diazepam Nasal Spray/Cluster or Acute Repetitive Seizures***

Diazepam Nasal Spray is a proprietary formulation of diazepam that we are developing as a treatment for

the management of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS. Currently, the only approved outpatient treatment option for people who experience this type of seizure activity is DIASTAT<sup>®</sup> AcuDial<sup>™</sup> (diazepam rectal gel), a rectally administered gel formulation of diazepam. Diazepam is also available in other formulations, such as used for intramuscular and intravenous administration, for certain indications. Our current understanding is that many patients would prefer a therapeutic delivered intranasally rather than delivery options of rectal or intramuscular administration, but we cannot be certain that physicians would prescribe Diazepam Nasal Spray in preference over other available formulations of diazepam. Also, if we obtain FDA approval for and launch Diazepam Nasal Spray, it may be more expensive than some or all of the generic or branded versions of diazepam otherwise available. Furthermore, we are aware that Pfizer is developing an intramuscular delivery system for diazepam, Neurelis is developing an intranasal diazepam spray, and Upsher Smith is developing a nasal delivery form of midazolam, which could have a labeled indication similar to Diazepam Nasal Spray. Diazepam Nasal Spray could be subject to substantial competition from these potential products, depending on whether and when they receive FDA approval, their cost, their labeled indications, patient acceptance, and other factors.

In addition to these examples, there are numerous other companies with early stage development programs for the treatment of epilepsy, cluster or breakthrough seizures, and acute repetitive seizures that could compete with Diazepam Nasal Spray in the future.

## **Government Regulation**

### ***FDA Regulation and Product Approval***

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the preclinical testing, clinical development, manufacture, distribution and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising, sale, promotion, import and export of our products and product candidates.

In the U.S., Ampyra, Zanaflex Capsules and Zanaflex tablets and our product candidates are regulated by the FDA as drugs. Some 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 tested, 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 Investigational New Drug, or IND, an application which must become effective before human clinical trials may begin;
- completion of 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 a New Drug Application, or 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.

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 and size of clinical trials intended to form the primary basis of an effectiveness claim. 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, but the agreement is not binding if the sponsor and the FDA agree in writing or if a substantial scientific issue essential to determining the safety or effectiveness of the drug is identified after the testing has begun. 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 safety and effectiveness (for a drug) and safety, purity and potency (for a biologic) of the compound from laboratory, animal and clinical testing, as well as data and information on manufacturing, product stability, and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA or BLA and must be registered with the FDA. The application will generally not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug or biological product, and determines that the facility is in compliance with cGMP requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products. The FDA may also inspect clinical trial sites and will not approve the product unless the clinical studies have been conducted in compliance with GCP.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing a BLA or NDA and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees could 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, with two additional months added to each period for new molecular entities. 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 preclinical or 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 risk evaluation and mitigation strategy, or REMS, or otherwise limit the scope of any approval. 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 that 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 harm 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. Foreign drug manufacturers must comply with similar local requirements and may be subject to inspections by FDA or local regulatory agencies. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMPs and other regulatory requirements. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In addition to inspections related to manufacturing, we are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements that apply to marketed drugs manufactured or distributed by us. 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 U.S. or foreign 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 healthcare costs in the U.S. and in foreign markets could result in new government regulations that could harm our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that 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 did 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 the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. If the FDA approves someone else's application for the same drug that has orphan exclusivity, but for a different use, the competing drug could be prescribed by physicians outside its FDA approval for the orphan use, notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another person from receiving approval for the same or a similar drug for the same or other uses.

### ***Generic Drugs, AB Ratings and Pharmacy Substitution***

Generic drugs are approved through an abbreviated 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. The 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. Solid oral dosage form drug products that are considered therapeutically equivalent are generally rated "AB" in the Orange Book.

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 currently 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.

### ***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 Union, or EU, registration procedures are available to companies wishing to market a product in the entire European Economic Area, or EEA, or in more than one individual EU member state. This centralized procedure is mandatory for certain products. 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. For products to be 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, or 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. In addition, under legislative changes made in 2009, discounted prices must also be offered for certain DOD purchases for its TRICARE program via a rebate system, and we may be required to make payments to cover discounts on certain past purchases. 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.

Under the Affordable Care Act, beginning in August 2013, pharmaceutical manufacturers will be subject to new federal reporting and disclosure requirements with regard to payments or other transfers of value made to healthcare providers. Reports submitted under these new requirements will be placed on a public database. Similarly, pharmaceutical manufacturers will also be required to report samples of prescription drugs requested by and distributed to healthcare providers based on forthcoming guidance from the FDA. 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.

### ***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 healthcare 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, or MMA, enacted in December 2003, altered federal reimbursement for physician-administered drugs covered by Medicare. Under the reimbursement methodology set forth in the MMA, 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 MMA 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 healthcare 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 average manufacturer price (AMP) and best price are reported to the government and the formula for calculating 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 AMP 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) is 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 healthcare is financed by both governmental and private insurers, enrollment in federal healthcare programs, reimbursement changes, increased funding for comparative effectiveness research for use in the healthcare industry, and enhancements to fraud and abuse requirements and enforcement, that will affect existing government healthcare programs and will result in the development of new programs.

We are unable to predict the future course of federal or state healthcare 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 healthcare 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 healthcare 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, Micromedex, DrugDex, or Clinical Pharmacology. Another commonly cited compendium, for example under Medicaid, is the DrugDex Information System.

Different pricing and reimbursement schemes exist in other countries. For example, in the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare 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 healthcare 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 Health and 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 commercial pressure on pricing within a country.

## **EMPLOYEES**

As of February 13, 2013, we had 378 employees. Of the 378 employees, 90 perform research and development activities, including preclinical programs, clinical trials, regulatory affairs, biostatistics, and drug safety, and 288 work in sales, marketing, managed markets, business development, manufacturing, technical operations, 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 420 Saw Mill River Road, Ardsley, New York 10502. Our telephone number is (914) 347-4300. Our website is [www.acorda.com](http://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 "Investors" and then "SEC Filings" captions) 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 2013 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2013 proxy statement within 120 days after the end of our 2012 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 2013 proxy statement.

### **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, although we were profitable in 2012, we may not be able to sustain profitability.*

As of December 31, 2012, we had an accumulated deficit of approximately \$254.5 million. Although we had net income of \$155.0 million for the year ended December 31, 2012, which includes a tax benefit recorded for a release of our deferred tax asset valuation allowance, and \$30.6 million for the year ended December 31, 2011, prior to 2011 we had operating losses each year 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 will continue to invest significant amounts in marketing our approved products, in our product development and research and development activities, and, potentially, to acquire new products and product candidates.

Our prospects for sustaining profitability will depend primarily on how successful we are in:

- Increasing our sales levels for Ampyra in the U.S. and supporting Biogen Idec's efforts to successfully obtain and maintain regulatory approval for Fampyra (as Fampridine Prolonged Release tablets) in the EU and other markets outside the U.S.;
- expanding the Ampyra franchise through additional patent protection for Ampyra, new formulations, and additional indications in MS and possibly other conditions such as cerebral palsy and post-stroke deficits;
- Obtaining FDA approval for, and commercializing, the Diazepam Nasal Spray product that we acquired from Neuronex, Inc. in December 2012;
- continuing to advance clinical development of our AC105, rHIgM22, and GGF2 programs;
- continuing to develop our preclinical product candidates and advance them into clinical trials; and
- evaluating and potentially expanding our product development pipeline through the potential inlicensing and/or acquisition of additional products and technologies.

If we are not successful in executing our business plan, we may not sustain profitability. Also, even if we are successful in executing our business plan, our profitability may fluctuate from period to period due to our level of investments in marketing, research and development, and product and product candidate acquisitions. For example, in 2013 we expect to invest a significant amount in continuing the development of, and seeking FDA approval for, the Diazepam Nasal Spray product.

***Our ability to use net operating loss carry forwards to reduce future tax payments may be limited if taxable income does not reach sufficient levels or there is a change in ownership of Acorda.***

In general, under the Internal Revenue Code of 1986, as amended, a corporation is subject to limitations on its ability to utilize net operating losses (NOLs), to offset future taxable income. As of December 31, 2012, we had approximately \$205.1 million of NOLs available to reduce taxable income in future years. Losses for federal income tax purposes can generally be carried forward for a period of 20 years. We believe it is more likely than not that we will use these net operating losses. However, the ability to use net operating loss carryforwards will be dependent on our ability to generate taxable income. The net operating loss carryforwards could expire before we generate sufficient taxable income.

Our ability to utilize the NOL's may be further limited if we undergo an ownership change, as defined in section 382. This ownership change could be triggered by substantial changes in the ownership of our outstanding stock, which are generally outside of our control. An ownership change would exist if the stockholders, or group of stockholders, who own or have owned, directly or indirectly, 5% or more of the value of our stock, or are otherwise treated as 5% stockholders under section 382 and the regulations promulgated thereunder, increase their aggregate percentage ownership of our stock by more than 50 percentage points over the lowest percentage of our stock owned by these stockholders at any time during the testing period, which is generally the three-year period preceding the potential ownership change. In the event of an ownership change, section 382 imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change NOL's. If an ownership change were to occur, the annual limitation under Section 382 could result in a material amount of our NOLs expiring unused. This would significantly impair the value of our NOL asset and, as a result, could have a negative impact on our financial position and results of operations.

***We may have exposure to additional tax liabilities, which could have a material impact on our results of operations and financial position.***

We are subject to income taxes, as well as non-income based taxes, in both the United States and Puerto Rico. Significant judgment is required in determining our tax liabilities. Although we believe our estimates are reasonable, the ultimate outcome with respect to the taxes we owe may differ from the amounts recorded in our financial statements. If the Internal Revenue Service, or other taxing authority, disagrees with the positions taken by our company, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. In addition, the United States government may adopt tax reform measures that significantly increase our worldwide tax liabilities, which could materially harm our business, financial condition and results of operations.

***We will be highly dependent on the commercial success of Ampyra in the U.S. for the foreseeable future, as sales of Zanaflex Capsules continue declining due to generic competition; we may be unable to meet our expectations with respect to Ampyra sales and/or sustain profitability and positive cash flow from operations.***

We currently derive substantially all of our revenue from the sale of Ampyra. We believe that sales of Ampyra will continue to constitute a significant and growing portion of our total revenue for the foreseeable future. Net revenue from Zanaflex Capsules declined significantly in 2012 due to the introduction of generic versions of tizanidine hydrochloride capsules, including our own authorized generic version, and we expect that net revenue from this product will continue to decline further in 2013 and beyond. The continued commercial success of Ampyra, which first became commercially available in March 2010, will depend on a number of factors, including:

- 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, instead of Ampyra, 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.

***We have no manufacturing capabilities and are dependent upon Alkermes (formerly Elan) and other third-parties to supply the materials for, and to manufacture, Ampyra and our other commercial products and products in development.***

We do not own or operate, and currently do not plan to own or operate, facilities for production and packaging of Ampyra or our other commercial products. 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 on Alkermes to supply us with our requirements for Ampyra. Under our supply agreement with Alkermes, we are obligated to purchase at least 75% of our yearly supply of Ampyra from Alkermes, and we are required to make compensatory payments if we do not purchase 100% of our requirements from Alkermes, subject to specified exceptions. We and Alkermes 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 Alkermes also rely on a single third-party manufacturer, Regis, to supply dalfampridine, the active pharmaceutical ingredient, or API, in Ampyra. If Regis experiences any disruption in their operations, a delay or interruption in the supply of our Ampyra product could result until Regis cures the problem or we locate an alternate source of supply.

Under our supply agreement with Alkermes, we provide Alkermes with monthly written 18-month forecasts, and with annual written five-year forecasts for our supply requirements of Ampyra. In each of the 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. Alkermes 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.

We similarly rely on Alkermes and other third parties for the manufacture of our Zanaflex and authorized tizanidine hydrochloride generic products and the supply of tizanidine hydrochloride, the API in those products, and for the supply of materials for our research and development activities, particularly clinical trials. Also, we have not yet established arrangements for the manufacture of Diazepam Nasal Spray or the supply of the API for Diazepam Nasal Spray, which will be subject to FDA approval, but we will rely on third parties as we do for our other products. Our dependence on others to manufacture and provide the API for our marketed products and clinical trial materials may harm 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.

The manufacture and distribution of our products, including product components such as API, is highly regulated, and any failure by us or our third party suppliers to comply with regulatory requirements could adversely affect our supply of products. U.S. and foreign governments and regulatory authorities continue to propose legislative and other measures relating to the manufacture or distribution of pharmaceutical products, including revisions to current good manufacturing practices (“cGMPs”). For example, new rules that take effect in the EU on July 2, 2013 permit the import of API from outside the EU only if it has been manufactured in accordance with cGMPs equivalent to those applicable in the EU and is accompanied by written confirmation from the regulatory authority in the country of manufacture. Compliance with such new legislative or regulatory measures may increase the price we must pay for our products or otherwise adversely affect our supply of products.

***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 risk evaluation and mitigation strategy, or REMS, a commitment to report all seizures we learn about in post-approval use to the FDA on an expedited basis. 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 meet our post-approval commitments could lead to negative regulatory action by the FDA, which could include withdrawal of regulatory approval. The marketing approval for Ampyra was also subject to requirements for follow-up animal and clinical studies and analyses. We have completed these studies and we believe we have satisfied these requirements, but they remain subject to FDA review. Also, our Ampyra post-marketing approval requirements included a commitment to the FDA to conduct a trial to evaluate a 5mg twice daily dosing regimen, the results from which we announced in August 2012. Although we believe that the study failed to confirm efficacy of the 5mg dose, and that the study, together with the Ampyra registration studies, continue to show that 10 mg. twice daily is the appropriate, safe and effective dose, the study results were provided to the FDA and we cannot predict whether the FDA will request that we conduct any additional studies or make a lower dose of Ampyra available.

***The FDA-approved product labeling for Ampyra limits promotional opportunities for Ampyra, which may harm market acceptance of Ampyra.***

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.

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. For example, in June 2012 we received an untitled letter from the FDA stating that one of our Ampyra promotional videos did not comply with applicable law and was misleading because it overstated the efficacy of and minimized important safety information associated with Ampyra. In compliance with the untitled FDA letter, we discontinued use of the video, and in light of the FDA letter we also evaluated and discontinued the use of some other promotional materials. Based on a September 2012 letter from the FDA, we believe that we have resolved the specific issues identified by the FDA in the June untitled letter but we have a continuing obligation to ensure that our promotional materials are compliant.

***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 harmed 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 and increase our expenses, which would impair our business.

Furthermore, since 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 result in harm to Ampyra sales and our profitability. For example, as part of an annual REMS review of Ampyra, in July 2012 the FDA issued a safety communication relating to seizures based on post-marketing data from March 2010 through March 2011. These data showed no new safety signals related to seizure risk with Ampyra and are consistent with the data from clinical trials of Ampyra. However, the FDA safety updates and related changes that we have made to the Ampyra product labeling, or additional changes that we might have to make in the future, could change perceptions about Ampyra safety and therefore harm sales. We also constantly monitor adverse event reports for signals regarding potential additional adverse events, which could result in the need for further label changes, which might harm Ampyra sales. For example, in September 2012 we made another label change relating to reports of anaphylactic reactions.

Under FDA regulations and our REMS for Ampyra, we are required to monitor the safety of Ampyra and inform health care professionals about the risks of drug-associated seizures with 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. For example, in late 2010 and early 2011, we learned that two of the specialty pharmacies that dispense Ampyra failed to timely report to us some of the reports of adverse events that they received, which we believe was in violation of our contracts with them. We reported these adverse events to the FDA immediately upon receipt. However, because the specialty pharmacies did not report these adverse events to us in a timely manner, they were considered late reports to the FDA. In 2011 the FDA conducted an inspection focused primarily on our adverse event reporting system, including the timeliness of reporting of adverse events by our specialty pharmacies. Issues were identified on a September 2011 Form 483, and then in May 2012 we received a warning letter from the FDA regarding some of the issues identified in the inspection. In December 2012 and January 2013, the FDA conducted two additional inspections. The first focused on our adherence to the Ampyra REMS and resulted in issuance of a FDA Form 483 with one written observation as well as six verbal comments. The second focused on adverse event reporting and resulted in the issuance of a Form 483 with six written observations as well as three verbal comments. The Form 483s and warning letter are discussed in further detail below in these risk factors. The FDA could take further regulatory action against us if our responses to the FDA 483 and warning letter items are not adequate or if we are unable to demonstrate adequate control over our adverse event reporting system. If the specialty pharmacies that we rely upon to sell Ampyra in the U.S. fail timely to report adverse events to us, or if we do not meet the requirements for safety reporting, our business may be harmed.

***Our success in increasing sales of 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 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 dispense or support Ampyra;
- reduce their efforts or discontinue dispensing or supporting Ampyra;
- not devote the resources necessary to dispense 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.

***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, outside the U.S., 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 promotion of a drug other than in accordance with labeling approved by the FDA or other applicable regulatory agency. Companies may not promote drugs for off-label uses. Accordingly, we may not promote Ampyra in the U.S. for any indications other than improving walking ability in people with MS. 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 engaged in off-label promotion may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other applicable 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 off-label promotion restrictions, 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. In June 2012 we received an untitled letter from the FDA stating that one of our Ampyra promotional videos did not comply with applicable law and was misleading because it overstated the efficacy of Ampyra and minimized important risk information. This untitled FDA letter is discussed in further detail above in these risk factors.

***We are dependent on our collaboration with Biogen Idec to commercialize Ampyra outside of the U.S. (known as Fampyra outside 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 or adequate product reimbursement in a timely manner, or at all, as discussed in further detail below in these risk factors;
- 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 some 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.

***Our collaboration partner, Biogen Idec, will need to obtain regulatory approval in foreign jurisdictions where they seek to market Fampyra.***

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 harm 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 Fampyra or other product candidates in foreign markets could materially harm our business prospects.

Under the Collaboration Agreement, Biogen Idec has the right to develop and commercialize Fampyra 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) for Ampyra, known outside the U.S. as Fampyra (fampridine). In January 2011 the EMA's Committee for Medicinal Products for Human Use, or CHMP, decided against approval. Biogen Idec, working closely with us, filed a formal appeal of the decision. In May 2011, the CHMP recommended conditional marketing authorization of, and in July 2011 Biogen Idec received conditional approval from the European Commission for, Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). The conditional approval must be renewed annually, and there can be no assurance that Biogen Idec will be able to satisfy the requirements for maintaining the approval. For example, Biogen Idec needs to carry out additional studies of the benefits and safety of Fampyra, and the results of these studies could affect renewal of the approval. Any requirements to conduct supplemental trials would add to the cost and risks of development and approval. Additional or supplemental trials with respect to Fampyra 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.

***Some of our drug development programs are in early stages of development and may never be commercialized.***

We have several research and development programs that are early-stage and either have not advanced to clinical trials or are only in Phase 1 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 and through clinical trials. These product candidates will require significant development, preclinical studies and clinical trials, regulatory clearances and substantial additional investment before they can be commercialized.

Our early-stage research and development 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, including, for example, development goals for our product candidates and programs set forth in this report. However, given the complex nature of the drug discovery and development process, it is difficult to predict accurately if and when we will achieve these goals. If we are unsuccessful in advancing our research and development programs into clinical testing or in obtaining regulatory approval, our long-term business prospects will be harmed.

In addition to our research and development of new drugs, we are assessing new formulations of Ampyra, additional uses of Ampyra in MS, and the possible use of Ampyra in cerebral palsy, post-stroke deficits, and other neurological conditions. These are early stage programs and similarly may never lead to any new commercialized products or expansion of the Ampyra label for additional uses. These programs will require significant development, preclinical studies and clinical trials, regulatory approvals and substantial additional investment before they can be commercialized, if ever.

***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, including our clinical trials described in this report for our neuregulin Glial Growth Factor 2, our AC105 program, or rHIgM22, 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 harm 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 rHIgM22 under cGMP filed for bankruptcy in 2008, delaying an IND filing that we had targeted for late 2009.

***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. In order to conduct clinical trials to obtain FDA approval to commercialize any product candidate, an investigational new drug, or IND, application must first be submitted to the FDA and must become effective before clinical trials may begin. Subsequently, if the product candidate is regulated as a drug, a new drug application, or NDA, must be submitted to the FDA and approved before commercial marketing may begin. The NDA must include 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. If the product candidate, such as an antibody, is regulated as a biologic, a biologic application, or BLA, must be submitted and approved before commercial marketing may begin. Of the large number of drugs in development, only a small percentage result in the submission of an NDA or BLA to the FDA, and even fewer are approved for commercialization. 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 of those standards are not complied with in a clinical trial, the resulting data from the clinical trial may not be usable or we, an institutional review board or the FDA may suspend or terminate a trial, which would severely delay our development and possibly end the development of the 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 those regulations on us, although they could impose significant restrictions on our business and we may have to incur additional expenses to comply with them.

We also are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to other regulatory requirements that apply to drugs manufactured or distributed by us. If we receive a notice of inspectional observations or deficiencies from the 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 two inspections beginning in July 2011. The first inspection focused on our REMS and the second inspection focused on our adverse event reporting system. The REMS inspection resulted in verbal comments pertaining to formalization of procedures and enhanced quality assurance responsibilities. The adverse event reporting inspection resulted in a September 2011 FDA Form 483 focused primarily on timeliness of reporting, formalization and enhancement of certain procedures and processes, communication of Ampyra post-marketing commitments, and Acorda access to source documentation. Acorda provided the FDA with formal responses to the inspectional observations as well as to the verbal comments and commenced the process of implementing specific actions to address the FDA's concerns and enhance our overall pharmacovigilance process. However, in May 2012 the FDA issued a written warning letter based on some of the issues identified in the 2011 inspections. The FDA warning letter identified some of the FDA's observations as repeat observations from prior FDA inspections. We have responded to the warning letter, advising the FDA of the corrective actions we are taking to address all of the matters covered in the warning letter.

The FDA also conducted two inspections in December 2012 and January 2013. The first inspection focused on Ampyra REMS adherence and resulted in the issuance of an FDA Form 483 with one written observation and six verbal comments. The written observation described a lack of timely distribution of REMS required letters to prescribers and pharmacists. The verbal comments pertained to verification and document control processes for REMS required letters, process control for creation and distribution of these letters and the medication guide, and the timing of prescriber surveys in relation to mailing of letters to the prescribers. The second inspection focused on adverse event reporting and was a follow-up to our responses to the 2011 FDA 483 and Warning Letter. This inspection resulted in an FDA Form 483 with six written observations and three verbal comments. The written observations noted late adverse event reporting, one late quarterly Periodic Adverse Experience Report, or PADER, and one late field alert. The FDA also noted that certain solicited adverse events were not reported in our PADERS and lack of consistent adherence to procedures for timely case follow-up and investigations. The verbal comments covered completeness and timeliness of investigations as well as need for further clarification of an existing procedure. We have responded to the Form 483s and oral comments, and intend to take and are taking necessary corrective actions. However, the FDA may decide that our responses and corrective actions are not adequate, or may conclude that we have not demonstrated adequate control over our current processes, and could take action against us, without further notice. Action by the FDA against us could require us to take further corrective actions or even that we stop marketing Ampyra and/or result in monetary

fines, and any of such actions by the FDA could harm our business.

In addition, our third-party suppliers' drug product manufacturing sites are subject to inspection by the FDA. Some of these sites have been inspected by the FDA and could be inspected by the FDA in the future. If the FDA inspects the process validation efforts and manufacturing process at these sites, 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.

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. These events could increase our costs, cause us to lose revenue, and damage our reputation. 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. We filed several field alerts in 2011, with respect to both Zanaflex Capsules and Ampyra, related to two reports of empty Zanaflex Capsules, two reports of empty Ampyra bottles and two incidents related to Ampyra bottle labels. While the issues contributing to these field alerts have been identified and addressed and the field alerts have been closed, inspections in the future could lead to product recalls and interruption of supplies, which in turn could harm our business.

***Our products and product candidates may not gain market acceptance among physicians, patients and the medical community, and may not achieve adequate reimbursement, 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 Ampyra are meaningful for patients. As described above in these risk factors, FDA-approved product labeling for Ampyra is limited and may harm its market acceptance. Also, 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.

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 harm 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 government authorities can delay commercialization. Even if reimbursement is available, reimbursement policies may negatively impact revenue from sales of our products and therefore our ability or that of our partners, such as Biogen Idec, to sell our products on a profitable basis. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of products by us or our partners, such as Biogen Idec, and exert commercial pressure on pricing within a country.

In response to the recent downturn in global economic conditions, governments in a number of international markets have announced or implemented measures aimed at reducing healthcare costs to constrain the overall level of government expenditures. This includes Germany and other countries in the EU, where Biogen Idec has obtained approval for Fampyra. The measures vary by country and include, among other things, mandatory rebates and discounts, price reductions and suspensions on pricing increases on pharmaceuticals. These measures may negatively impact net revenue from Biogen Idec sales of Fampyra and therefore the amount of the royalty we receive from Biogen Idec. Furthermore, if these measures prevent Biogen Idec from selling Fampyra on a profitable basis in a particular country, they could prevent the commercial launch of Fampyra in that country.

For example, in 2011 the German government implemented new legislation to manage pricing related to new drug products introduced within the German market through a review of each product's comparative efficacy. Fampyra was launched by Biogen Idec in Germany in August 2011. In August 2012 the German Joint Federal Committee (G-BA) publicly announced its final assessment of the additional benefit of Fampyra, giving Fampyra a rating of no added benefit compared to physiotherapy. Although the G-BA decision did not impact access to Fampyra for patients in Germany, it provided a comparator price range that was the basis for Biogen Idec's negotiation of a price for Fampyra in Germany with the Federal Association of Statutory Health Insurance Funds. The comparator price range is substantially lower than the price of Fampyra at launch in Germany. In addition, German prices are typically used by a number of other countries as a reference price, which therefore can negatively impact the price to be paid for reimbursement of Fampyra by other countries, particularly in the EU. A reduction in the price of Fampyra will reduce the amount of royalties Biogen Idec must pay us.

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 market acceptance of our products in the U.S., EU, or other countries does not meet expectations, our revenues or royalties from product sales would suffer and this could 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, or other applicable legal requirements, we may be subject to civil or criminal penalties or additional reimbursement requirements and sanctions, which could harm our business, financial condition, results of operations and growth prospects.***

The distribution, sale and promotion of drug and biological products are 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, as amended, and similar state laws. Because of the breadth of these laws and the narrowness of safe harbors under these laws, it is possible that some of our business activities could be subject to challenge under one or more of these laws. All of these activities are also subject to federal and state consumer protection and unfair competition 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.

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. Numerous 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 government-funded health plans to correct for insufficient rebates by us or overpayments made to us, 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. For products to be made available to authorized users of the Federal Supply Schedule, additional pricing laws and requirements apply, as do certain obligations imposed by the Federal Acquisition Regulations. Under the Veterans Health Care

Act of 1992, as amended (VHCA), we are required to offer certain drugs at a reduced price to a number of federal agencies, including the Veterans Administration, 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. Legislative changes in 2009 purport to require that discounted prices be offered for certain DOD purchases for its TRICARE program via a rebate system, and we may be required to make payments to cover discounts on certain past purchases. 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.

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 healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. This law contains a number of provisions, including provisions governing enrollment in federal healthcare programs, reimbursement changes, the increased development of comparative effectiveness research for use in healthcare decision-making, and enhancements to fraud and abuse requirements and enforcement, that will affect existing government healthcare programs and will result in the development of new programs.

In June 2012, the United States Supreme Court upheld the constitutionality of the 2010 Patient Protection and Affordable Care Act's mandate to purchase health insurance but rejected specific funding provisions that incentivized states to expand their current Medicaid programs. As a result of this ruling, we currently expect implementation of most of the major provisions of the Act to continue. Changes to the Affordable Care Act, or other federal legislation regarding health care access, financing, or delivery and other actions taken by individual states concerning the possible expansion of Medicaid could impact our financial position or results of operations.

A number of provisions contained in the Affordable Care Act may harm our net revenue for our marketed products and any future products. The 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. Government efforts to reduce Medicaid expenses may also lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

The law also 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.” 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) is 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 provisions affecting compliance. For example, beginning in August 2013, pharmaceutical manufacturers will be required to collect information on payments or other transfers of value made to healthcare providers. The collected information will have to be disclosed in reports that will be placed on a public database. Similarly, pharmaceutical manufacturers will also be required to report samples of prescription drugs requested by and distributed to healthcare providers based on forthcoming guidance from the FDA. 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.

We are unable to predict the future course of federal or state healthcare 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 harm our business, financial condition and results of operations and cash flows.

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

Our ability to increase sales and profitability 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 our other marketed products, or potential products. Our business could be materially harmed 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 harmed 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 than we believe is appropriate.

Third-party payers frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. We have agreed to provide such discounts and rebates to some third-party payers in relation to Ampyra. 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 also require prior authorization for, or even refuse to provide, reimbursement for Ampyra, and others 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 harmed. 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 harm our results of operations.

The Medicare Part D outpatient prescription drug 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 support 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.” 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 harm 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 spinal cord injury, or SCI.

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 harm 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.

For example, we are aware that Catalyst Pharmaceuticals is developing a 3,4 diaminopyridine product, licensed from Biomarin, 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 therapy 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 some of our product candidates.

Also, Diazepam Nasal Spray is a proprietary nasal spray formulation of diazepam, which is currently available as an FDA approved rectal gel and in other formulations, such as used for intramuscular and intravenous administration. Our current understanding is that many patients would prefer a therapeutic delivered intranasally rather than delivery options of rectal or intramuscular administration, but we cannot be certain that physicians would prescribe Diazepam Nasal Spray in preference over the other available formulations of diazepam. Also, if

we obtain FDA approval for and launch Diazepam Nasal Spray, it may be more expensive than some or all of the generic or branded versions of diazepam otherwise available. Furthermore, we are aware that Pfizer is developing an intramuscular delivery system for diazepam, Neurelis is developing an intranasal diazepam spray, and Upsher Smith is developing a nasal delivery form of midazolam, which could have a labeled indication similar to Diazepam Nasal Spray. Diazepam Nasal Spray could be subject to substantial competition from these potential products, depending on whether and when they receive FDA approval, their cost, their labeled indications, patient acceptance, and other factors. In addition to these examples, there are numerous other companies with early stage development programs for the treatment of epilepsy, cluster or breakthrough seizures, and acute repetitive seizures that could compete with Diazepam Nasal Spray in the future.

Composition of matter patents on tizanidine, the active ingredient in Zanaflex Capsules and Zanaflex tablets, expired in 2002. A number of companies are marketing generic versions of tizanidine hydrochloride tablets. In addition, on February 6, 2012, Apotex Inc. launched generic tizanidine hydrochloride capsules and we launched an authorized generic version of Zanaflex Capsules under our agreement with Watson Pharma (a subsidiary of Actavis). In May 2012, we received a Paragraph IV Certification Notice from Mylan Laboratories Limited advising us that Mylan Laboratories has filed an Abbreviated New Drug Application for generic versions of the three dosage strengths of Zanaflex Capsules. The FDA approved Mylan's ANDA on November 9, 2012. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. Our net revenue from Zanaflex Capsules has declined significantly due to competition from existing generic versions, and we expect it will continue to decline significantly in 2013 and beyond due to competition from existing and potentially other generic versions.

***We may expand our business through the acquisition of companies or businesses or inlicensing 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 inlicensing 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 products or product candidates, for example by overestimating approvability by the FDA or the market potential of acquired or in-licensed products or product candidates. 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 harm 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. Also, although we may from time to time announce that we have entered into agreements to acquire other companies or assets, we cannot assure you that these acquisitions will be completed in a timely manner or at all. These transactions are subject to an inherent risk that they may not be completed, for example because required closing conditions cannot be met at all or within specified time periods, termination rights may be exercised such as due to a breach by one of the parties, or other contingencies may arise that affect the transaction.

***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 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 Ampyra, 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 Alkermes (formerly 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 new standards set out in the Pediatric Research Equity Act (PREA) and reauthorized by both the 2007 FDA Amendments Act (FDAAA) and the 2012 Food and Drug

Administration Safety and Innovation Act (FDASIA) and concluded that the report 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. In June 2011, the FDA informally advised us that they would be amending the pediatric commitment for Zanaflex Capsules to require a non-clinical juvenile toxicology study, as well as formalize the timeline for the required pediatric studies. In December 2012, the FDA issued a formal written request that confirmed the information in its informal June 2011 request, and set forth specific deadlines for the required pediatric nonclinical and clinical studies. In January 2013, we submitted a written request to extend the deadlines for these studies, and we are awaiting a response from the FDA. Additionally, a clinical electrocardiogram study in adult humans to investigate potential QT prolongation (heart rhythm measure) has also been requested. 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, which might require us to change our product labeling and could harm product sales. We also may be subject to penalties for not meeting our pediatric study commitments, including a court-imposed injunction to conduct studies.

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

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

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

***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.

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 healthcare providers; 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, Massachusetts, Minnesota, 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 providers and/or impose reporting and disclosure requirements upon pharmaceutical companies pertaining to drug pricing, payments and/or costs associated with pharmaceutical marketing, advertising and other 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 continue to evolve, 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 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.

***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, 2012, we had approximately \$333.2 million in cash, cash equivalents, short-term and long-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 fewer resources to marketing Ampyra or our other commercial products.

***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.***

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 validly exercise its right to cause us to repurchase the right we assigned to it, we may have to use funds that we planned to use for other purposes. 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.

On August 3, 2012, we received a letter from PRF alleging that we breached specified covenants and representations in the PRF agreement and purporting to exercise the put option. The letter also includes an allegation that PRF has suffered injuries beyond what is covered by their purported exercise of the put option, although it does not specify or quantify those injuries. We believe that the allegations are without merit and that the put option has not been validly exercised. We cannot predict whether these allegations will lead to any legal actions or, if they are initiated, the outcome or impact on us of any such legal actions.

***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, buprenorphine, sodium pentobarbital, ether, acetonitrile, hexanes, chloroform, xylene, dehydrated alcohol, methanol, ethyl alcohol, isopropanol and formaldehyde. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. If we fail to comply with environmental regulations,

we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any substantial liability could exceed our resources.

We currently maintain a general liability insurance policy that has a \$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 \$30 million of liability in excess of the general liability policy's \$2 million limit. This amount of insurance coverage may not be adequate to cover all liabilities or defense costs we might incur. In addition, the cost of compliance with environmental and health and safety regulations may be substantial.

### **Risks related to our 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 research 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.

There are seven major families of subject matter in our patent portfolio, including Ampyra, Zanaflex Capsules, neuregulins, remyelinating antibodies, chondroitinase, AC105, and Diazepam Nasal Spray, comprised of both our own and in-licensed patents and patent applications. Our intellectual property also includes copyrights, confidential and trade secret information and a portfolio of trademarks. 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 harm us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.

***If third parties successfully claim that we infringe their patents or proprietary rights, our ability to continue to develop and successfully commercialize our product candidates could be delayed or prevented.***

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.

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 Alkermes 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 Alkermes in markets outside the U.S. if we fail to launch a product within 180 days of NDA-equivalent approvals and receipt of other needed regulatory approvals in those countries. Alkermes 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;
- 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 15, 2013, we had outstanding 40,280,070 shares of voting common stock. Also, options to acquire 5,703,039 shares of common stock were outstanding as of February 15, 2013, exercisable at an average exercise price of \$22.36 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, 2012, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 41% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval or mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

- Our board of directors has the right to elect directors to fill a vacancy created by the expansion of the

board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors.

- Our board of directors may issue, without stockholder approval, shares of preferred stock with rights, preferences and privileges determined by the board of directors. The ability to authorize and issue preferred stock with voting or other rights or preferences makes it possible for our board of directors to issue preferred stock with super voting, special approval, dividend or other rights or preferences on a discriminatory basis that could impede the success of any attempt to acquire us.
- Our board of directors is divided into three classes, each with staggered three-year terms. As a result, only one class of directors will be elected at each annual meeting of stockholders, and each of the two other classes of directors will continue to serve for the remainder of their respective three-year terms, limiting the ability of stockholders to reconstitute the board of directors.
- The vote of the holders of 75% of the outstanding shares of our common stock is required in order to take certain actions, including amendment of our bylaws, removal of directors for cause and certain amendments to our certificate of incorporation.

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

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

We have not paid cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. The success of your investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares.

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

Not applicable.

#### **Item 2. Properties.**

Until the end of June 2012, our principal executive offices were located in an approximately 52,785 square foot facility in Hawthorne, NY. The annual rent for this facility was approximately \$1.1 million. The lease for this facility was previously scheduled to expire in December 2012. However, in connection with our entering into a lease for a new headquarters facility, described below, we exercised our right to accelerate the termination date to June 2012.

In June 2011, we entered into a 15 year lease for an aggregate of approximately 138,000 square feet of office and laboratory space in Ardsley, New York. In July 2012, we relocated our corporate headquarters, and all employees based at our Hawthorne, NY location, to the Ardsley facility. We have grown substantially over the last several years, and the new facility provides state-of-the art office and laboratory space that will accommodate our current needs and allow for future growth. We have options to extend the term of the lease for three additional five-year periods, and we have an option to terminate the lease after 10 years subject to payment of an early termination fee. Also, we have rights to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. Our extension, early termination, and expansion rights are subject to

specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that we not be in default under the lease.

The Ardsley lease provides for monthly payments of rent during the term. These payments consist of base rent, which takes into account the costs of the facility improvements being funded by the facility owner prior to our occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges. The base rent is initially \$3.4 million per year, and is subject to a 2.5% annual increase.

### **Item 3. Legal Proceedings.**

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc., advising that it had submitted an Abbreviated New Drug Application, or 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 in the U.S. District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557. In September 2011, the Court ruled against us and, following our appeal, in June 2012 the U.S. Court of Appeals for the Federal Circuit affirmed the decision. We did not seek any further appeals of the decision. On September 6, 2011, we filed a citizen petition with the FDA requesting that the FDA not approve Apotex's ANDA because of public-safety concerns about Apotex's proposed drug. On December 2, 2011, Apotex filed suit against us in the U.S. District Court for the Southern District of New York. In that suit, Apotex alleged, among other claims, that we engaged in anticompetitive behavior and false advertising in connection with the development and marketing of Zanaflex Capsules, including that the citizen petition we filed with the FDA delayed FDA approval of Apotex's generic tizanidine capsules. On January 26, 2012, we moved to dismiss or stay Apotex's suit. On February 3, 2012, the FDA denied the citizen petition that we filed and approved Apotex's ANDA for a generic version of Zanaflex Capsules. On February 21, 2012, Apotex filed an amended complaint that incorporated the FDA action, but otherwise made allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits, recovery of litigation costs, and injunctive relief. Following our filing of a motion to dismiss the amended complaint, in 2013 the Court dismissed six of the seven counts in the amended complaint, including all of the antitrust claims, leaving only a claim under the Lanham Act relating to alleged product promotional activities. We have filed a motion for reconsideration of the decision regarding the Lanham Act claim. The Company intends to defend itself vigorously in the litigation.

### **Item 4. Mine Safety Disclosures.**

Not applicable.

## PART II

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

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

	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended December 31, 2012</b>		
Fourth Quarter .....	\$27.36	\$22.37
Third Quarter .....	\$26.65	\$21.33
Second Quarter .....	\$27.17	\$21.04
First Quarter .....	\$27.74	\$23.99
	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended December 31, 2011</b>		
Fourth Quarter .....	\$24.08	\$18.36
Third Quarter .....	\$32.66	\$19.77
Second Quarter .....	\$33.48	\$20.90
First Quarter .....	\$31.67	\$20.43

Registrar and Transfer Company is the transfer agent and registrar for our common stock. As of February 15, 2013, we had approximately 27 registered holders of record of our common stock.

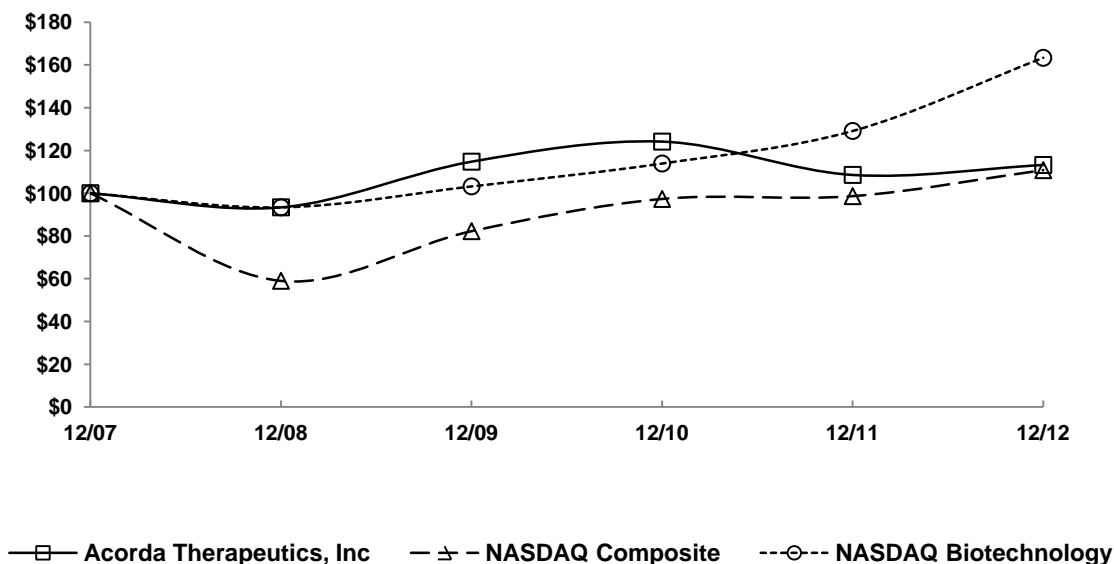
#### Stock Price Performance Graph

The following graph compares the cumulative five-year 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 December 31, 2007 and its relative performance is tracked through December 31, 2012.



## COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among Acorda Therapeutics, Inc, the NASDAQ Composite Index,  
and the NASDAQ Biotechnology Index



\*\$100 invested on 12/31/07 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.

	12/07	12/08	12/09	12/10	12/11	12/12
Acorda Therapeutics, Inc	100.00	93.40	114.75	124.13	108.56	113.21
NASDAQ Composite	100.00	59.03	82.25	97.32	98.63	110.78
NASDAQ Biotechnology	100.00	93.40	103.19	113.89	129.12	163.33

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

### Dividend Policy

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

### Issuer Purchases of Equity Securities

Acorda did not repurchase any shares of its Common Stock during the fiscal year ended December 31, 2012. Acorda has not announced any plans or programs for the repurchase of its Common Stock.

## Item 6. Selected Financial Data.

The following unaudited selected consolidated financial data for each of the five years in the period ended December 31, 2012 are derived from our audited consolidated financial statements. These data should be read in conjunction with our audited consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K and with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Item 7 below.

	Year Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Total net revenues	\$305,814	\$292,237	\$191,005	\$54,673	\$47,827
Costs and expenses:					
Cost of sales	57,007	64,183	35,518	11,059	11,355
Cost of milestone and license revenue	634	2,384	660	330	—
Research and development	53,881	42,108	30,600	34,611	36,604
Selling, general and administrative	168,690	148,508	132,657	89,930	73,307
Total operating expenses	<u>280,212</u>	<u>257,183</u>	<u>199,435</u>	<u>135,930</u>	<u>121,266</u>
Operating income (loss)	25,602	35,054	(8,430)	(81,257)	(73,439)
Other expense:					
Interest and amortization of debt discount expense	(1,880)	(3,570)	(3,922)	(4,415)	(5,591)
Interest income	552	552	575	1,750	4,682
Other income (expense)	(6)	(18)	8	(18)	8
Total other expense	<u>(1,334)</u>	<u>(3,036)</u>	<u>(3,339)</u>	<u>(2,683)</u>	<u>(901)</u>
Income (loss) before income taxes	24,268	32,018	(11,769)	(83,940)	(74,340)
Benefit (provision) for income taxes	130,690	(1,413)	—	—	—
Net income (loss)	<u>\$154,958</u>	<u>\$30,605</u>	<u>\$(11,769)</u>	<u>\$(83,940)</u>	<u>\$(74,340)</u>
Net income (loss) per share —basic	\$3.93	\$0.78	\$(0.31)	\$(2.22)	\$(2.19)
Net income (loss) per share —diluted	\$3.84	\$0.76	\$(0.31)	\$(2.22)	\$(2.19)
Weighted average shares of common stock outstanding used in computing net income (loss) per share —basic	39,459	39,000	38,355	37,735	33,939
Weighted average shares of common stock outstanding used in computing net income (loss) per share —diluted	40,332	40,064	38,355	37,735	33,939

As of December 31,

	2012	2011	2010 (in thousands)	2009	2008
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$41,876	\$57,954	\$34,641	\$47,314	\$29,613
Investments	291,312	237,953	205,389	224,778	216,435
Working capital	234,192	273,599	217,274	220,380	207,445
Deferred tax asset	136,727	—	—	—	—
Total assets	565,332	379,488	342,101	319,471	281,501
Deferred product revenue—Zanaflex Capsules	29,275	30,599	31,296	30,704	24,303
Current portion of deferred license revenue	9,057	9,057	9,429	9,429	—
Non-current portion of deferred license revenue	68,685	77,742	86,429	95,857	—
Current portion of revenue interest liability—PRF transaction	1,134	1,001	1,297	6,179	6,181
Put/call option liability—PRF transaction	329	1,030	391	638	338
Non-current portion of revenue interest liability—PRF transaction	1,111	1,898	3,586	5,631	12,498
Long term convertible notes payable	4,244	5,230	6,186	7,112	6,905
Total stockholders' equity	385,921	205,209	151,261	137,333	207,157

## 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

We are a commercial-stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis, or MS, spinal cord injury, or SCI, and other disorders of the nervous system.

### *Ampyra*

#### *General*

Ampyra was approved by the FDA in January 2010 for the improvement of walking in people with MS. 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 United States in March 2010. Net revenue for Ampyra was \$266.1 million for the year ended December 31, 2012 and \$210.5 million for the year ended December 31, 2011. More than 73,000 new patients have tried Ampyra therapy since the 2010 launch.

Ampyra is marketed in the United States through our own specialty sales force and commercial infrastructure. We currently have approximately 90 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Managed Markets account managers who provide information and assistance to

payers and physicians on Ampyra, and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of the Company's strategic initiatives.

Ampyra is distributed in the United States exclusively through: a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which is the exclusive specialty pharmacy distributor for Ampyra to the U.S. Department of Veterans Affairs, or VA. All of these customers are contractually obligated to hold no more than an agreed number of days of inventory, ranging from between 10 to 30 days.

We have contracted with a third party organization with extensive experience in coordinating patient benefits to run Ampyra Patient Support Services, or APSS, a dedicated resource that coordinates the prescription process among healthcare providers, people with MS, and insurance carriers. Processing of most incoming requests for prescriptions by APSS begins within 24 hours of receipt. Patients will experience a range of times to receive their first shipment based on the processing time for insurance requirements. As with any prescription product, patients who are members of benefit plans that have restrictive prior authorizations may experience delays in receiving their prescription.

Three of the largest national health plans in the U.S. – Aetna, United Healthcare and Cigna – have listed Ampyra in the lowest branded co-pay tier of their commercial preferred drug list or formulary. This formulary status at all three health plans was renewed in 2012. Approximately 75% of commercially insured individuals in the U.S. continue to have no or limited prior authorizations, or PA's, 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 a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by commercial health plans.

#### *License and Collaboration Agreement with Biogen Idec*

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec International GmbH, or Biogen Idec, under a license and collaboration agreement that we entered into in June 2009. Fampyra is commercially available in a number of European Union countries and in Canada, Australia, New Zealand and Israel, and Biogen Idec anticipates making Fampyra commercially available in additional markets in 2013, as well as filing for regulatory approval in other countries. We received a \$25 million milestone payment from Biogen Idec in 2011, which was triggered by Biogen Idec's receipt of conditional approval from the European Commission for Fampyra. The next expected milestone payment would be \$15 million, due when ex-U.S. net sales exceed \$100 million over four consecutive quarters.

#### *Ampyra Development Programs*

We believe there may be potential for Ampyra to be applied to other indications within MS and also in other neurological conditions. For example, in December 2011, we initiated a Phase 2 proof-of-concept clinical study of dalfampridine in adults with cerebral palsy, or CP. The first phase of this proof-of-concept study, which has been completed, was a single-dose phase primarily to evaluate safety and tolerability prior to proceeding to a multi-dose cohort. This 10-person, single dose phase of the study detected no safety signals that would prevent additional study of the drug in the treatment of CP. We completed enrollment for the second phase, a multi-dose study including 20 adults with CP, to evaluate both safety and efficacy. We expect to announce topline results of this phase of the study in the second quarter of 2013. Also, in June 2012 we enrolled the first patient in a Phase 2 proof-of-concept trial of dalfampridine in post-stroke deficits, and we expect to announce topline study results in the second quarter of 2013. This study is exploring the use of dalfampridine in patients who have experienced a stroke and who have stabilized with chronic neurologic deficits, which may include walking impairment and upper extremity function impairment, such as arm weakness. Over the first six months following a stroke, patients typically show some degree of spontaneous recovery of function, which may be enhanced by rehabilitation and physical therapy. This trial is targeting motor impairments that remain after such recovery. We

also are providing grants for investigator-initiated studies looking for potential benefits on a range of functional deficits in MS and other neurological disorders.

We are also working with external partners on a once-daily formulation of Ampyra.

#### *Ampyra Patent Update*

We have two issued patents listed in the Orange Book for Ampyra, as follows:

- The first is U.S. Patent No. US 8,007,826 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the United States Patent and Trademark Office, or USPTO, this patent will extend into 2027.
- The second is U.S. Patent No. 5,540,938 (“the ‘938 patent”), the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In October 2012, the USPTO determined that the ‘938 patent is entitled to a full five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the ‘938 patent would expire in 2018. We have an exclusive license to this patent from Alkermes (originally with Elan, but transferred to Alkermes as part of its acquisition of Elan’s Drug Technologies business).

On January 15, 2013, the USPTO issued U.S. Patent No. 8,354,437 (U.S. Patent Application No. 11/102,559) with claims relating to methods to improve walking, walking speed, lower extremity muscle tone and lower extremity muscle strength in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. In 2011, the European Patent Office, or EPO, granted the counterpart European patent with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging this granted European patent. We intend to vigorously defend the European patent, although the outcome of opposition proceedings is unpredictable.

#### *Dalfampridine-ER 5 mg. Post-Approval Commitment Study*

In August 2012, we announced results from a post-approval commitment study examining the use of a 5mg dose of dalfampridine-ER to improve walking in people with MS. The study failed to confirm efficacy of the 5mg dose. We believe that this study, together with Ampyra registration studies, continue to show that 10mg twice daily is the appropriate, safe, and effective dose. The study results were provided to the FDA and will be presented in peer-reviewed scientific forums.

#### ***Zanaflex***

Zanaflex Capsules and Zanaflex tablets are FDA-approved as short-acting drugs for the management of spasticity, a symptom of many central nervous system, or CNS, disorders, including MS and SCI. These products contain tizanidine hydrochloride, one of the two leading drugs used to treat spasticity. We launched Zanaflex Capsules in April 2005 as part of our strategy to build a commercial platform for the potential market launch of Ampyra. Combined net revenue of Zanaflex Capsules and Zanaflex tablets was \$13.2 million for the year ended December 31, 2012 and \$45.8 million for the year ended December 31, 2011. In February 2012, Apotex commercially launched a generic version of tizanidine hydrochloride capsules, and we also launched our own authorized generic version, which is being marketed by Watson Pharma (a subsidiary of Actavis). The commercial launch of generic tizanidine hydrochloride capsules has caused a significant decline in net revenue of Zanaflex Capsules, and the launch of these generic versions and the potential launch of other generic versions is expected to cause the Company’s net revenue from Zanaflex Capsules to decline further in 2013 and beyond. In May 2012, we received a Paragraph IV Certification Notice from Mylan Laboratories Limited advising us that

Mylan Laboratories has filed an Abbreviated New Drug Application for generic versions of the three dosage strengths of Zanaflex Capsules. The FDA approved Mylan's ANDA on November 9, 2012. Based upon our request, the FDA delisted from the Orange Book the patent against which Mylan Laboratories filed the Paragraph IV Certification Notice.

### *Research & Development Programs*

Our lead research and development programs include three distinct therapeutic approaches to restoring neurologic and cardiac function and a fourth program, initiated in 2011, to develop an acute treatment for neurological trauma. We believe that these programs have broad applicability and have the potential to be first-in-class therapies. While our existing programs have been focused on MS and SCI, we believe they may be applicable across a number of CNS disorders, including stroke and traumatic brain injury, or TBI, because many of the mechanisms of tissue damage and repair are similar. In addition, we believe that some of our research and development programs may have applicability beyond the nervous system, including in the field of cardiology.

#### *Glial Growth Factor 2*

We have completed our GGF2 Phase 1 clinical trial in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. We have completed analysis of the three-month data, and we plan to present findings in a platform presentation at the American College of Cardiology (ACC) annual meeting in March 2013. We will also discuss the data with the FDA before proceeding to a multiple dose study. 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 independently or to enter into a partnership, most likely with a cardiovascular-focused company.

#### *Remyelinating Antibodies*

We have an open IND application for one of the remyelinating antibodies, rHIgM22, for the treatment of MS and plan to initiate enrollment in a Phase 1 safety study in MS patients in the first half of 2013. We had previously announced problems with a bioactivity assay that had delayed the filing but we successfully completed the qualification of the bioactivity assay in the second quarter of 2012. In preparation for an IND filing, we worked with a contract manufacturer to complete the scale-up manufacturing and purification processes and completed formal preclinical safety and toxicity studies.

#### *Chondroitinase Program*

We are continuing research on the potential use of chondroitinases for the treatment of injuries to the brain and spinal cord, as well as other neurotraumatic indications. The chondroitinase program is in the research and translational development phase and has not yet entered formal preclinical development.

#### *AC105*

In June 2011, we entered into a License Agreement with Medtronic, Inc. and one of its affiliates, pursuant to which we acquired worldwide development and commercialization rights to certain formulations of magnesium with a polymer such as polyethylene glycol (which we refer to as AC105). Pursuant to the License Agreement, we paid Medtronic an upfront fee of \$3 million and are obligated to pay up to an additional \$32 million upon the achievement of specified regulatory and development milestones. If we commercialize AC105, we will also be obligated to pay a single-digit royalty on sales. We plan to study AC105 as an acute treatment for patients who have suffered neurological trauma, such as SCI and TBI. We submitted a Phase 2 clinical trial protocol for AC105 for acute treatment of SCI to the FDA for review. The protocol has been reviewed by the FDA, and we are preparing to initiate the trial in the first half of 2013.

## *Corporate Updates*

In July 2012, we relocated our corporate headquarters from Hawthorne, New York, to a facility in Ardsley, New York consisting of an aggregate of approximately 138,000 square feet of office and laboratory space. Base rent is initially \$3.4 million per year, subject to a 2.5% annual increase. Our lease of the facility has a 15 year term, but we have options to extend the lease term for three additional five-year periods, and we may terminate the lease after 10 years, subject to payment of an early termination fee. We also have the right to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location.

In October 2012, we named Jane Wasman as President, International. Ms. Wasman most recently has served as the Company's Chief, Strategic Development and General Counsel. In her new role, Ms. Wasman will lead our efforts to identify and launch inlicensing and commercial opportunities outside the United States. She will also be responsible for managing our collaboration with Biogen Idec in their international development and commercialization of Fampyra (prolonged-release fampridine tablets). Ms. Wasman will also continue to lead our global strategic development and will retain the title of General Counsel and Corporate Secretary.

## **Outlook for 2013**

### *Financial Guidance for 2013*

We are providing the following guidance with respect to our 2013 financial performance:

- We expect 2013 net revenue from the sale of Ampyra to range from \$285 million to \$315 million.
- We expect Zanaflex (tizanidine hydrochloride) and ex-U.S. Fampyra 2013 revenue to be \$25 million, which includes sales of branded Zanaflex products, royalties from ex-U.S. Fampyra and authorized generic tizanidine hydrochloride capsules sales, and \$9.1 million in amortized licensing revenue from the \$110 million payment we received from Biogen Idec in 2009 for Fampyra ex-U.S. development and commercialization rights.
- Research and development expenses in 2013 are expected to range from \$60 million to \$70 million, excluding share-based compensation charges. Research and development expenses in 2013 related to Ampyra include proof-of-concept studies in CP and post-stroke deficits, and sponsorship of investigator-initiated studies. Additional expenses include clinical trials for AC105 and rHlgM22, continued development of Diazepam Nasal Spray and GGF2, as well as ongoing preclinical studies. A substantial portion of the increase in research and development in 2013 over 2012 is related to Diazepam Nasal Spray expenses.
- Selling, general and administrative expenses in 2013 are expected to range from \$170 million to \$180 million, excluding share-based compensation charges. SG&A expenses will be primarily driven by commercial and administrative costs related to Ampyra. The majority of the increase in SG&A in 2013 over 2012 is related to Diazepam Nasal Spray expenses.
- We expect to be cash flow positive in 2013.

The range of SG&A and R&D expenditures for 2013 are non-GAAP financial measures because they exclude share-based compensation charges. 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, when viewed in conjunction with actual GAAP results, provides investors with a more meaningful understanding of our projected operating performance because they exclude non-cash charges that are substantially dependent on changes in the market price of our common stock. We believe that non-GAAP financial measures that exclude share-based compensation charges help indicate underlying trends in our business, and are important in comparing current results with prior period results and understanding expected

operating performance. Also, our management uses non-GAAP financial measures that exclude share-based compensation charges to establish budgets and operational goals, and to manage our business and to evaluate its performance.

### ***Key 2013 Initiatives and Expected Developments***

Our key initiatives and expected developments during 2013 are as follows:

#### *Biogen Idec*

Fampyra is commercially available in a number of European Union countries and in Canada, Australia, New Zealand and Israel, and Biogen Idec anticipates making Fampyra commercially available in additional markets in 2013, as well as filing for regulatory approval in other countries.

#### *Targeted Development Milestones*

Our goals with respect to our development pipeline in 2013 are as follows:

- Pending additional clinical and manufacturing data, we plan to submit a 505(b)(2)-type New Drug Application for Diazepam Nasal Spray to the FDA in 2013, with potential FDA approval and commercial launch in 2014. We anticipate that our current infrastructure can support sales and marketing of this product, and market planning is underway.
- We completed enrollment for the second phase of our Phase 2 proof-of-concept clinical trial of dalfampridine in adults with CP. This phase is a multi-dose study including 20 adults with CP, to evaluate both safety and efficacy. We expect to announce topline results of this phase of the study in the second quarter of 2013.
- We have an open IND for rHIgM22 for the treatment of MS and plan to initiate enrollment in a Phase 1 safety study in MS patients in the first half of 2013.
- We have completed analysis of the three-month data from our Phase 1 clinical trial of GGF2 in heart failure patients, and we plan to present findings in a platform presentation at the American College of Cardiology (ACC) annual meeting in March 2013.
- A Phase 2 proof-of-concept clinical trial of dalfampridine in patients with post stroke deficits began in the second quarter of 2012. We expect to announce topline study results in the second quarter of 2013.
- We submitted a Phase 2 clinical trial protocol for AC105 for acute treatment of SCI to the FDA for review. The protocol has been reviewed by the FDA, and we are preparing to initiate the trial in the first half of 2013.
- Funding of investigator-initiated studies of Ampyra in MS, focused on a range of functional deficits in MS and other neurological disorders, will be ongoing in 2013.



## Results of Operations

### *Year Ended December 31, 2012 Compared to Year Ended December 31, 2011*

#### Net Revenue

##### *Ampyra*

We recognize product sales of Ampyra following shipment of product to our network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra to these customers of \$266.1 million and \$210.5 million for the years ended December 31, 2012 and 2011, respectively. This net revenue reflected a 15% increase in our sale price for Ampyra effective January 3, 2012. The net revenue increase was comprised of net volume increases of \$20.6 million and price increases and discount and allowance adjustments of \$35.0 million. Net revenue from sales of Ampyra increased for the year ended December 31, 2012 compared to the year ended December 31, 2011 due to our price increase and greater demand we believe due to, in part, the success of certain marketing programs such as our First Step program. Effective January 2, 2013, we increased our sale price to our customers by 10.75%.

Discounts and allowances which are included as an offset in net revenue consist of allowances for customer credits, including estimated chargebacks, rebates, discounts, and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. Adjustments are recorded for estimated chargebacks, rebates, and discounts. Discounts and allowances also consist of discounts provided to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the “donut hole”). Payment of coverage gap discounts is required under the Affordable Care Act, the health care reform legislation enacted in 2010. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future.

##### *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 also recognize product sales on the transfer price of product sold for an authorized generic of Zanaflex Capsules during the year ended December 31, 2012. We recognized net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$13.2 million for the year ended December 31, 2012, as compared to \$45.8 million for the year ended December 31, 2011. The decrease was primarily due to the commercial launch of generic versions of tizanidine hydrochloride capsules in February 2012. Net product revenues also include \$3.1 million, which represents the sale of our Zanaflex Capsules authorized generic product to Watson Pharma (a subsidiary of Actavis) for the year ended December 31, 2012. Generic competition has caused a significant decline in net revenue of Zanaflex Capsules and is expected to cause the Company’s net revenue from Zanaflex Capsules to decline further in 2013 and beyond. The decrease in net revenues was also the result of a disproportionate decrease in discounts and allowances due to the mix of customers continuing to purchase our product. These customers receive higher levels of rebates and allowances.

Discounts and allowances, which are included as an offset in net revenue, consist of allowances for customer credits, including estimated chargebacks, rebates, and discounts. Adjustments are recorded for estimated chargebacks, rebates, and discounts.

#### Healthcare Reform

In March 2010, healthcare reform legislation was enacted in the U.S. This legislation contained several provisions that affected our business. Beginning in 2011, the new law required 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”). These charges are included in our discounts and allowances.

In June 2012, the United States Supreme Court upheld the constitutionality of the 2010 Patient Protection and Affordable Care Act's mandate to purchase health insurance but rejected specific funding provisions that incentivized states to expand their current Medicaid programs. As a result of this ruling, we currently expect implementation of most of the major provisions of the Act to continue. Changes to the Affordable Care Act, or other federal legislation regarding health care access, financing, or delivery and other actions taken by individual states concerning the possible expansion of Medicaid could impact our financial position or results of operations in the future.

#### License Revenue

We recognized \$9.1 million in amortized license revenue for the years ended December 31, 2012 and 2011, respectively, related to the \$110.0 million received from Biogen Idec in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

#### Royalty Revenue

We recognized \$7.1 million and \$1.9 million in royalty revenue for the years ended December 31, 2012 and 2011, respectively related to ex-U.S. sales of Fampyra by Biogen Idec. In 2011, the German government implemented new legislation to manage pricing related to new drug products introduced within the German market through a review of each product's comparative efficacy. Biogen Idec launched Fampyra in Germany in August 2011. During the three-month period ended June 30, 2012, the government agency completed its comparative efficacy assessment of Fampyra indicating a range of pricing below Biogen Idec's initial launch price, which was unregulated for the first 12 months after launch consistent with German law. The Company recognized royalty revenue during a portion of 2012 based on the lowest point of the initially indicated German pricing authority range. The Company will recognize royalty revenue at the negotiated fixed price effective upon the signing of Biogen Idec's pricing agreement in 2013, which is expected to be finalized in the first quarter of 2013.

We recognized \$7.2 million in royalty revenue for the year ended December 31, 2012 related to the authorized generic sale of Zanaflex Capsules which started in February 2012.

#### Milestone Revenue

We recognized \$25.0 million in milestone revenue during the year ended December 31, 2011 as part of our ex-U.S. license agreement with Biogen Idec. In July 2011, Biogen Idec reached an agreement milestone when they received conditional approval from the European Commission for Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). For revenue recognition purposes, the milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in the three-month period ended September 30, 2011. We did not reach any milestones during the year ended December 31, 2012.

#### Cost of Sales

##### *Ampyra*

We recorded cost of sales of \$51.8 million for the year ended December 31, 2012 as compared to \$41.9 million for the year ended December 31, 2011. Cost of sales for the year ended December 31, 2012 consisted primarily of \$44.7 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2012 also consisted of \$6.3 million in royalty fees based on net sales, \$590,000 in amortization of intangible assets, and \$178,000 in period costs related to freight and stability testing.

Cost of sales for the year ended December 31, 2011 consisted primarily of \$36.3 million in inventory

costs related to recognized revenues. Cost of sales for the year ended December 31, 2011 also consisted of \$4.4 million in royalty fees based on net sales, \$1.1 million in amortization of intangible assets, and \$180,000 in period costs related to packaging, freight and stability testing.

### *Zanaflex*

We recorded cost of sales of \$2.2 million for the year ended December 31, 2012 as compared to \$22.3 million for the year ended December 31, 2011. Cost of sales for the year ended December 31, 2012 consisted of \$1.4 million in inventory costs primarily related to recognized revenues, \$697,000 in royalty fees based on net product shipments, and \$83,000 in period costs related to packaging, freight and stability testing. Cost of sales also includes \$3.1 million, which represents the cost of Zanaflex Capsules authorized generic product sold for the year ended December 31, 2012.

Cost of sales for the year ended December 31, 2011 consisted of \$14.0 million in amortization of intangibles assets including an asset impairment charge of \$13.0 million due to the Apotex patent litigation trial court decision. Cost of sales for the year ended December 31, 2011 also consisted of \$5.1 million in inventory costs consisting of a charge of \$4.1 million related to recognized revenues and an inventory reserve charge of \$1.0 million, \$3.0 million in royalty fees based on net product shipments, and \$192,000 in period costs related to freight and stability testing.

### *Cost of Milestone & License Revenue*

We recorded cost of license revenue of \$634,000 for the years ended December 31, 2012 and 2011, respectively. Cost of license revenue represents the recognition of a portion of the deferred \$7.7 million paid to Alkermes in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement. We recorded cost of milestone revenue of \$1.8 million for the year ended December 31, 2011. Cost of milestone revenue represents a 7% payment to Alkermes on the \$25.0 million milestone revenue received from Biogen Idec during the year ended December 31, 2011 in accordance with our worldwide license and supply agreement with Alkermes. For revenue recognition purposes, the related milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in this period. The corresponding cost of milestone revenue was also recognized in its entirety during the year ended December 31, 2011. We did not record milestone revenue or a corresponding cost of milestone revenue for the year ended December 31, 2012.

### *Research and Development*

Research and development expenses for the year ended December 31, 2012 were \$53.9 million as compared to \$42.1 million for the year ended December 31, 2011, an increase of approximately \$11.8 million, or 28%. The increase was primarily due to a \$6.6 million net charge for Neuronex expenses representing the \$2.0 million upfront payment, payments of \$1.5 million for research funding per the terms of the agreement we entered into with Neuronex, and an expense of \$6.8 million, including payments of \$6.5 million, representing closing consideration for purchasing Neuronex during the fourth quarter of 2012 less net assets acquired of \$3.7 million which were primarily the taxable amount of the Neuronex net operating loss carryforwards.

The increase was also due to an increase in overall research and development staff, compensation and related expenses of \$4.7 million to support the various research and development initiatives. The increase was also due to an increase of \$1.4 million in our life cycle management program for Ampyra, a \$1.6 million increase in Phase 1 GGF2 preclinical and clinical trial expenses, a \$1.3 million increase in technical operations costs associated with our various pipeline initiatives, an increase of \$1.2 million related to our AC105 research, and an increase of \$381,000 in research costs related to our chondroitinase program. The increases in research and development expenses for the year ended December 31, 2012 were partially offset by a decrease attributable to the Medtronic AC105 license expense of \$3.0 million during 2011 and a decrease of \$2.4 million in preclinical expenses for the remyelinating antibodies program (rHlgM22).

### Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2012 were \$105.3 million compared to \$86.9 million for the year ended December 31, 2011, an increase of approximately \$18.4 million, or 21%. The increase was attributable to an increase in overall marketing, selling, distribution, and market research expenses for Ampyra of \$13.3 million. The increase was also related to an increase in overall compensation, benefits, and other selling expenses attributable to Ampyra of \$7.0 million. These increases were partially offset by a decrease in selling, marketing, and distribution expenses for Zanaflex Capsules of \$1.9 million due to the introduction of generic competition in the marketplace.

General and administrative expenses for the year ended December 31, 2012 were \$63.4 million compared to \$61.6 million for the year ended December 31, 2011, an increase of approximately \$1.8 million, or 3%. This increase was primarily related to an increase in staff, compensation and related expenses to support the overall growth of the organization of \$7.1 million and an increase in safety and surveillance expenses of \$1.9 million. The overall increase in general and administrative expenses was partially offset by a decrease in expenses related to the Zanaflex Capsule patent infringement litigation of \$4.1 million, a decrease due to a gain in our put/call liability related to the PRF revenue interest agreement recorded in 2011 due to the Zanaflex patent infringement trial court decision of \$1.3 million, and a decrease in post-approval Ampyra technical work of \$1.1 million.

### Other Expense

Other expense was \$1.3 million for the year ended December 31, 2012 compared to \$3.0 million for the year ended December 31, 2011, a decrease of approximately \$1.7 million, or 56%. The decrease was due to a decrease in interest expense of \$1.7 million primarily related to the PRF revenue interest agreement due to a decrease in Zanaflex sales.

### Benefit (Provision) for Income Taxes

We recorded a \$130.7 million benefit for income taxes for the year ended December 31, 2012 as compared to a \$1.4 million provision for income taxes for the year ended December 31, 2011. The benefit for 2012 was primarily related to the release of our valuation allowance against our net deferred tax assets because we believe it is more likely than not that we will realize a benefit from these assets in the future. This was partially offset by a provision of certain state and local income taxes. The provision for 2011 was only comprised of the Federal Alternate Minimum Tax (AMT) and gross receipts taxes for certain states. We currently do not anticipate income tax benefits of this magnitude in the foreseeable future. We expect that future periods will include taxes at a normalized rate relative to the federal and state statutory rates as compared to the effective rate for 2012 which was primarily driven by the benefit of the valuation allowance release.

On a periodic basis, we evaluate our ability to realize our deferred tax assets net of deferred tax liabilities and adjust such amounts in light of changing facts and circumstances, including but not limited to our level of past and future taxable income, the current and future expected utilization of tax benefit carryforwards, and any regulatory or legislative actions by relevant authorities with respect to the Ampyra patents. We consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is required to reduce the net deferred tax assets to the amount that is more likely than not to be realized in future periods.

### *Positive:*

- The Company is no longer in a three-year cumulative pre-tax loss position. According to the guidance this is a significant factor to weigh heavily when looking at positive and negative evidence.
- We achieved our second consecutive profitable year with a 2012 pre-tax income of \$24.3 million.
- Our Ampyra U.S. Patent No. US 8,007,826 patent extends into 2027.
- Our projections show that the deferred tax assets for our net operating loss carryforwards and research and development tax credits will be realized prior to their expiration.

*Negative:*

- There is an inherent risk in the ability to meet budgeted forecasts.
- If we were to experience a future 382 ownership change, the ability to utilize net operating losses may be limited, depending on the market value of the company at the time of any such ownership change.
- We may acquire other compounds in the future, which may generate losses.

We will continue to evaluate the realizability of our deferred tax assets and liabilities on a periodic basis, and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities and the progress of ongoing tax audits, if any.

***Year Ended December 31, 2011 Compared to Year Ended December 31, 2010***

*Net Revenue*

*Ampyra*

We recognize product sales of Ampyra following shipment of product to our network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra to these customers of \$210.5 million and \$133.1 million for the years ended December 31, 2011 and 2010, respectively. This net revenue reflected a 7.5% increase in our sale price for Ampyra effective March 4, 2011. The net revenue increase was comprised of net volume increases of \$69.0 million and price increases and discount and allowance adjustments of \$8.4 million. Effective January 3, 2012, we increased our sale price to our customers by 15%.

Discounts and allowances which are included as an offset in net revenue consist of allowances for customer credits, including estimated chargebacks, rebates, discounts and returns. Discounts and allowances are recorded following shipment of Ampyra tablets to our network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. Adjustments are recorded for estimated chargebacks, rebates, and discounts. For the year ended December 31, 2011 discounts and allowances also consisted of discounts provided to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the “donut hole”). Payment of coverage gap discounts is required under the Affordable Care Act, the health care reform legislation enacted in 2010. Discounts and allowances may increase as a percentage of sales as we enter into managed care contracts in the future and we incur costs incurred related to new Healthcare Reform Medicare rebates described under the “Healthcare Reform” header below.

*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 net revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$45.8 million for the year ended December 31, 2011, as compared to \$48.5 million for the year ended December 31, 2010. 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 14% price increase for Zanaflex Capsules effective October 1, 2011.

Discounts and allowances, which are included as an offset in net revenue, consist of allowances for customer credits, including estimated chargebacks, rebates, and discounts. Adjustments are recorded for estimated chargebacks, rebates, and discounts.

### Healthcare Reform

In March 2010, healthcare reform legislation was enacted in the U.S. This legislation contained several provisions that affected our business. Beginning in 2011, the new law required 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”). These charges are included in our discounts and allowances.

Also, beginning in 2011, the new healthcare reform legislation requires certain drug manufactures to pay a new excise drug fee. It is based on certain government sales of certain branded prescription drug sales in 2009. This fee was not material to our 2011 financial statements.

### Milestone Revenue

The Company recognized \$25.0 million in milestone revenue for the three-month period ended September 30, 2011 as part of its ex-U.S. license agreement with Biogen Idec. In July 2011, Biogen Idec reached an agreement milestone when they received conditional approval from the European Commission for Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). For revenue recognition purposes, the milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in this period. Substantive uncertainty existed at the inception of the arrangement as to whether the milestone would be achieved because of the numerous variables, such as the high rate of failure inherent in the research and development of new products and the uncertainty involved with obtaining regulatory approval. Biogen Idec leveraged Acorda’s U.S. Ampyra study results that contributed to the regulatory approval process. Therefore, the milestone was achieved based in part on Acorda’s past performance. The milestone was also reasonable relative to all deliverable and payment terms of the collaboration arrangement.

### License Revenue

The Company recognized \$9.1 million and \$9.4 million in amortized license revenue for the years ended December 31, 2011 and 2010, respectively related to the \$110.0 million received from Biogen Idec in 2009 as part of our collaboration agreement. We currently estimate the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

### Royalty Revenue

The Company recognized \$1.9 million in royalty revenue for the year ended December 31, 2011 related to ex-U.S. sales of Fampyra by Biogen Idec.

### Cost of Sales

#### *Ampyra*

We recorded cost of sales of \$41.9 million for the year ended December 31, 2011 as compared to \$26.1 million for the year ended December 31, 2010. Cost of sales for the year ended December 31, 2011 consisted primarily of \$36.3 million in inventory costs related to recognized revenues. Cost of sales for the year ended December 31, 2011 also consisted of \$4.4 million in royalty fees based on net sales, \$1.1 million in amortization of intangible assets, and \$180,000 in period costs related to packaging, freight and stability testing.

Cost of sales for the year ended December 31, 2010 consisted primarily of \$22.2 million in inventory costs related to recognized revenues. In 2010, our launch stock inventory was received in bulk form prior to regulatory approval; therefore, the manufacturing cost associated with this inventory was classified as research and development expense as there was no alternative future use prior to regulatory approval. This expensed inventory represented approximately 8% of the total cost basis of our launch stock inventory. The remaining packaged portion of the inventory cost was received 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 cost 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 \$22.3 million for the year ended December 31, 2011 as compared to \$9.5 million for the year ended December 31, 2010. Cost of sales for the year ended December 31, 2011 consisted of \$14.0 million in amortization of intangibles assets including an asset impairment charge of \$13.0 million due to the Apotex patent litigation trial court decision. Cost of sales for the year ended December 31, 2011 also consisted of \$5.1 million in inventory costs consisting of a charge of \$4.1 million related to recognized revenues and an inventory reserve charge of \$1.0 million, \$3.0 million in royalty fees based on net product shipments, and \$192,000 in period costs related to freight and stability testing.

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 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.

### *Cost of Milestone & License Revenue*

We recorded cost of milestone and license revenue of \$2.4 million and \$660,000 for the years ended December 31, 2011 and 2010, respectively. Cost of milestone revenue represents a 7% payment to Elan on the \$25.0 million milestone revenue received from Biogen Idec in accordance with our worldwide license and supply agreement with Elan. For revenue recognition purposes, the related milestone revenue was considered to be substantive and was, therefore, recognized in its entirety in this period. The corresponding cost of milestone revenue was also recognized in its entirety in this period. Cost of License revenue represents the recognition of a portion of the deferred \$7.7 million paid to Elan in 2009 in connection with the \$110.0 million received from Biogen Idec as a result of our collaboration agreement.

### *Research and Development*

Research and development expenses for the year ended December 31, 2011 were \$42.1 million as compared to \$30.6 million for the year ended December 31, 2010, an increase of approximately \$11.5 million, or 38%. The increase was attributable to an increase in clinical trial expenses of \$7.3 million related to post-marketing clinical studies of Ampyra, the Medtronic AC105 license expense of \$3.0 million, an increase in overall research and development staff and compensation of \$3.1 million to support the various pipeline initiatives, an increase of \$2.6 million for work on our life cycle management program for Ampyra, and an increase of \$2.5 million for our rHIgM22 pipeline product.

The overall increase in research and development expenses was partially offset by a decrease of \$3.7 million in clinical costs associated with the completion of our MS extension study and a decrease related to a reduction in expenses allocated to research and development of \$1.7 million for Ampyra manufacturing and stability work that was classified as research and development for the year ended December 31, 2010 as it was incurred prior to FDA approval of the drug. The overall increase in research and development expense was also partially offset by a decrease of \$1.2 million in milestone payments 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. Finally, the overall increase in research and development expenses was further offset by a slight decrease in total GGF2 project costs of approximately \$610,000.

#### Selling, General and Administrative

Sales and marketing expenses for the year ended December 31, 2011 were \$86.9 million compared to \$87.8 million for the year ended December 31, 2010, a decrease of approximately \$900,000, or 1%. The decrease was primarily attributable to a decrease in overall Ampyra sales and marketing expenses as compared to the launch year of Ampyra. The decrease in sales and marketing expense was partially offset by a net increase in Zanaflex sales and marketing expense of \$422,000 resulting from a sample inventory reserve charge and a bad debt expense charge offset by a decrease in overall Zanaflex marketing spend.

General and administrative expenses for the year ended December 31, 2011 were \$61.6 million compared to \$44.9 million for the year ended December 31, 2010, an increase of approximately \$16.7 million, or 37%. This increase was the result of a \$7.4 million increase in Ampyra post-approval regulatory expenses and other expenses related to supporting the growth of the overall organization including an increase of \$3.9 million for staff and compensation expenses. General and administrative expenses for the year ended December 31, 2011 also included an increase in the loss of our put/call liability related to the PRF revenue interest agreement of \$639,000, a \$5.1 million increase in other expenses related to the Zanaflex Capsule patent infringement litigation and an increase in medical affairs expenses including educational programs of \$2.2 million.

#### Other Expense

Other expense was \$3.0 million for the year ended December 31, 2011 compared to \$3.3 million for the year ended December 31, 2010, a decrease of approximately \$303,000, or 9%. The decrease was primarily due to a decrease in interest expense of \$352,000 principally related to the PRF revenue interest agreement, a decrease in interest income of \$24,000 resulting from lower average interest rates in 2011, as well as realized loss on foreign currency exchange of 18,000.

#### Provision for Income Taxes

We recorded a \$1.4 million provision for income taxes for the year ended December 31, 2011 which represents Federal AMT and gross receipts taxes for certain states.

#### Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of our common stock and preferred stock, payments received under our collaboration and licensing agreements, sales of Ampyra and Zanaflex Capsules, and, to a lesser extent, from loans, government grants and our financing arrangement with PRF.

We were cash flow positive in 2012 and, at December 31, 2012, we had \$333.2 million of cash, cash equivalents and short-term and long-term investments, compared to \$295.9 million at December 31, 2011. Any investments classified as long-term had maturity dates of no later than April 15, 2014. We believe that we have sufficient cash, cash equivalents and short-term and long-term investments on hand, in addition to cash expected to be generated from operations, to fund our 2013 business plan, including our currently anticipated development pipeline activities in 2013.

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 amount and timing of milestone or other payments payable under collaboration, license and acquisition agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, and the extent to which we acquire or in-license new products



and compounds including the development costs relating to those products or compounds. 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 our operations. If we require additional financing in the future, we cannot assure you that it will be available to us on favorable terms, or at all.

### *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, 2012, \$5.4 million of these promissory notes was outstanding, which amount includes accrued interest.

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. An additional \$5.0 million was due to us if net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone was met and the receivable was reflected in our December 31, 2006 financial statements. Under the terms of the amendment, we repaid PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010 since the net revenues milestone was met.

Under the agreement and the amendment, 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, 2012, referred to as the revenue interest liability, of approximately \$2.2 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.

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 \$329,000 as of December 31, 2012 related to the put/call option to reflect its current estimated fair value. This liability is revalued on an as needed 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, 2012, cash and cash equivalents, short-term and long-term investments were approximately \$333.2 million, as compared to \$295.9 million at December 31, 2011. 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 US Treasury 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, 2012, our cash and cash equivalents were \$41.9 million, as compared to \$58.0 million as of December 31, 2011. 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 \$192.0 million as of December 31, 2012, as compared to \$238.0 million as of December 31, 2011. Our long-term investments consist of US Treasury bonds with original maturities greater than one year. The balance of these investments was \$99.4 million as of December 31, 2012, as compared to zero as of December 31, 2011.

#### *Net Cash Provided by Operations*

Net cash provided by operations was \$52.1 million and \$66.3 million for year ended December 31, 2012 and 2011, respectively. Cash provided by operations for the year ended December 31, 2012 was primarily attributable to net income of \$155.0 million principally resulting from an increase in net product and royalty revenues, a non-cash share-based compensation expense of \$21.4 million, depreciation and amortization of \$4.7 million, amortization of net premiums and discounts on short-term investments of \$4.4 million, and an asset impairment charge of \$664,000. Net cash provided by operations was also attributable to a net increase of \$11.9 million due to changes in working capital items primarily due to an increase of \$11.7 million in accounts payable, accrued expenses, and other current liabilities resulting from payment timing, an increase of \$7.4 million in inventory held by the Company and by others, and an increase of \$600,000 in revenue interest liability interest payable. These working capital increases were partially offset by an increase of \$3.5 million in accounts receivable, an increase of \$2.9 million in prepaid expenses and other current assets, and a net decrease of \$1.3 million in deferred product revenue. Cash provided by operations was partially offset by a non-cash benefit of \$133.0 million primarily resulting from a release of our deferred tax valuation allowance, a decrease in deferred license revenue of \$9.1 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009, an increase in other assets of approximately \$3.8 million resulting from the acquisition of Neuronex’s tangible net assets of \$3.7 million which were primarily the taxable amount of net operating loss carryforwards, a decrease in deferred cost of license revenue of \$634,000 due to the amortization of the payment made to Elan related to this upfront collaboration payment, and a gain on our put/call liability of \$701,000.

Net cash provided by operations was \$66.3 million and \$19.2 million for year ended December 31, 2011 and 2010, respectively. Cash provided by operations for the year ended December 31, 2011 was primarily attributable to net income of \$30.6 million principally resulting from a milestone revenue payment from Biogen Idec, a non-cash share-based compensation expense of \$19.3 million, an asset impairment charge of \$13.0 million, a decrease in inventory held by the Company of \$9.0 million, amortization of net premiums and discounts on short-term investments of \$6.8 million, depreciation and amortization of \$4.6 million, a decrease in the noncurrent portion of deferred cost of license revenue of \$608,000, and a \$639,000 loss on our put/call liability. Cash provided by operations was partially offset by a net decrease of \$8.5 million due to changes in working capital items primarily due to the payment of 2010 accruals and prepaid items during the year ended December 31, 2011. The offset to cash provided by operations was also attributable to a decrease in deferred license revenue of \$9.1 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009 and an increase in accounts receivable of \$556,000.

#### *Net Cash Used in Investing*

Net used in investing activities for the year ended December 31, 2012 was \$71.3 million, primarily due to \$322.5 million in purchases of short-term and long-term investments, purchases of property and equipment of \$10.4 million, and purchases of intangible assets of \$3.2 million partially offset by \$264.8 million in proceeds from maturities and sales of short-term investments.

#### *Net Cash Provided by Financing*

Net cash provided by financing activities for the year ended December 31, 2012 was \$3.1 million, primarily due to \$4.3 million in net proceeds from the exercise of stock options partially offset by \$1.3 million in repayments to PRF.

### **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, 2012 and the effect such obligations are expected to have on our liquidity and cash flow in future periods.

(In thousands)	Payments due by period (1)			
	Total	Less than 1 year	1-3 years	4-5 years
Convertible note payable (2) .....	\$5,721	\$1,144	\$3,433	\$1,144
Operating leases (3) .....	21,991	3,443	10,853	7,695
Inventory purchase commitments (4).....	22,219	22,219	—	—
Total .....	<u>\$49,931</u>	<u>\$26,806</u>	<u>\$14,286</u>	<u>\$8,839</u>

- (1) Excludes PRF principal and interest payments, due to uncertainty as to the amount and timing of such payments.
- (2) Represents the remaining 5 annual payments of principal and interest to be made on the convertible note payable to Saints Capital.
- (3) Represents payments for new lease for Ardsley, NY lease.
- (4) 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 Alkermes ships

inventory to us. Under our supply agreement with Alkermes, we provide Alkermes 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 Alkermes, unless Alkermes is unable or unwilling to meet its requirements, for a percentage of net product sales and the quantity of product shipped by Alkermes to us.

Under certain 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 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 \$202 million as part of our various agreements, 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, 2012, 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.

#### *Revenue Recognition*

##### Ampyra

Ampyra is available in the U.S. only through a network of specialty pharmacy providers that provide the medication to patients by mail; Kaiser Permanente (Kaiser), which distributes Ampyra to patients through a closed network of on-site pharmacies; and Amerisource Specialty Distribution Healthcare, which is the exclusive specialty pharmacy distributor for the U.S. Department of Veterans Affairs (VA). 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, and the amount of returns can be reasonably estimated and collectability is reasonably assured. We

recognize product sales of Ampyra following shipment of product to these customers. Our customers are contractually obligated to hold no more than an agreed number of days of inventory, ranging from between 10 to 30 days.

Our net revenues represent total revenues less allowances for customer credits, including estimated rebates and discounts. 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 our customers, an adjustment is recorded for estimated chargebacks and rebates. 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 and discounts are established based on the contractual terms with customers, historical trends, 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 the data that we receive from our customers, and returns experience of other specialty products with similar selling models, we have been able to make a reasonable estimate for product returns. We revised our returns good policy in December 2012 and no longer accept returns of Ampyra except for product damaged in shipping. Historically, it has been rare for us to have product damaged in shipping. We will exchange product from inventory for product damaged in shipping.

#### Zanaflex

We apply the revenue recognition guidance in Accounting Standards Codification (ASC) 605-15-25, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. We have accumulated some sales history with Zanaflex Capsules; however, due to existing and potential generic competition and customer conversion from Zanaflex tablets to Zanaflex Capsules, we cannot reasonably determine a return rate at this time and, thus, are not permitted to recognize revenue based on shipments to wholesalers. As a result, we account for sales of these products using a deferred revenue recognition model. We continue to accumulate data and when we are able to reasonably estimate product returns based on this data and based on greater certainty regarding generic competition we will then begin to recognize revenue based on shipments of product to our wholesale drug distributors.

Under our deferred revenue model, we do not recognize revenue following shipment of Zanaflex Capsules and Zanaflex tablets to our wholesale drug distributors. Instead, we record deferred revenue at gross invoice sales price, and classify the cost basis of the inventory held by the wholesaler as a component of inventory. We recognize revenue when prescriptions are filled to an end-user because once a prescription is filled the product cannot be returned. We use monthly prescription data that we purchase to determine the amount of revenue to be recognized. When we receive the prescription data, we use the number of units of product prescribed to record gross sales. We then reduce deferred revenue and record cost of goods sold.

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

Our net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. 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, should be characterized as a reduction of revenue when recognized in the vendor's statement of income. Adjustments are recorded for estimated chargebacks, rebates, and discounts. These allowances are established by management as its best estimate based on available information and are adjusted to reflect known changes in the factors that impact such reserves. Allowances for chargebacks, rebates and discounts are established based on the contractual terms with customers, analysis of historical levels of discounts, chargebacks and rebates, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for each product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales.

We accept returns of Zanaflex Capsules and Zanaflex tablets for six months prior to and twelve months after their expiration date. We provide a credit to customers with whom we have a direct relationship or a cash payment to those with whom we do not have a direct relationship. We do not exchange product from inventory for the returned product. Returns of products sold by us are charged directly against deferred revenue, reducing the amount of deferred revenue that we may recognize. In addition, we record a charge to cost of goods sold for the cost basis of the estimated product returns we believe may ultimately be realized at the time of product shipment to wholesalers. We recognize this charge at the date of shipment since it is probable that we will receive a level of returned products; upon the return of such product we will be unable to resell the product considering its expiration dating; and, we can reasonably estimate a range of returns. This charge represents the cost basis for the low end of the range of the Company's estimated returns. The charge to cost of goods sold amounted to \$313,000 and \$1.3 million for the years ended December 31, 2012 and 2011, respectively. A 10% change in this expense estimate would have had an approximate \$31,300 and \$130,000 effect on the Company's cost of sales for the years ended December 31, 2012 and 2011, respectively.

We initiated a product recall for three lots of Zanaflex Capsules in February 2011 due to two reports of empty Zanaflex Capsules that had been distributed to pharmacies and sold to patients. Returns of this recalled product are charged directly against deferred revenue, reducing the amount of deferred revenue that we may recognize. Some shipments of Zanaflex Capsules during the twelve-month period ended December 31, 2011 were likely to replace this recalled product. As of December 31, 2012 we received approximately \$3.5 million in recall returns which was charged directly against deferred revenue. Under the terms of our agreement with Alkermes, they are responsible for the cost of replacing the inventory and any reasonable and actual costs and expenses incurred in connection with the recall.

#### *Discounts and Allowances*

Reserves for Ampyra and Zanaflex with respect to customer credits, including estimated rebates, wholesaler fees for services, discounts and returns have been established. Discounts and allowances are recorded following shipment of product and the appropriate reserves are credited. These allowances are established by management as its best estimate of historical experience and data points available and are adjusted to reflect known changes in the factors that impact such reserves. Allowances for customer credits, rebates, wholesaler fees for services, and discounts are established based on contractual terms with customers and analyses of historical usage of these items. The nature of our allowances and accruals requiring critical estimates, and the specific considerations it uses in estimating their amounts are as follows:

*Government Chargebacks and Rebates:* We contract for Medicaid other government programs such as the Federal Supply Schedule which commits us to providing favorable pricing. This ensures that our products remain eligible for purchase or reimbursement under these government-funded programs. We also contract with the Centers for Medicare and Medicaid Services to participate in the Coverage Gap Discount Program (the program given rise by the Affordable Care Act which closes the Medicare Part D "donut hole"). Based upon our contracts and the most recent experience with respect to sales through each of these channels, we provide an allowance for chargebacks and rebates. We monitor the sales trends and adjust the chargebacks and rebate percentages on a regular basis to reflect the most recent chargebacks and rebate experience. Our chargebacks and rebate accruals were \$2.8 million and \$3.1 million at December 31, 2012 and December 31, 2011, respectively. A 10% change in our chargebacks and rebate

allowances would have had an approximate \$1.5 million and \$998,000 effect on our net revenue for the years ended December 31, 2012 and December 31, 2011, respectively.

*Managed Care Contract Rebates:* We contract with various managed care organizations including health insurance companies and pharmacy benefit managers in order to provide improved access to Ampyra for patients that are members of such organizations. These contracts stipulate that rebates and, in some cases, administrative fees, are paid to these organizations provided Ampyra is represented as having been placed on a specific tier on the organizations drug formulary. Based upon our contracts and the most recent experience with respect to sales through managed care channels, we provide an allowance for managed care contract rebates. We began to enter into these contracts during the three months ended December 31, 2010. We continue to monitor the sales trends and adjust the allowance on a regular basis to reflect the most recent rebate experience. Our managed care contract rebate accruals were \$740,000 and \$273,000 at December 31, 2012 and December 31, 2011, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate \$312,000 and \$146,000 effect on our net revenue for the years ended December 31, 2012 and December 31, 2011, respectively.

*Copay Mitigation Rebates:* We offer copay mitigation to commercially insured patients who have coverage for Ampyra (in accordance with applicable law) and are responsible for a cost share regardless of financial need (income status). The copay mitigation program is intended to reduce the patient's financial responsibility for Ampyra to a specified dollar amount. Based upon our contracts and the most recent experience with respect to actual copay assistance provided, we provide an allowance for copay mitigation rebates. We monitor the sales trends and adjust the rebate percentages on a regular basis to reflect the most recent rebate experience. Our copay mitigation rebate accruals were \$222,000 and \$135,000 at December 31, 2012 and December 31, 2011, respectively. A 10% change in our managed care contract rebate allowances would have had an approximate \$499,000 and \$489,000 effect on our net revenue for the years ended December 31, 2012 and December 31, 2011, respectively.

*Cash Discounts:* We sell Ampyra directly to our network of specialty pharmacies, Kaiser and the specialty distributor to the U.S. Department of Veterans Affairs (VA) and Zanaflex directly to wholesalers and generally provide invoice discounts for prompt payment. We estimate our cash discounts based on the terms offered to its customers. Discounts are accrued based on historical usage rates at the time of product shipment. We adjust accruals based on actual activity as necessary. Cash discounts are typically settled with wholesalers within 30 days after the end of each calendar month. Our cash discounts accruals were \$293,000 and \$303,000 at December 31, 2012 and December 31, 2011, respectively. A 10% change in our cash discounts would have had an approximate \$319,000 and \$336,000 effect on our net revenue for the years ended December 31, 2012 and December 31, 2011, respectively.

*Product Returns:* Prior to December 1, 2012, our specialty pharmacies had the right to return any unopened product during the eight-month period beginning two months prior to the labeled expiration date and ending six months after the labeled expiration date. Once product had been prescribed, it was no longer eligible for return. If specialty pharmacies returned product, they were to be given a credit against amounts owed to us. We did not replace returned product with new product unless it had been damaged in shipping. As of the year ended December 31, 2011, the Company had not received any product returns of Ampyra. As of December 1, 2012, we changed our returned goods policy with respect to Ampyra and will no longer accept returned product with the exception of that damaged in shipping. Therefore, we reversed the majority of its returns accrual for Ampyra during the three-month period ended December 31, 2012. Our returns accrual was \$10,000 and \$480,000 at December 31, 2012 and December 31, 2011, respectively. We record Zanaflex Capsule and tablet revenue based on a deferred revenue model and recognize revenue when prescriptions are filled to an end-user because once a prescription is filled the product cannot be returned. Therefore, there is no returns reserve for Zanaflex.

*Data Fees and Fees for Service Payable to Wholesalers:* We have contracted with the specialty pharmacies (not including the specialty distributor to the VA) to obtain transactional data related to Ampyra in order to ascertain a better understanding of our selling channel as well as patient activity and utilization by the Medicaid program and other government agencies and managed care organizations. These contracts stipulate that the specialty pharmacies provide data directly to us, as well as indirectly through Ampyra Patient Support Services (APSS), which in turn provides data to us. We pay a data fee to the specialty pharmacies for each line of data provided and the Company provides an allowance for these data fees. A line of data is defined as data pertaining to a single prescription. We pay a fee for service to certain wholesalers on contractually determined rates for distribution, inventory management and data reporting services. We estimate our fee for service accruals and allowances based on sales to each wholesaler and the applicable contracted rate. Our fee for service expenses are accrued at the time of product shipment and are typically settled with the wholesalers within 60 days after the end of each respective quarter. Our data fee and fee for service accruals were \$792,000 and \$998,000 at December 31, 2012 and December 31, 2011, respectively. A 10% change in our data fee and fee for service allowances would have had an approximate \$346,000 and \$466,000 effect on our net revenue for the years ended December 31, 2012 and 2011, respectively.

We have adjusted our allowances in the past based on actual experience, and we will likely be required to make adjustments to these allowances and accruals in the future. The historical adjustments have not been significant to operations. We continually monitor our allowances and accruals and makes adjustments when we believe actual experience may differ from its estimates. The allowances included in the table below reflect these adjustments.



The following table provides a summary of activity with respect to the Company's sales discounts and allowances during 2012, 2011, and 2010:

(in thousands)	Government chargebacks and rebates	Managed care contract rebates	Copay mitigation rebates	Cash discounts	Product returns	Data fees and fees for services payable to wholesalers	Total
<b>Balance at December 31, 2009</b>	1,765	-	-	232	-	762	2,759
Allowances for sales 2010	5,291	333	2,961	2,579	353	3,726	15,243
Allowances for prior year sales	(361)	-	-	-	-	26	(335)
Actual credits for sales during 2010	(3,384)	(111)	(2,930)	(2,428)	-	(2,482)	(11,335)
Actual credits for prior year sales	(521)	-	-	(59)	-	(789)	(1,369)
<b>Balance at December 31, 2010</b>	2,790	222	31	324	353	1,243	4,963
Allowances for sales 2011	10,139	1,534	4,888	3,406	127	4,976	25,070
Allowances for prior year sales	(157)	(70)	(2)	(43)	-	(321)	(593)
Actual credits for sales during 2011	(7,242)	(1,260)	(4,753)	(3,188)	-	(3,978)	(20,421)
Actual credits for prior year sales	(2,431)	(153)	(29)	(196)	-	(922)	(3,731)
<b>Balance at December 31, 2011</b>	3,099	273	135	303	480	998	5,288
Allowances for sales 2012	14,609	3,126	5,073	3,265	-	3,481	29,554
Allowances for prior year sales	72	(10)	(86)	(71)	(452)	(17)	(564)
Actual credits for sales during 2012	(11,651)	(2,386)	(4,851)	(2,967)	(18)	(2,688)	(24,561)
Actual credits for prior year sales	(3,280)	(263)	(49)	(237)	-	(982)	(4,811)
<b>Balance at December 31, 2012</b>	\$2,849	\$740	\$222	\$293	\$10	\$792	\$4,906

### *Collaborations*

We recognize collaboration revenues by analyzing each element of the agreement to determine if it shall be accounted for as a separate element or single unit of accounting. If an element shall be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue shall be recognized. If an element shall not be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue shall be recognized. Payments received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met.

### *Milestones and royalties*

In order to determine the revenue recognition for contingent milestones, we evaluate the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards (FASB) guidance on the milestone method of revenue recognition. At the inception of a collaboration agreement we evaluate if payments are substantive. The criteria requires that (i) we determine if the milestone is commensurate with either its performance to achieve the milestone or the enhancement of value resulting from our activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the

milestone is achieved. Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

#### *License Revenue and Cost of License Revenue*

Under the Collaboration Agreement with Biogen Idec, we were entitled to a non-refundable upfront payment of \$110.0 million as of June 30, 2009, the date of the agreement, which was received on July 1, 2009. As a result of such payment to us, \$7.7 million became payable by us to Elan under our existing agreements with Elan. These agreements obligate us to pay an amount equal to 7% of any upfront and milestone payments that we receive from the sublicensing of rights to Ampyra or other aminopyridine products. We estimate the revenue recognition period for the upfront payment that we received from Biogen Idec, and for any milestone payments made to us by Biogen Idec, and for the corresponding payments that we make to Elan, to be approximately 12 years from the date of the receipt of payment from Biogen.

#### *Ampyra Inventory*

Prior to regulatory approval of Ampyra in the three-month period ended March 31, 2010, we incurred expenses for the manufacture of several batches of Ampyra that ultimately became available to support the commercial launch of this drug candidate. Until the necessary initial regulatory approval was received, we charged all such amounts to research and development expenses. As a result, our initial sales of Ampyra resulted in higher gross margins than if the inventory costs had not previously been expensed. Upon regulatory approval of Ampyra, we began capitalizing the commercial inventory costs associated with manufacturing with Alkermes plc (Alkermes), formerly Elan Corporate, plc (Elan), and at its second manufacturer, Patheon. During the third quarter of 2011, Alkermes acquired the Elan business that supplies our Ampyra inventory.

The cost of Ampyra inventory manufactured by Alkermes is based on specified prices calculated as a percentage of net product sales of the product shipped by Alkermes to Acorda. In the event Alkermes does not manufacture the products, Alkermes is entitled to a compensating payment for the quantities of product provided by the alternative manufacturer. This compensating payment is included in our inventory balances.

#### *Cost of Sales*

##### *Ampyra*

Cost of sales consists of cost of inventory, expense due to inventory reserves when necessary, royalty expense, milestone amortization of intangible assets associated with our agreement with Alkermes and well as the capitalization of milestone achievements with the Canadian Spinal Research Organization (CSRO) during the three months ended March 31, 2010, packaging costs, freight and required inventory stability testing costs. Our inventory costs, royalty obligations and milestone obligations are set forth in the agreements entered into with Alkermes. These agreements require us to pay Alkermes a percentage of our net selling price for each inventory lot purchased from Alkermes. The cost for each lot is calculated based on an agreed upon estimated net selling price which is based on an actual historical net selling price. At the end of each quarter, we perform a calculation to adjust the inventory value for any lots received in the current quarter to that quarter's actual net selling price. This payment is recorded as an adjustment to inventory as well as an accrual on our balance sheet and is required to be paid within 45 days of the quarter end. In the event we have sold any inventory purchased from Alkermes during that respective quarter, we would also record an adjustment to the cost of goods sold and an additional accrual on the balance sheet to be paid to Alkermes. The agreement with Alkermes allows us to purchase up to 25% of our annual inventory requirements from an alternative manufacturer but stipulates a compensating payment to be made to Alkermes for any inventory purchased from this alternative manufacturer. This payment is determined at the end of the quarter in which any new lots have been purchased exclusive from Alkermes using the actual net selling price for the respective quarter net of an agreed upon amount as stipulated by the Alkermes agreement. This payment is recorded as an adjustment to inventory as well as an accrual on our balance sheet.

## *Zanaflex*

Cost of sales consists of cost of inventory, expense due to inventory reserves when necessary, royalty expense, milestone amortization of intangible assets associated with the Zanaflex acquisition prior to 2011, intangible write-off expense in 2011, packaging costs, freight and required inventory stability testing costs. Our inventory costs, royalty obligations and milestone obligations are set forth in the agreements entered into in connection with our Zanaflex acquisition. Any payments we make to PRF in connection with the revenue interest assignment transaction entered into in December 2005 will not constitute royalty expense or otherwise affect our cost of sales. See “—Liquidity and Capital Resources—Financing Arrangements.”

## *Research and Development*

We are developing Diazepam Nasal Spray, which we acquired in December 2012, for the treatment of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS. Pending additional clinical and manufacturing data, we plan to submit an NDA to the FDA for Diazepam Nasal Spray in 2013. We are also studying dalfampridine to improve a range of functional impairments, in addition to walking disability, caused by MS, as well as its potential use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, we have several research and development programs focused on distinct therapeutic approaches to restoring neurologic and/or cardiac function. We are developing clinical stage compounds AC105 for acute treatment of SCI, GGF2 for the treatment of heart failure, and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and SCI. Chondroitinase, an enzyme that encourages nerve plasticity in SCI, is in preclinical development.

We consider the active management and development of our research, preclinical and clinical pipeline an important component of the long-term process of introducing new products. We manage our overall research, development and inlicensing efforts in a highly disciplined manner designed to advance only high quality, differentiated agents into clinical development. The duration of each phase of research and preclinical and clinical development and the probabilities of success for approval of drug candidates entering clinical development will be impacted by a variety of factors, including the quality of the molecule, the validity of the target and disease indication, early clinical data, investment in the program, competition and commercial viability. Due to the risks inherent in the clinical trial process and the early stage nature of our pipeline development programs, we are unable to estimate with any certainty completion dates, the proportion of our R&D investments assigned to any one program or to the future cash inflows from these potential programs.

Research and development expense consists primarily of:

- salaries and related benefits and share-based compensation for research and development personnel;
- costs of facilities and equipment that have no alternative future use;
- fees paid to professional service providers in conjunction with independently monitoring our clinical trials and acquiring and evaluating data in conjunction with our clinical trials;
- fees paid to contract research organizations (CROs) in conjunction with preclinical studies;
- fees paid to organizations in conjunction with contract manufacturing;
- costs of materials used in research and development;
- upfront and milestone payments under contractual agreements;
- consulting, license and sponsored research fees paid to third parties; and
- depreciation of capital resources used to develop our products.

For those studies that we administer ourselves, we account for our clinical study costs by estimating the patient cost per visit in each clinical trial and recognizing this cost as visits occur, beginning when the patient enrolls in the trial. This estimated cost includes payments to the trial site and patient-related costs, including

laboratory costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, and the length of the treatment period for each patient. For those studies for which we use a CRO, we account for our clinical study costs according to the terms of the CRO contract. These costs include upfront, milestone and monthly expenses as well as reimbursement for pass through costs. As actual costs become known to us, we adjust our accrual; such changes in estimate may be a material change in our clinical study accrual, which could also materially affect our results of operations. All research and development costs are expensed as incurred except when we are accounting for nonrefundable advance payments for goods or services to be used in future research and development activities. In these cases, these payments are capitalized at the time of payment and expensed ratably over the period the research and development activity is performed.

We use our employee and infrastructure resources across several projects, and many of our costs are not attributable to an individually-named project, but are broadly applicable research projects. Accordingly, we do not account for internal research and development costs on a project-by-project basis. Unallocated costs are represented as operating expenses in the table below.

The following table shows, for each of the years ended, (i) the total third parties expenses for clinical development, preclinical research and development, on a project-by-project basis, (ii) our unallocated research and development operating expenses, and (iii) acquisitions, licenses and milestone payments, on a project-by-project basis:

(in thousands)	Year Ended December 31,		
	2012	2011	2010
<b>Preclinical and clinical development:</b>			
Contract expenses—Ampyra (1)	\$12,840	\$11,429	\$6,873
Contract expenses—Diazepam Nasal Spray	843	-	-
Contract expenses—GGF2	6,182	4,610	1,123
Contract expenses—rHlgM22	1,219	3,608	5,288
Contract expenses—AC105	1,197	132	-
Contract expenses—Chondroitinase	498	118	150
<b>Research and development operating expenses:</b>	23,929	19,211	16,041
<b>Acquisitions, licenses and milestones:</b>			
Diazepam nasal spray	6,653	-	-
GGF2	-	-	1,125
AC105	500	3,000	-
Other	20	-	-
<b>Total research and development</b>	<b>\$53,881</b>	<b>\$42,108</b>	<b>\$30,600</b>

(1) Year ended 2010 includes approximately \$1.1 million for pre-approval expensed launch stock inventory for Ampyra.

With respect to previously established clinical study accruals in prior periods and for the twelve-month period ended December 31, 2012 we did not make any significant adjustments to our clinical study costs.

### *Sales and Marketing Expenses*

Sales and marketing expenses include personnel costs, related benefits and share-based compensation for our sales, managed markets and marketing personnel, the cost of Ampyra and Zanaflex sales and marketing initiatives as well as the pre-market marketing costs for future products.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of personnel costs, related benefits and share-based compensation for personnel serving executive, finance, medical affairs, safety, business development, legal, quality assurance, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development or sales and marketing expense and professional fees for legal and accounting services.

### *Other Income (Expense)*

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

### *Income Taxes*

Our annual effective tax rate is based on pre-tax earnings, existing statutory tax rates, and permanent adjustments affecting taxable income. Significant judgment is required in evaluating our tax position.

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. In accordance with ASC 740, we account for income taxes by the asset and liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

At December 31, 2012, we had \$136.7 million of net deferred tax assets, which included the effects of net operating loss carryforwards of \$64.1 million, tax credits of \$4.6 million and other items. For the three-months ended December 31, 2012, we reduced our valuation allowance in full because we believe it is more likely than not that we will realize the benefits of our deferred tax assets. In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible or the NOLs and credit carryforwards can be utilized. When considering the reversal of the valuation allowance, we consider the level of past and anticipated future taxable income and the utilization of the carryforwards. Based upon these considerations, we reduced our valuation allowance in full. This valuation adjustment resulted in a benefit from income taxes for the year ended December 31, 2012. We expect that future periods will include income taxes at a higher effective rate. Revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

On a periodic basis, we evaluate our ability to realize our deferred tax assets net of deferred tax liabilities and adjust such amounts in light of changing facts and circumstances, including but not limited to our level of past and future taxable income, the current and future expected utilization of tax benefit carryforwards, and any regulatory or legislative actions by relevant authorities with respect to the Ampyra patents. We consider all available evidence, both positive and negative, to determine whether, based on the weight of that evidence, a valuation allowance is required to reduce the net deferred tax assets to the amount that is more likely than not to be realized in future periods.

#### Positive:

- The Company is no longer in a three-year cumulative pre-tax loss position. According to the guidance this is a significant factor to weigh heavily when looking at positive and negative evidence.
- We achieved our second consecutive profitable year with a 2012 pre-tax income of \$24.3 million.
- Our Ampyra U.S. Patent No. US 8,007,826 patent extends into 2027.
- Our projections show that the deferred tax assets for our net operating loss carryforwards and research and development tax credits will be realized prior to their expiration.

#### Negative:

- There is an inherent risk in the ability to meet budgeted forecasts.

- If we were to experience a future 382 ownership change, the ability to utilize net operating losses may be limited, depending on the market value of the company at the time of any such ownership change.
- We may acquire other compounds in the future, which may generate losses.

We will continue to evaluate the realizability of our deferred tax assets and liabilities on a periodic basis, and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, tax legislation, rulings by relevant tax authorities and the progress of ongoing tax audits, if any.

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

We account for stock options and restricted stock granted to employees and non-employees by recognizing the costs resulting from all share-based payment transactions in the financial statements at their fair values. We estimate the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions for the expected term of the stock options, expected volatility of our common stock, prevailing interest rates, and an estimated forfeiture rate.

We have based our current assumptions on the following:

<u>Assumption</u>	<u>Method of estimating</u>
• Estimated expected term of options .....	• Historical term of our options based on exercise data
• Expected volatility .....	• Historic volatility of our common stock
• Risk-free interest rate .....	• Yields of U.S. Treasury securities corresponding with the expected life of option grants
• Forfeiture rates .....	• Historical forfeiture data

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

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Our financial instruments consist of cash and cash equivalents, short-term and long-term investments, grants receivable, convertible notes payable, accounts payable, and put/call liability. The estimated fair values of all of our financial instruments approximate their carrying amounts at December 31, 2012.

We have cash equivalents and short-term and long-term investments at December 31, 2012, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the nature of our investments in money market funds and US Treasury bonds, the carrying value of our cash equivalents and short-term and long-term investments approximate their fair value at December 31, 2012. Our investments designated as long-term as of December 31, 2012 had maturity dates no later than April 15, 2014. At December 31, 2012, we held \$333.2 million in cash and cash equivalents and short-term and long-term investments which had an average interest rate of approximately 0.1%.

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity and to meet operating needs. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase.

However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments.

#### **Item 8. Financial Statements and Supplementary Data.**

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

#### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

#### **Item 9A. Controls and Procedures.**

##### *Evaluation of disclosure controls and procedures*

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (the “Exchange Act”), we carried out an evaluation of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of our 2012 fiscal year (the period covered by this report). This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer. Based on that evaluation, these officers have concluded that, as of December 31, 2012, our disclosure controls and procedures were effective to achieve their stated purpose.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules, regulations, and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding disclosure.

##### *Change in internal control over financial reporting*

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, including our chief executive officer and chief financial officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

##### *Limitations on the effectiveness of controls*

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

##### *Management’s Report on Internal Control Over Financial Reporting*

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

Under the supervision of and with the participation of our chief executive officer and our chief financial officer, our management conducted an assessment of the effectiveness of our internal control over financial

reporting as of the end of 2012 (the period covered by this report) based on the framework and criteria established in Internal Control—Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management has concluded that, as of December 31, 2012, our internal control over financial reporting was effective. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions.

Ernst & Young LLP, the independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on the Company's internal control over financial reporting as of December 31, 2012. This attestation report appears below.



## **Report of Independent Registered Public Accounting Firm**

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

We have audited Acorda Therapeutics, Inc. internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Acorda Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Acorda Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2012 consolidated financial statements of Acorda Therapeutics, Inc. and subsidiaries and our report dated February 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
February 28, 2013

**Item 9B. Other Information.**

None.

**PART III****Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this item will be contained in our 2013 Proxy Statement under the caption for the proposal relating to the “Election of Directors,” as well as the captions “Information Concerning Executive Officers,” “Executive Compensation,” and “Additional Information,” and such information is incorporated herein by this reference.

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

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

**Item 11. Executive Compensation.**

The information required by this item will be contained in our 2013 Proxy Statement under the caption for the proposal relating to the “Election of Directors,” as well as the captions “Information Concerning Executive Officers,” “Compensation Committee Report,” “Compensation Discussion and Analysis,” “Executive Compensation,” and “Additional Information,” and such information is incorporated herein by this reference.

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

The information required by this item will be contained in our 2013 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management,” “Information Concerning Executive Officers” and “Additional Information” and is incorporated herein by this reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item will be contained in our 2013 Proxy Statement under the caption for the proposal relating to the “Election of Directors,” as well as the caption “Certain Relationships and Related Transactions,” and such information is incorporated herein by this reference.

**Item 14. Principal Accounting Fees and Services.**

The information required by this item will be contained in our 2013 Proxy Statement under the caption for the proposal relating to the “Ratification of Independent Auditors” and is incorporated herein by this reference.

## PART IV

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

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

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

Financial Statements of Acorda Therapeutics, Inc. and Subsidiaries:

Report of Ernst and Young LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2012 and 2011

Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010

Notes to Financial Statements

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying consolidated balance sheets of Acorda Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Acorda Therapeutics, Inc. and subsidiaries at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
February 28, 2013

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Consolidated Balance Sheets**

(In thousands, except share amounts)

	December 31,	
	2012	2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$41,876	\$57,954
Restricted cash .....	380	303
Short-term investments .....	191,949	237,953
Trade accounts receivable, net of allowances of \$555 and \$879, as of December 31, 2012 and 2011, respectively .....	26,327	22,828
Prepaid expenses .....	6,936	6,534
Finished goods inventory held by the Company .....	20,176	27,256
Finished goods inventory held by others .....	781	1,126
Deferred tax asset .....	35,091	—
Other current assets .....	9,547	6,988
Total current assets .....	333,063	360,942
Long-term investments .....	99,363	—
Property and equipment, net of accumulated depreciation .....	16,706	3,858
Deferred tax asset .....	101,636	—
Intangible assets, net of accumulated amortization .....	9,319	8,769
Non-current portion of deferred cost of license revenue .....	4,808	5,442
Other assets .....	437	477
Total assets .....	\$565,332	\$379,488
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable .....	\$22,503	\$21,393
Accrued expenses and other current liabilities .....	35,758	24,149
Deferred product revenue—Zanaflex .....	29,275	30,599
Current portion of deferred license revenue .....	9,057	9,057
Current portion of revenue interest liability .....	1,134	1,001
Current portion of convertible notes payable .....	1,144	1,144
Total current liabilities .....	98,871	87,343
Non-current portion of deferred license revenue .....	68,685	77,742
Put/call liability .....	329	1,030
Non-current portion of revenue interest liability .....	1,111	1,898
Non-current portion of convertible notes payable .....	4,244	5,230
Other non-current liabilities .....	6,171	1,036
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at December 31, 2012 and 2011; issued and outstanding 39,804,493 and 39,328,495 shares, including those held in treasury, as of December 31, 2012 and 2011, respectively .....	40	39
Treasury stock at cost (12,420 shares at December 31, 2012 and December 31, 2011) .....	(329)	(329)
Additional paid-in capital .....	640,671	614,914
Accumulated deficit .....	(254,523)	(409,481)
Accumulated other comprehensive income .....	62	66
Total stockholders' equity .....	385,921	205,209
Total liabilities and stockholders' equity .....	\$565,332	\$379,488

See accompanying Notes to Consolidated Financial Statements

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Operations**

(In thousands, except per share data)

	<u>Year ended December 31,</u>	<u>Year ended December 31,</u>	<u>Year ended December 31,</u>
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Revenues:			
Net product revenues.....	\$282,381	\$256,271	\$181,545
Milestone revenue .....	—	25,000	—
License revenue.....	9,057	9,057	9,428
Royalty revenues.....	14,376	1,909	32
Total net revenues .....	<u>305,814</u>	<u>292,237</u>	<u>191,005</u>
Costs and expenses:			
Cost of sales .....	57,007	64,183	35,518
Cost of milestone and license revenue .....	634	2,384	660
Research and development.....	53,881	42,108	30,600
Selling, general and administrative .....	168,690	148,508	132,657
Total operating expenses.....	<u>280,212</u>	<u>257,183</u>	<u>199,435</u>
Operating income (loss) .....	<u>25,602</u>	<u>35,054</u>	<u>(8,430)</u>
Other expense (net):			
Interest and amortization of debt discount expense.....	(1,880)	(3,570)	(3,922)
Interest income .....	552	552	575
Other income (expense) .....	(6)	(18)	8
Total other expense (net).....	<u>(1,334)</u>	<u>(3,036)</u>	<u>(3,339)</u>
Income (loss) before taxes .....	24,268	32,018	(11,769)
Benefit from (provision for) income taxes .....	130,690	(1,413)	—
Net income (loss) .....	<u>\$154,958</u>	<u>\$ 30,605</u>	<u>\$ (11,769)</u>
Net income (loss) per share—basic.....	\$3.93	\$0.78	\$(0.31)
Net income (loss) per share—diluted.....	\$3.84	\$0.76	\$(0.31)
Weighted average common shares outstanding used in			
computing net income (loss) per share—basic.....	39,459	39,000	38,355
Weighted average common shares outstanding used in			
computing net income (loss) per share—diluted.....	40,332	40,064	38,355

See accompanying Notes to Consolidated Financial Statements

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Comprehensive Income (Loss)**

(In thousands)

	<u>Year ended December 31,</u>	<u>Year ended December 31,</u>	<u>Year ended December 31,</u>
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Net income (loss) .....	\$154,958	\$30,605	\$ (11,769)
Other comprehensive income (loss):			
Unrealized gains (losses) on available for sale securities, net of tax .....	<u>(4)</u>	<u>78</u>	<u>(121)</u>
Other comprehensive income (loss), net of tax .....	<u>(4)</u>	<u>78</u>	<u>(121)</u>
Comprehensive income (loss).....	<u>\$154,954</u>	<u>\$30,683</u>	<u>\$(11,890)</u>

See accompanying Notes to Consolidated Financial Statements



**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Changes in Stockholders' Equity**

(In thousands)

	Common stock			Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders' equity
	Number of shares	Par value	Treasury stock				
Balance at December 31, 2009.....	37,935	\$38	\$0	\$565,503	\$(428,317)	\$109	\$137,333
Compensation expense for issuance of stock options to employees .....	—	—	—	12,464	—	—	12,464
Compensation expense for issuance of restricted stock to employees .....	196	—	(329)	5,313	—	—	4,984
Exercise of stock options .....	648	1	—	8,369	—	—	8,370
Other comprehensive loss .....	—	—	—	—	—	(121)	(121)
Net loss .....	—	—	—	—	(11,769)	—	(11,769)
Balance at December 31, 2010.....	<u>38,779</u>	<u>\$39</u>	<u>\$(329)</u>	<u>\$591,649</u>	<u>\$(440,086)</u>	<u>\$(12)</u>	<u>\$151,261</u>
Compensation expense for issuance of stock options to employees .....	—	—	—	13,675	—	—	13,675
Compensation expense for issuance of restricted stock to employees .....	220	—	—	5,628	—	—	5,628
Exercise of stock options .....	329	—	—	3,962	—	—	3,962
Other comprehensive income .....	—	—	—	—	—	78	78
Net income .....	—	—	—	—	30,605	—	30,605
Balance at December 31, 2011.....	<u>39,328</u>	<u>\$39</u>	<u>\$(329)</u>	<u>\$614,914</u>	<u>\$(409,481)</u>	<u>\$66</u>	<u>\$205,209</u>
Compensation expense for issuance of stock options to employees .....	—	—	—	15,206	—	—	15,206
Compensation expense for issuance of restricted stock to employees .....	224	—	—	6,212	—	—	6,212
Exercise of stock options .....	252	1	—	4,339	—	—	4,340
Other comprehensive loss, net of tax .....	—	—	—	—	—	(4)	(4)
Net income .....	—	—	—	—	154,958	—	154,958
Balance at December 31, 2012.....	<u>39,804</u>	<u>\$40</u>	<u>\$(329)</u>	<u>\$640,671</u>	<u>\$(254,523)</u>	<u>\$62</u>	<u>\$385,921</u>

See accompanying Notes to Consolidated Financial Statements

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Consolidated Statements of Cash Flows**

(In thousands)

	<u>Year ended December 31,</u>	<u>Year ended December 31,</u>	<u>Year ended December 31</u>
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Cash flows from operating activities:			
Net income (loss) .....	\$154,958	\$30,605	\$(11,769)
Adjustments to reconcile net loss to net cash provided by/(used in) operating activities:			
Share-based compensation expense.....	21,418	19,303	17,777
Amortization of net premiums and discounts on investments.....	4,382	6,750	4,473
Amortization of revenue interest issuance cost.....	67	104	96
Depreciation and amortization expense.....	4,663	4,625	3,951
Intangible asset impairment.....	664	13,038	—
(Gain) loss on put/call liability .....	(701)	639	(246)
Deferred tax benefit.....	(133,042)	—	—
Changes in assets and liabilities:			
Increase in accounts receivable.....	(3,499)	(556)	(16,533)
Increase in prepaid expenses and other current assets.....	(2,961)	(3,375)	(1,892)
Decrease (increase) in inventory held by the Company.....	7,082	8,976	(31,735)
Decrease in inventory held by others.....	345	1,060	209
Decrease in non-current portion of deferred cost of license revenue .....	634	608	660
(Decrease) increase in other assets.....	(3,753)	(237)	1
(Decrease) increase in accounts payable, accrued expenses, other current liabilities .....	11,743	(6,108)	24,706
(Decrease) increase in revenue interest liability interest payable.....	600	(23)	(76)
Decrease in current portion of deferred license revenue .....	—	(371)	—
Decrease in non-current portion of deferred license revenue .....	(9,057)	(8,686)	(9,428)
(Decrease) Increase in other non-current liabilities.....	(22)	682	—
(Decrease) increase in deferred product revenue—Zanaflex .....	(1,325)	(697)	592
Restricted cash.....	(77)	(1)	(1)
Net cash (used in)/provided by operating activities .....	<u>52,119</u>	<u>66,336</u>	<u>(19,215)</u>
Cash flows from investing activities:			
Purchases of property and equipment.....	(10,384)	(2,192)	(2,446)
Purchases of intangible assets.....	(3,194)	(3,595)	(6,998)
Purchases of investments.....	(322,455)	(266,736)	(310,955)
Proceeds from maturities of investments.....	264,750	227,500	325,750
Net cash (used in)/provided by investing activities.....	<u>(71,283)</u>	<u>(45,023)</u>	<u>5,351</u>
Cash flows from financing activities:			
Proceeds from stock option exercises.....	4,339	3,962	8,370
Purchase of treasury stock.....	—	—	(329)
Repayments of revenue interest liability.....	(1,253)	(1,962)	(6,850)
Net cash provided by financing activities .....	<u>3,086</u>	<u>2,000</u>	<u>1,191</u>
Net increase (decrease) in cash and cash equivalents.....	(16,078)	23,313	(12,673)
Cash and cash equivalents at beginning of period .....	<u>57,954</u>	<u>34,641</u>	<u>47,314</u>
Cash and cash equivalents at end of period .....	<u>\$41,876</u>	<u>\$57,954</u>	<u>\$34,641</u>
Supplemental disclosure:			
Cash paid for interest.....	\$1,122	\$3,404	\$3,781
Cash paid for taxes .....	2,706	1,176	—

See accompanying Notes to Consolidated Financial Statements.

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

**(1) Organization and Business Activities**

Acorda Therapeutics, Inc. (“Acorda” or the “Company”) is a commercial stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis (MS), spinal cord injury (SCI) and other disorders of the central nervous system.

The management of the Company is responsible for the accompanying audited consolidated financial statements and the related information included in the notes to the consolidated financial statements. In the opinion of management, the audited consolidated financial statements reflect all adjustments, including normal recurring adjustments necessary for the fair presentation of the Company's financial position and results of operations and cash flows for the periods presented.

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

*Principles of Consolidation*

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

*Use of Estimates*

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

*Cash and Cash Equivalents*

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

*Restricted Cash*

Restricted cash represents a certificate of deposit placed by the Company with a bank for issuance of a letter of credit to the Company's lessor for office space and a bank account with funds to cover its self-funded employee health insurance.

*Investments*

Both short-term and long-term investments consist of US Treasury bonds. The Company classifies marketable securities available to fund current operations as short-term investments in current assets on its

consolidated balance sheets. Marketable securities are classified as long-term investments in long-term assets on the consolidated balance sheets if the Company has the ability and intent to hold them and such holding period may be longer than one year. The Company classifies its short-term and long-term investments as available-for-sale. Available-for-sale securities are recorded at fair value of the investments based on quoted market prices.

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

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

### ***Inventory***

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

### ***Ampyra***

The cost of Ampyra inventory manufactured by Alkermes plc (Alkermes) is based on specified prices calculated as a percentage of net product sales of the product shipped by Alkermes to Acorda. In the event Alkermes does not manufacture the products, Alkermes is entitled to a compensating payment for the quantities of product provided by Patheon, the Company's alternative manufacturer. This compensating payment is included in the Company's inventory balances.

### ***Property and Equipment***

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

### ***Intangible Assets***

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

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

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired. The Company evaluates the realizability of its long-lived assets based on profitability and cash flow expectations for the related assets. Any write-downs are treated as permanent reductions in the carrying amount of the assets.

### ***Patent Costs***

Patent application and maintenance costs are expensed as incurred.

### ***Research and Development***

Research and development expenses include the costs associated with the Company's internal research and development activities, including salaries and benefits, occupancy costs, and research and development conducted for it by third parties, such as contract research organizations (CROs), sponsored university-based research, clinical trials, contract manufacturing for its research and development programs, and regulatory expenses. In addition, research and development expenses include the cost of clinical trial drug supply shipped to the Company's clinical study vendors. For those studies that the Company administers itself, the Company accounts for its clinical study costs by estimating the patient cost per visit in each clinical trial and recognizes this cost as visits occur, beginning when the patient enrolls in the trial. This estimated cost includes payments to the trial site and patient-related costs, including laboratory costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, and the length of the treatment period for each patient. For those studies for which the Company uses a CRO, the Company accounts for its clinical study costs according to the terms of the CRO contract. These costs include upfront, milestone and monthly expenses as well as reimbursement for pass through costs. As actual costs become known to the Company, it adjusts the accrual; such changes in estimate may be a material change in its clinical study accrual, which could also materially affect its results of operations. All research and development costs are expensed as incurred except when accounting for nonrefundable advance payments for goods or services to be used in future research and development activities. These payments are capitalized at the time of payment and expensed ratably over the period the research and development activity is performed.

### ***Accounting for Income Taxes***

The Company provides for income taxes in accordance with ASC Topic 740 (ASC 740). Income taxes are accounted for under the asset and liability method with deferred tax assets and liabilities recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be reversed or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance for the amounts of any tax benefits which, more likely than not, will not be realized.

In determining whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits, a two-step process is utilized whereby the threshold for recognition is a more likely-than-not test that the tax position will be sustained upon examination and the tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement.

## ***Revenue Recognition***

### *Ampyra*

Ampyra is available only through a network of specialty pharmacy providers that provide the medication to patients by mail; Kaiser Permanente (Kaiser), which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which is the exclusive specialty pharmacy distributor for Ampyra to the U.S. Department of Veterans Affairs (VA). Ampyra is not available in retail pharmacies. The Company does 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 the Company, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, and the amount of returns can be reasonably estimated and collectability is reasonably assured. The Company recognizes product sales of Ampyra following shipment of product to a network of specialty pharmacy providers, Kaiser, and the specialty distributor to the VA. The specialty pharmacy providers, Kaiser, and the specialty distributor to the VA are contractually obligated to hold no more than an agreed number of days of inventory, ranging from between 10 to 30 days.

The Company's 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, Kaiser and the specialty distributor to the VA, an adjustment is recorded for estimated rebates, discounts 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 allowances. Allowances for rebates, discounts and returns are established based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products. Product shipping and handling costs are included in cost of sales. Effective December 1, 2012, the Company no longer accepts returns of Ampyra with the exception of product damages that occur during shipping.

### *Zanaflex*

The Company applies the revenue recognition guidance in Accounting Standards Codification (ASC) 605-15-25, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. The amount of future tablet returns is uncertain due to generic competition and customer conversion to Zanaflex Capsules. The Company has accumulated some sales history with Zanaflex Capsules; however, due to existing and potential generic competition and customer conversion from Zanaflex tablets to Zanaflex Capsules, we do not believe we can reasonably determine a return rate at this time. As a result, the Company accounts for these product shipments using a deferred revenue recognition model. Under the deferred revenue model, the Company does not recognize revenue upon product shipment. For these product shipments, the Company invoices the wholesaler, records deferred revenue at gross invoice sales price, and classifies the cost basis of the product held by the wholesaler as a component of inventory. The Company recognizes revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company's revenue to be recognized is based on (1) the estimated prescription demand, based on pharmacy sales for its products; and (2) the Company's analysis of third party information, including third party market research data. The Company's estimates are subject to the inherent limitations of estimates that rely on third party data, as certain third party information is itself in the form of estimates, and reflect other limitations. The Company's sales and revenue recognition reflects the Company's estimates of actual product prescribed to the end-user. The Company expects to be able to apply a more traditional revenue recognition policy such that revenue is recognized following shipment to the customer when it believes it has sufficient data to develop reasonable estimates of expected returns based upon historical returns and greater certainty regarding generic competition.

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

### *Milestones and royalties*

In order to determine the revenue recognition for contingent milestones, the Company evaluates the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards (FASB) guidance on the milestone method of revenue recognition. At the inception of a collaboration agreement the Company evaluates if payments are substantive. The criteria requires that (i) the Company determines if the milestone is commensurate with either its performance to achieve the milestone or the enhancement of value resulting from the Company's activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonably relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved. Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

### *Collaborations*

The Company recognizes collaboration revenues and expenses by analyzing each element of the agreement to determine if it shall be accounted for as a separate element or single unit of accounting. If an element shall be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue shall be recognized. If an element shall not be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue shall be recognized. Payments received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met.

### *Concentration of Risk*

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

The Company does not own or operate, and currently does not plan to own or operate, facilities for production and packaging of Ampyra or its other commercial products, Zanaflex Capsules or Zanaflex tablets. It

relies and expects to continue to rely on third parties for the production and packaging of its commercial products and clinical trial materials for those and other products.

The Company relies on Alkermes to supply us with its requirements for Ampyra. Under its supply agreement with Alkermes, the Company is obligated to purchase at least 75% of its yearly supply of Ampyra from Alkermes, and it is required to make compensatory payments if it does not purchase 100% of its requirements from Alkermes, subject to specified certain exceptions. The Company and Alkermes have agreed that it may purchase up to 25% of its annual requirements from Patheon, a mutually agreed-upon second manufacturing source, with compensatory payment. The Company and Alkermes also rely on a single third-party manufacturer, Regis, to supply dalfampridine, the active pharmaceutical ingredient, or API, in Ampyra. If Regis experiences any disruption in their operations, a delay or interruption in the supply of Ampyra product could result until Regis cures the problem or we locate an alternate source of supply.

The Company's principal direct customers as of December 31, 2012 were a network of specialty pharmacies, Kaiser, and the specialty distributor to the VA for Ampyra and wholesale pharmaceutical distributors for Zanaflex Capsules and Zanaflex tablets. The Company periodically assesses the financial strength of these customers and establishes allowances for anticipated losses, if necessary.

#### ***Allowance for Cash Discounts***

An allowance for cash discounts is accrued based on historical usage rates at the time of product shipment. The Company adjusts accruals based on actual activity as necessary. Cash discounts are typically settled with customers within 30 days after the end of each calendar month. The Company has cash discount allowances of \$3.2 million and \$3.4 million for the years ended December 31, 2012 and 2011, respectively. The Company's accruals for cash discount allowances were \$293,000 and \$303,000 as of December 31, 2012 and 2011, respectively.

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

A portion of the Company's accounts receivable may not be collected due principally to customer disputes and sales returns. The Company provides reserves for these situations based on the evaluation of the aging of its trade receivable portfolio and an analysis of high-risk customers. The Company has not historically experienced losses related to credit risk. The Company has recognized an allowance related to one customer of approximately \$260,000 and \$600,000 as of December 31, 2012, and December 31, 2011, respectively. For the year ended December 31, 2012, the Company recorded a provision of \$60,000 and write-offs of \$400,000. For the year ended December 31, 2011, the Company recorded a provision of \$600,000 and did not record any write-offs.

#### ***Contingencies***

The Company accrues for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. Litigation expenses are expensed as incurred.

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

The fair value of a financial instrument represents the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced sale or liquidation. Significant differences can arise between the fair value and carrying amounts of financial instruments that are recognized at historical cost amounts. The Company considers that fair value should be based on the assumptions market participants would use when pricing the asset or liability.

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



- (a) Cash equivalents, grants receivables, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these instruments;
- (b) Available-for-sale securities are recorded based primarily on quoted market prices;
- (c) Put/call liability's fair value is based on revenue projections and business, general economic and market conditions that could be reasonably evaluated as of the valuation date;

It is not practical for the Company to estimate the fair value of the convertible notes payable due to the specific provisions of these notes. The terms of these notes are disclosed at Note 9. See Note 14 for discussion on fair value measurements.

### ***Earnings per Share***

Basic net income (loss) per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares outstanding during the period plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted stock. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the "assumed" buyback of additional shares, thereby reducing the dilutive impact of stock options. Common equivalent shares have not been included in the net income (loss) per share calculations for the year ended 2010 because the effect of including them would have been anti-dilutive. See Note 7 for discussion on earnings per share.

### ***Share-based Compensation***

The Company has various share-based employee and non-employee compensation plans, which are described more fully in Note 6.

The Company accounts for stock options and restricted stock granted to employees and non-employees by recognizing the costs resulting from all share-based payment transactions in the consolidated financial statements at their fair values. The Company estimates the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions of expected volatility of its common stock, prevailing interest rates, an estimated forfeiture rate, and the expected term of the stock options, and we recognize that cost as an expense ratably over the associated employee service period.

### ***Segment Information***

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business with respect to any of its products or product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate products or product candidates or by location and does not have separately reportable segments.

### ***Comprehensive Income***

Unrealized gains (losses) from the Company's investment securities are included in accumulated other comprehensive income (loss) within the consolidated balance sheet.

### ***Recent Accounting Pronouncements***

In June 2011, the FASB issued an accounting standards update regarding the presentation of comprehensive income in financial statements. The provisions of this standard provide an option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. The Company reports components of comprehensive income in two separate consecutive statements in accordance with the Financial Accounting Standard Board's amended guidance on the presentation of comprehensive income. The new guidance was effective for the Company January 1, 2012.

In May 2011, the FASB issued ASU No. 2011-04, "Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs" (ASU 2011-04). This newly issued accounting standard clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. The provisions of this new disclosure standard are effective January 1, 2012. This accounting standard update did not have a material effect on the Company's financial statements.

### ***Subsequent Events***

Subsequent events are defined as those events or transactions that occur after the balance sheet date, but before the financial statements are filed with the Securities and Exchange Commission. The Company completed an evaluation of the impact of any subsequent events through the date these financial statements were issued, and determined there were no subsequent events requiring disclosure in or requiring adjustment to these financial statements.

### **(3) Investments**

The Company has determined that all of its investments are classified as available-for-sale. Available-for-sale securities are carried at fair value with interest on these securities included in interest income and are recorded based primarily on quoted market prices. Available-for-sale securities consisted of the following:

(In thousands)	<u>Amortized Cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Estimated fair value</u>
December 31, 2012				
US Treasury bonds .....	\$291,209	\$104	\$(1)	\$291,312
December 31, 2011				
US Treasury bonds .....	\$237,887	\$72	\$(6)	\$237,953

The Company's short-term and long-term investments consist of US Treasury bonds. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value. The impairment would be charged to earnings for the difference between the investment's cost and fair value at such date and a new cost basis for the security established. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the issuer; adverse changes in the general market condition in which the issuer operates; the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment; and, issues that raise concerns about the issuer's ability to continue as a going concern. The Company has determined that there were no other-than-temporary declines in the fair values of its short term investments as of December 31, 2012.

Short-term investments with maturity of three months or less from date of purchase have been classified as cash and cash equivalents, and amounted to \$27.9 million and \$38.3 million as of December 31, 2012 and 2011, respectively. Short-term investments have original maturities of greater than 3 months but less than 1 year and long-term investments are greater than 1 year and up to 16 months.

#### (4) Property and Equipment

Property and equipment consisted of the following:

(In thousands)	December 31, 2012	December 31, 2011	Estimated useful lives used
Leasehold improvements .....	\$10,167	\$3,240	Remaining lease term
Computer equipment .....	8,651	5,859	2-3 years
Laboratory equipment .....	3,562	2,534	5 years
Furniture and fixtures .....	1,645	760	7 years
Capital in progress .....	1,810	1,093	2-3 years
	<u>25,835</u>	<u>13,486</u>	
Less accumulated depreciation.....	(9,129)	(9,628)	
	<u>\$16,706</u>	<u>\$3,858</u>	

Depreciation and amortization expense on property and equipment was \$2.7 million and \$1.5 million for the years ended December 31, 2012 and 2011, respectively.

#### (5) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	December 31, 2012	December 31, 2011
Accrued inventory .....	\$9,222	\$2,464
Bonus payable .....	6,361	4,725
Ampyra and Zanaflex discount and allowances accruals.....	4,603	4,680
Commercial and marketing expense accruals .....	3,367	1,811
Research and development expense accruals.....	2,182	640
Sales force commissions and incentive payments payable .....	1,820	1,893
Royalties payable .....	1,680	1,977
Ampyra milestone .....	—	2,500
Other accrued expenses.....	6,523	3,459
	<u>\$35,758</u>	<u>\$24,149</u>

#### (6) Common Stock Options and Restricted Stock

On June 18, 1999, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 1999 Employee Stock Option Plan (the 1999 Plan). All employees of the Company were eligible to participate in the 1999 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The number of shares authorized for issuance under the 1999 Plan was 2,481,334.

On January 12, 2006, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 2006 Employee Incentive Plan (the 2006 Plan). This 2006 Plan serves as the successor to the Company's 1999 Plan, as amended, and no further option grants or stock issuances shall be made under the 1999 Plan after the effective date, as determined under Section 14 of the 2006 Plan. All employees of the Company are eligible to participate in the 2006 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The 2006 Plan also covers the issuance of restricted stock. The 2006 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals to be granted options and restricted stock, determines the time or times at which options and restricted stock shall be granted under the 2006 Plan, determines the number of shares to be granted subject to any option or restricted stock under the 2006 Plan and the duration of each option and restricted stock, and makes any other determinations necessary, advisable, and/or appropriate to administer the 2006 Plan. Under the 2006 Plan, each

option granted expires no later than the tenth anniversary of the date of its grant. The number of shares of common stock reserved for issuance pursuant to awards made under the 2006 Plan as of December 31, 2012 is 9,954,385 shares of stock. The total number of shares of common stock available for issuance under this 2006 Plan, including shares of common stock subject to the then outstanding awards, shall automatically increase on January 1 of each year during the term of this plan, beginning 2007, by a number of shares of common stock equal to 4% of the outstanding shares of common stock on that date, unless otherwise determined by the Board of Directors. The Board approved the automatic increases of 4% for 2012, 2011, and 2010. Upon the exercise of options in the future, the Company intends to issue new shares.

The fair value of each option granted is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Year ended December 31,		
	2012	2011	2010
Employees and directors:			
Estimated volatility .....	60.67%	62.80%	66.31%
Expected life in years .....	5.64	5.47	5.50
Risk free interest rate .....	1.16%	2.23%	2.57%
Dividend yield .....	—	—	—

The Company estimated volatility for purposes of computing compensation expense on its employee and non-employee options using the historic volatility of the Company's stock price. The expected life used to estimate the fair value of employee options is 5.64 years which is based on the historical life of the Company's options based on exercise data.

The weighted average fair value per share of options granted to employees and directors for the years ended December 31, 2012, 2011 and 2010 amounted to approximately \$13.67, \$13.02, and \$19.29, respectively. No options were granted to non-employees for the years ended December 31, 2012, 2011 and 2010.

During the year ended December 31, 2012, the Company granted 1,612,037 stock options and restricted stock awards to employees and directors under the 2006 Plan. These stock options were issued with a weighted average exercise price of \$25.69 per share. 500 of these options vested immediately, 71,372 of these options vest over a one-year vesting schedule and 1,219,982 will vest over a four-year vesting schedule. The 320,183 restricted stock awards granted in 2012 vest over a four-year vesting schedule. As a result of these grants the total compensation charge to be recognized over the service period is \$24.4 million, of which \$5.5 million was recognized during the year ended December 31, 2012.

Compensation costs for options and restricted stock granted to employees and directors amounted to \$21.4 million, \$19.3 million, and \$17.8 million, for the years ended December 31, 2012, 2011 and 2010, respectively. There were no compensation costs capitalized in inventory balances. Compensation expense for options and restricted stock granted to employees and directors are classified between research and development, sales and marketing and general and administrative expense based on employee job function.

The following table summarizes share-based compensation expense included within our consolidated statements of operations:

(In thousands)	Year ended December 31,		
	2012	2011	2010
Research and development	\$ 5,122	\$ 5,801	\$ 5,247
Selling, general and administrative	16,296	13,502	12,530
Total	<u>\$ 21,418</u>	<u>\$ 19,303</u>	<u>\$ 17,777</u>

A summary of share-based compensation activity for the year ended December 31, 2012 is presented below:

**Stock Option Activity**

	Number of Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value (In thousands)
Balance at December 31, 2009 .....	3,712	\$15.25		
Granted .....	1,136	32.49		
Forfeited and expired .....	(116)	25.09		
Exercised .....	(648)	13.00		
Balance at December 31, 2010 .....	4,084	20.13		
Granted .....	1,239	23.52		
Forfeited and expired .....	(201)	25.97		
Exercised .....	(329)	12.06		
Balance at December 31, 2011 .....	4,793	21.31		
Granted .....	1,292	25.69		
Forfeited and expired .....	(166)	27.98		
Exercised .....	(252)	17.24		
Balance at December 31, 2012 .....	5,667	\$22.30	6.6	\$24,937
Vested and expected to vest at December 31, 2012 .....	5,609	\$22.27	6.6	\$24,892
Vested and exercisable at December 31, 2012 .....	3,639	\$20.35	5.5	\$22,925

Range of exercise price	Options Outstanding			Options Exercisable	
	Outstanding as of December 31, 2012 (In thousands)	Weighted-average remaining contractual life	Weighted-average exercise price	Exercisable as of December 31, 2012 (In thousands)	Weighted-average exercise price
\$2.45-\$16.88 .....	989	2.38	\$7.35	989	\$7.35
\$17.52-\$21.97 .....	917	5.97	20.25	810	20.14
\$22.00-\$24.39 .....	1,352	7.48	22.35	704	22.33
\$24.51-\$29.92 .....	1,433	8.64	26.55	453	26.96
\$30.12-\$37.48 .....	976	7.38	33.05	683	5.23
	<u>5,667</u>	<u>6.62</u>	<u>\$22.30</u>	<u>3,639</u>	<u>\$20.35</u>

## Restricted Stock Activity

<u>Restricted Stock</u>	<u>Number of Shares (In thousands)</u>
Nonvested at December 31, 2009.....	204
Granted .....	334
Vested.....	(196)
Forfeited .....	(18)
Nonvested at December 31, 2010.....	324
Granted .....	302
Vested.....	(221)
Forfeited .....	(28)
Nonvested at December 31, 2011.....	377
Granted .....	320
Vested.....	(224)
Forfeited .....	(15)
Nonvested at December 31, 2012.....	<u>458</u>

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2012 totaled \$36.0 million and is expected to be recognized over a weighted average period of approximately 2.4 years.

## (7) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2012, 2011 and 2010:

(In thousands, except per share data)	<u>Year ended December 31, 2012</u>	<u>Year ended December 31, 2011</u>	<u>Year ended December 31, 2010</u>
<b>Basic and diluted</b>			
Net income (loss) .....	\$154,958	\$30,605	\$(11,769)
Weighted average common shares outstanding used in computing net income (loss) per share—basic .....	39,459	39,000	38,355
Plus: net effect of dilutive stock options and restricted common shares .....	873	1,064	—
Weighted average common shares outstanding used in computing net income (loss) per share—diluted .....	40,332	40,064	38,355
Net income (loss) per share—basic .....	\$3.93	\$0.78	\$(0.31)
Net income (loss) per share—diluted .....	<u>\$3.84</u>	<u>\$0.76</u>	<u>\$(0.31)</u>

The difference between basic and diluted shares is that diluted shares include the dilutive effect of the assumed exercise of outstanding securities. The Company's stock options and unvested shares of restricted common stock could have the most significant impact on diluted shares.

Securities that could potentially be dilutive are excluded from the computation of diluted earnings per share when a loss from continuing operations exists or when the exercise price exceeds the average closing price of the Company's common stock during the period, because their inclusion would result in an anti-dilutive effect on per share amounts.

The following amounts were not included in the calculation of net income per diluted share because their effects were anti-dilutive:

(In thousands)	Year ended December 31, 2012	Year ended December 31, 2011	Year ended December 31, 2010
<b>Denominator</b>			
Stock options and restricted common shares ...	5,252	4,106	4,408
Convertible note.....	48	58	67

## (8) Income Taxes

The income tax provision (benefit) is based on income before income taxes as follows:

(In thousands)	Year ended December 31, 2012	Year ended December 31, 2011	Year ended December 31, 2010
Income (loss) before taxes	\$24,268	\$32,018	\$(11,769)

The benefit from/(provision for) income taxes in 2012, 2011 and 2010 consists of current and deferred federal, state and foreign taxes as follows:

(In thousands)	Year ended December 31, 2012	Year ended December 31, 2011	Year ended December 31, 2010
Current:			
Federal.....	\$(640)	\$(912)	\$—
State.....	(1,138)	(501)	—
Foreign .....	(574)	—	—
	<u>(2,352)</u>	<u>(1,413)</u>	<u>—</u>
Deferred:			
Federal.....	119,247	—	—
State.....	13,795	—	—
Foreign .....	—	—	—
	<u>133,042</u>	<u>—</u>	<u>—</u>
Total benefit from/(provision for) income taxes .....	<u>\$130,690</u>	<u>\$(1,413)</u>	<u>\$—</u>

In the fourth quarter of 2012, the Company reversed the valuation allowance recorded against its net deferred tax assets. The decision to reverse the valuation allowance in full was made after management determined, based on an assessment of historical profitability and forecasts of future taxable income, that it was more likely than not that these deferred tax assets would be realized. It will continue to evaluate the necessity for a valuation allowance on these and future net deferred tax assets based on available evidence at each reporting period in conformity with ASC 740.

Due to the amount of net operating loss (NOL) and tax credit carryforwards, the Company does not currently pay substantial U.S. federal income taxes. The Company expects to pay cash taxes in various US states and Puerto Rico where it has operations and NOL carryforwards are not available. The Company was subject to the alternative minimum tax during 2011 and 2012 and expects to be subject to cash payments for this in the near term. The payment of an alternative minimum tax amount generates a credit that may be carried forward indefinitely and used to offset our regular income tax liability.

The Company had available federal NOL carryforwards of approximately \$205.1 million and \$229.7 million and state NOL carryforwards of approximately \$19.4 million and \$34.0 million as of December 31, 2012 and 2011, respectively, which are available to offset future taxable income. A tax benefit of \$8.6 million associated with the exercise of stock options will be recorded in additional paid-in capital when the associated net operating loss is recognized. The federal losses are expected to expire between 2023 and 2030 while the state losses are expected to expire during similar periods, although not all states conform to the federal carryforward period and occasionally limit the use of net operating losses for a period of time. The Company is no longer subject to federal or state income tax audits for tax years prior to 2007 however, such taxing authorities can review any net operating losses utilized by the Company in years subsequent to 1999. The Company also has research and development credit carry-forwards of \$4.4 million and \$4.2 million as of December 31, 2012 and 2011, respectively are subject to expiration starting in 2029. The Company also has Alternative Minimum Tax credit carry-forwards of \$1.8 million and \$1.1 million as of December 31, 2012 and 2011, respectively. Such credits can be carried forward indefinitely and have no expiration date.

The Tax Reform Act of 1986 contains certain provisions that can limit a taxpayer's ability to utilize net operating loss and tax credit carryforwards in any given year resulting from cumulative changes in ownership interests in excess of 50 percent over a three-year period. We have determined that these limiting provisions were triggered during a prior year and in the current year in connection with the Neuronex acquisition. However, we believe that such limitation is not expected to result in the expiration or loss of any of our federal NOL's and income tax credit carryforwards. Future ownership changes may limit the use of these carryforwards.

The provision (benefit) for income taxes differs from the U.S. federal statutory tax rate. The reconciliation of the statutory U.S. federal income tax rate to our effective income tax rate is as follows:

(In thousands)	Year ended December 31, 2012	Year ended December 31, 2011	Year ended December 31, 2010
U.S. federal statutory tax rate.....	35.0%	35.0%	35.0%
State and local income taxes .....	2.4%	1.0%	—
Foreign income tax.....	1.5%	—	—
Stock option compensation .....	1.9%	1.2%	—
Stock option shortfall .....	5.6%	—	—
Neuronex acquisition.....	9.4%	—	—
Other nondeductible and permanent differences .....	3.3%	(12.4%)	—
Provision (benefit) attributable to valuation allowance.....	(597.6%)	(20.4%)	(35%)
Effective income tax rate.....	<u>(538.5%)</u>	<u>4.4%</u>	<u>—</u>



Provisions have been made for deferred taxes based on the differences between the basis of the assets and liabilities for financial statement purposes and the basis of the assets and liabilities for tax purposes using currently enacted tax rates and regulations that will be in effect when the differences are expected to be recovered or settled. The components of the deferred tax assets and liabilities are as follows:

(In thousands)	<b>December 31, 2012</b>	<b>December 31, 2011</b>
<b>Deferred tax assets:</b>		
Net operating loss carryforwards .....	\$64,121	\$75,717
Tax credits.....	4,568	4,025
Deferred revenue.....	36,646	38,958
Stock based compensation .....	17,849	13,910
Other .....	14,756	15,518
Total deferred tax assets.....	137,940	148,128
Valuation allowance.....	—	(147,596)
Total deferred tax assets net of valuation allowance.....	137,940	532
<b>Deferred tax liabilities:</b>		
Property, plant and equipment .....	(1,213)	(532)
Total deferred tax liabilities .....	(1,213)	(532)
Net deferred tax asset.....	<u>\$136,727</u>	<u>\$ —</u>
(In thousands)	<b>December 31, 2012</b>	<b>December 31, 2011</b>
<b>Current deferred tax assets, net:</b>		
Current deferred tax assets, net of deferred tax liabilities .....	\$35,091	\$30,310
Valuation allowance.....	—	(30,310)
Current deferred tax assets, net.....	35,091	—
<b>Non-current deferred tax assets, net:</b>		
Non-current deferred tax assets, net of deferred tax liabilities.....	101,636	117,286
Valuation allowance.....	—	(117,286)
Non-current deferred tax assets, net.....	101,636	—
Net deferred tax asset.....	<u>\$136,727</u>	<u>\$ —</u>

The Company follows authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

The beginning and ending amounts of unrecognized tax benefits reconciles as follows:

(In thousands)	<b>Year ended December 31, 2012</b>	<b>Year ended December 31, 2011</b>	<b>Year ended December 31, 2010</b>
Beginning of period balance	\$—	\$—	\$—
Increases for tax positions taken during a prior period .....	1,936	—	—
Decreases for tax positions taken during a prior period.....	—	—	—
Increases for tax positions taken during the current period .....	—	—	—
Reduction as a result of a lapse of statute of limitations.....	—	—	—
	<u>\$1,936</u>	<u>\$—</u>	<u>\$—</u>

Due to the amount of the Company's NOLs and tax credit carryforwards, it has not accrued interest relating to these unrecognized tax benefits. Accrued interest and penalties, however, would be disclosed within the related liabilities lines in the consolidated balance sheet and recorded as a component of income tax expense. Unless related to excess tax benefits from stock options, all of our unrecognized tax benefits, if recognized, would impact the effective tax rate.

The Company files federal and state income tax returns in the U.S. and Puerto Rico. The U.S. and Puerto Rico have statute of limitations ranging from 3 to 5 years. However, the statute of limitations could be extended due to the Company's NOL carryforward position in a number of its jurisdictions. The tax authorities, generally, have the ability to review income tax returns for periods where the statute of limitation has previously expired and can subsequently adjust the NOL carryforward or tax credit amounts. Accordingly, the Company does not expect to reverse any portion of the unrecognized tax benefits within the next year.

## **(9) License, Research and Collaboration Agreements**

### *Alkermes plc, formerly Elan plc*

The Company has entered into agreements with Elan Corporation plc, including those described immediately below and elsewhere in these financial statements. In September 2011, Alkermes plc acquired Elan's Drug Technologies business and Elan transferred our agreements to Alkermes as part of that transaction. Throughout this report, references to "Alkermes" include Alkermes plc and also, as the context may require, Elan Corporation plc as the predecessor to Alkermes plc under our agreements.

The Company is a party to a 2003 amended and restated license agreement and a 2003 supply agreement with Alkermes for Ampyra, which replaced two prior license and supply agreements for Ampyra. Under the license agreement, the Company has exclusive worldwide rights to Ampyra, as well as Alkermes' formulation for any other mono or di-aminopyridines, for all indications, including multiple sclerosis and spinal cord injury. The Company is obligated to pay Alkermes milestone payments and royalties based on a percentage of net product sales and the quantity of product shipped by Alkermes to Acorda.

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

Under the supply agreement, Alkermes has the right to manufacture for the Company, subject to certain exceptions, Ampyra and other products covered by these agreements at specified prices calculated as a percentage of net product sales of the product shipped by Alkermes to Acorda. In the event Alkermes does not manufacture the products, it is entitled to a compensating payment for the quantities of product provided by the alternative manufacturer.

### *Convertible Note*

Under the Agreement, Alkermes also loaned to the Company an aggregate of \$7.5 million pursuant to two convertible promissory notes. On December 23, 2005, Alkermes transferred these promissory notes to funds affiliated with Saints Capital. One promissory note in the amount of \$5.0 million bears interest at a rate of 3% beginning on the first anniversary of the issuance of the note. The original unpaid principal was convertible into 67,476 shares of common stock. As of December 31, 2012 the unpaid principal was convertible into 48,197 shares of common stock. Principal and interest are repayable, if not converted, ratably over a seven-year period beginning one year after the Company receives certain regulatory approval for the products to be developed, subject to limitations related to gross margin on product sales. The \$5.0 million promissory note restricts the Company's ability to incur indebtedness that is senior to the notes, subject to certain exceptions, including for the Company's revenue interest assignment arrangement (See Note 13).

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

On January 22, 2010, the Company received regulatory approval for the product under development that was subject to this convertible note payable. Saints Capital held the option to convert the outstanding principal into common stock until the first anniversary of regulatory approval or January 22, 2011. Saints Capital did not convert by the first anniversary date, therefore the Company is obligated to pay the outstanding principal sum on the promissory note, together with all accrued and unpaid interest, subject to limitations related to gross margin on product sales, in seven equal installments, the first of which was paid on the maturity date, and the balance shall be paid on the six successive anniversaries of the maturity date. The Company, at its option, may at any time prepay in whole or in part, without penalty, the principal balance together with accrued interest to the date of payment, by giving Saints Capital written notice at least thirty days prior to the date of prepayment.

Interest on this convertible promissory note has been recorded using 3% on the \$5 million note.

#### *Supply Agreement*

The Company is a party to a 2003 supply agreement with Alkermes relating to the manufacture and supply of Ampyra by Alkermes. The Company is obligated to purchase at least 75% of its annual requirements of Ampyra from Alkermes, unless Alkermes is unable or unwilling to meet its requirements, for a percentage of net product sales and the quantity of product shipped by Alkermes to Acorda. In those circumstances, where the Company elects to purchase less than 100% of its requirements from Alkermes, the Company is obligated to make certain compensatory payments to Alkermes. Alkermes is required to assist the Company in qualifying a second manufacturer to manufacture and supply the Company with Ampyra subject to its obligations to Alkermes.

As permitted by the agreement with Alkermes, the Company has designated Patheon, Inc. (Patheon) as a qualified second manufacturing source of Ampyra. In connection with that designation, Alkermes assisted the Company in transferring manufacturing technology to Patheon. The Company and Alkermes have agreed that a purchase of up to 25% of annual requirements from Patheon is allowed if compensatory payments are made to Alkermes. In addition, Patheon may supply the Company with Ampyra if Alkermes is unable or unwilling to meet the Company's requirements.

#### *Rush-Presbyterian St. Luke's Medical Center*

In 1990, Alkermes licensed from Rush know-how relating to dalfampridine (4-aminopyridine, 4-AP, the formulation used in Ampyra), for the treatment of MS. The Company subsequently licensed this know-how from Alkermes. In September 2003, the Company entered into an agreement with Rush and Alkermes terminating the Rush license to Alkermes and providing for mutual releases. The Company also entered into a license agreement with Rush in 2003 in which Rush granted the Company an exclusive worldwide license to its know-how relating to dalfampridine for the treatment of MS. Rush has also assigned to the Company its Orphan Drug Designation for dalfampridine for the relief of symptoms of MS.

The Company 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. The FDA approval of Ampyra triggered the final milestone of \$750,000 which was paid during the three-months ended March 31, 2010. As of December 31, 2010, all milestone obligations were met and the Company had made an aggregate of \$850,000 in milestone payments under this agreement. As of December 31, 2012, the Company made or accrued royalty payments totaling \$13.0 million.

## ***Biogen Idec***

On June 30, 2009, the Company entered into an exclusive collaboration and license agreement with Biogen Idec International GmbH (Biogen Idec) to develop and commercialize Ampyra (known as Fampyra outside the U.S.) in markets outside the United States (the “Collaboration Agreement”). Under the Collaboration Agreement, Biogen Idec was granted the exclusive right to commercialize Ampyra and other products containing aminopyridines developed under that agreement in all countries outside of the United States, which grant includes a sublicense of the Company’s rights under an existing license agreement between the Company and Alkermes plc (Alkermes), formerly Elan Corporation, plc (Elan). Biogen Idec has responsibility for regulatory activities and future clinical development of Fampyra in ex-U.S. markets worldwide. The Company also entered into a related supply agreement with Biogen Idec (the “Supply Agreement”), pursuant to which the Company will supply Biogen Idec with its requirements for the licensed products through the Company’s existing supply agreement with Alkermes.

Under the Collaboration Agreement, the Company was entitled to an upfront payment of \$110.0 million as of June 30, 2009, which was received in July 2009, and a \$25 million milestone payment upon approval of the product in the European Union, which was received in August 2011. The Company is also entitled to receive additional payments of up to \$10 million based on the successful achievement of future regulatory milestones and up to \$365 million based on the successful achievement of future sales milestones. Due to the uncertainty surrounding the achievement of the future regulatory and sales milestones, these payments will not be recognized as revenue unless and until they are earned. The Company is not able to reasonably predict if and when the milestones will be achieved. Under the Collaboration Agreement, Biogen Idec will be required to make double-digit tiered royalty payments to the Company on ex-U.S. sales. In addition, the consideration that Biogen Idec will pay for licensed products under the Supply Agreement will reflect the price owed to the Company’s suppliers under its supply arrangements with Alkermes or other suppliers for ex-U.S. sales. The Company and Biogen Idec may also carry out future joint development activities regarding licensed product under a cost-sharing arrangement. Under the terms of the Collaboration Agreement, the Company, in part through its participation in joint committees with Biogen Idec, will participate in overseeing the development and commercialization of Ampyra and other licensed products in markets outside the United States pursuant to that agreement. Acorda will continue to develop and commercialize Ampyra independently in the United States.

As of June 30, 2009, the Company recorded a license receivable and deferred revenue of \$110.0 million for the upfront payment due to the Company from Biogen Idec under the Collaboration Agreement. Also, as a result of such payment to Acorda, a payment of \$7.7 million became payable by Acorda to Alkermes and was recorded as a cost of license payable and deferred expense. The payment of \$110.0 million was received from Biogen Idec on July 1, 2009 and the payment of \$7.7 million was made to Alkermes on July 7, 2009.

The Company considered the following deliverables with respect to the revenue recognition of the \$110.0 million upfront payment: (1) the license to use the Company’s technology, (2) the Collaboration Agreement to develop and commercialize licensed product in all countries outside the U.S., and (3) the Supply Agreement. Due to the inherent uncertainty in obtaining regulatory approval, the applicability of the Supply Agreement is outside the control of the Company and Biogen Idec. Accordingly, the Company has determined the Supply Agreement is a contingent deliverable at the onset of the agreement. As a result, the Company has determined the Supply Agreement does not meet the definition of a deliverable that needs to be accounted for at the inception of the arrangement. The Company has also determined that there is no significant and incremental discount related to the supply agreement since Biogen Idec will pay the same amount for inventory that the Company would pay and the Company effectively acts as a middle man in the arrangement for which it adds no significant value due to various factors such as the Company does not have any manufacturing capabilities or other knowhow with respect to the manufacturing process.

The Company has determined that the identified non-contingent deliverables (deliverables 1 and 2 immediately preceding) would have no value on a standalone basis if they were sold separately by a vendor and the customer could not resell the delivered items on a standalone basis, nor does the Company have objective and

reliable evidence of fair value for the deliverables. Accordingly, the non-contingent deliverables are treated as one unit of accounting. As a result, the Company will recognize the non-refundable upfront payment from Biogen Idec as revenue and the associated payment to Alkermes as expense ratably over the estimated term of regulatory exclusivity for the licensed products under the Collaboration Agreement as the Company had determined this was the most probable expected benefit period. The Company recognized \$9.1 million in amortized license revenue, a portion of the \$110.0 million received from Biogen Idec, and \$634,000 in cost of license revenue, a portion of the \$7.7 million paid to Alkermes, during each of the twelve-month periods ended December 31, 2012 and 2011.

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 Fampyra to improve walking ability in adult patients with multiple sclerosis. Biogen Idec, working closely with the Company, filed a formal appeal of the decision. In May 2011, the CHMP recommended conditional marketing authorization, and in July 2011 Biogen Idec received conditional approval from the European Commission for, Fampyra (prolonged-release fampridine tablets) for the improvement of walking in adult patients with MS with walking disability (Expanded Disability Status Scale of 4-7). The Company changed the amortization period on a prospective basis during the three-month period ended March 31, 2011 by five months and currently estimates the recognition period to be approximately 12 years from the date of the Collaboration Agreement.

As part of its ex-U.S. license agreement, Biogen Idec owes Acorda royalties based on ex-U.S. net sales, and milestones based on ex-U.S. regulatory approval, new indications, and ex-U.S. net sales. These milestones included a \$25 million payment for approval of the product in the European Union which was recorded and paid in the three month period ended September 30, 2011. Based on Acorda's worldwide license and supply agreement with Alkermes, Alkermes received 7% of this milestone payment from Acorda during the same period. For revenue recognition purposes, the Company has determined this milestone to be substantive in accordance with applicable accounting guidance related to milestone revenue. Substantive uncertainty existed at the inception of the arrangement as to whether the milestone would be achieved because of the numerous variables, such as the high rate of failure inherent in the research and development of new products and the uncertainty involved with obtaining regulatory approval. Biogen Idec leveraged Acorda's U.S. Ampyra study results that contributed to the regulatory approval process. Therefore, the milestone was achieved based in part on Acorda's past performance. The milestone was also reasonable relative to all deliverable and payment terms of the collaboration arrangement. Therefore, the payment was recognized in its entirety as revenue and the cost of the milestone revenue was recognized in its entirety as an expense during the three-month period ended September 30, 2011.

Cost of milestone and license revenue includes \$634,000 in cost of license revenue for the twelve-month periods ended December 31, 2012 and 2011, which represents the amortized portion of the \$7.7 million paid to Alkermes in 2009, for both of the twelve-month periods ended December 31, 2012 and 2011. For the twelve-month period ended December 31, 2011 it also includes \$1.8 million in cost of milestone revenue, which represents the 7% Alkermes portion of the \$25 million milestone paid during the three-month period ended September 30, 2011.

### ***Actavis/Watson***

The Company has an agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), to market tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules, which was launched in February 2012. In accordance with the Watson agreement, the Company receives a royalty based on Watson's gross margin, as defined by the agreement, of the authorized generic product. During the twelve-month period ended December 31, 2012, the Company recognized royalty revenue of \$7.2 million related to the gross margin of the Zanaflex Capsule authorized generic. During the twelve-month period ended December 31, 2012, the Company also recognized revenue and a corresponding cost of sales of \$3.1 million related to the purchase and sale of the related Zanaflex Capsule authorized generic product to Watson, which is recorded in net product revenues and cost of sales.

## *Neuronex*

In December 2012, the Company acquired Neuronex, Inc., a privately-held development stage pharmaceutical company (Neuronex). Neuronex is developing Diazepam Nasal Spray under Section 505(b)(2) of the Food, Drug and Cosmetic Act as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity also known as cluster or acute repetitive seizures, or ARS.

Under the terms of the agreement, the Company made an upfront payment of \$2.0 million in February 2012. The Company also paid \$1.5 million during the twelve month period ended December 31, 2012 pursuant to a commitment under the agreement to fund research to prepare for the Diazepam Nasal Spray pre-NDA meeting with the FDA. In December 2012, the Company completed the acquisition by paying \$6.8 million to former Neuronex shareholders less a \$300,000 holdback provision to be settled in December 2013.

The former equity holders of Neuronex are entitled to receive from Acorda up to an additional \$18 million in contingent earnout payments upon the achievement of specified regulatory and manufacturing-related milestones with respect to the Diazepam Nasal Spray product, and up to \$105 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. The former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments, ranging from the upper single digits to lower double digits, on worldwide net sales of Diazepam Nasal Spray products. These payments are payable on a country-by-country basis until the earlier to occur of ten years after the first commercial sale of a product in such country and the entry of generic competition in such country as defined in the Agreement.

The patent and other intellectual property and other rights relating to the Diazepam Nasal Spray product are licensed from SK Biopharmaceuticals Co., Ltd. (SK). Pursuant to the SK license, which granted worldwide rights to Neuronex, except certain specified Asian countries, the Company's subsidiary Neuronex is obligated to pay SK up to \$8 million upon the achievement of specified development milestones with respect to the Diazepam Nasal Spray product and up to \$3 million upon the achievement of specified sales milestones with respect to the Diazepam Nasal Spray product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products.

The Company evaluated the transaction based upon the guidance of ASC 805, *Business Combinations*, and concluded that it will only acquire inputs and did not acquire any processes. The Company will need to develop its own processes in order to produce an output. Therefore the Company accounted for the transaction as an asset acquisition and accordingly the \$2.0 million upfront payment, \$1.5 million in research funding and \$6.8 million of closing consideration net of tangible net assets acquired of \$3.7, million which were primarily the taxable amount of net operating loss carryforwards, were expensed as research and development expense during the twelve-month period ended December 31, 2012.

### **(10) Employee Benefit Plan**

Effective September 1, 1999, the Company adopted a defined contribution 401(k) savings plan (the 401(k) plan) covering all employees of the Company. Participants may elect to defer a percentage of their annual pretax compensation to the 401(k) plan, subject to defined limitations. Effective January 1, 2007, the Company amended the plan to include an employer match contribution to employee deferrals. For each dollar an employee invests up to 6% of his or her earnings, the Company will contribute an additional 50 cents into the funds. The Company's expense related to the plan was \$1.3 million, \$1.1 million and \$1.0 million for the years ended December 31, 2012, 2011, and 2010, respectively.

## (11) Commitments and Contingencies

### *Leases*

The lease for the Company's former corporate headquarters was scheduled to expire in December 2012. In connection with the Company entering into a lease for a new headquarters facility in 2011, it exercised its right to accelerate the termination date to June 2012. In June 2011, the Company entered into a 15 year lease for an aggregate of approximately 138,000 square feet of laboratory and office space in Ardsley, New York. The Company took possession of the new space in July 2012. The Company has options to extend the term of the lease for three additional five-year periods, and it has an option to terminate the lease after 10 years subject to payment of an early termination fee. Also, the Company has rights to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. Our extension, early termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that we not be in default under the lease. The lease provides for monthly payments of rent during the term. These payments consist of base rent, which takes into account the costs of the facility improvements being funded by the facility owner prior to our occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges. The base rent is initially \$3.4 million per year, and is subject to a 2.5% annual increase.

Future minimum commitments under all non-cancelable leases required subsequent to December 31, 2012 are as follows:

(In thousands)	
2013 .....	\$3,443
2014 .....	3,529
2015 .....	3,617
2016 .....	3,707
2017 .....	3,800
Later years .....	22,194
	<u>\$40,290</u>

Rent expense under these operating leases during the years ended December 31, 2012, 2011 and 2010 was \$3.5 million, \$1.1 million, and \$1.1 million, respectively.

### *License Agreements*

Under the Company's Ampyra license agreement with Alkermes, the Company is obligated to make milestone payments to Alkermes of up to \$15.0 million over the life of the contract and royalty payments as a percentage of net product sales and the quantity of product shipped by Alkermes to Acorda. In addition, under the Company's various other research, license and collaboration agreements with other parties, it is obligated to make milestone payments of up to an aggregate of approximately \$192 million over the life of the contracts. The FDA approval of Ampyra triggered a milestone of \$2.5 million to Alkermes that was paid during the quarter ended June 30, 2010. An additional milestone payment to Alkermes was paid during the quarter ended March 31, 2012 with an additional \$2.5 million recorded as an intangible asset. Further milestone amounts are payable in connection with additional indications.

Under the Company's Ampyra supply agreement with Alkermes, payments for product manufactured by Alkermes are calculated as a percentage of net product sales and the quantity of product shipped by Alkermes to Acorda. Under this agreement, Acorda also has the option to purchase an agreed to quantity of product from a second source provided Acorda makes a compensating payment to Alkermes for the quantities of product provided by the second source.

Under the Company's license agreement with Rush-Presbyterian-St. Luke's Medical Center, it is obligated to make royalty payments as a percentage of net sales in the United States and in countries other than the United States.

Under the Company's supply agreement with Alkermes, it provides Alkermes with monthly written 18-month forecasts, and with annual written five-year forecasts for its supply requirements of Ampyra and two-year forecasts for its 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 the Company is obligated to purchase the quantity specified in the forecast, even if its actual requirements are greater or less.

#### *Employment Agreements*

The Company has an employment agreement with its Chief Executive Officer under which the Chief Executive Officer is entitled to severance and other payments if his employment is terminated under certain circumstances. The employment agreement was amended in 2011. Under the employment agreement as amended, if the Company terminates the Chief Executive Officer for reasons other than cause or if the Chief Executive Officer terminates his employment for good reason, the Company must pay (i) an amount equal to the base salary the chief executive officer would have received during the 24 month period immediately following the date of termination, plus (ii) bonus equal to the Chief Executive Officer's last annual bonus, prorated based on the number of days in the calendar year elapsed as of the termination date. If the termination occurs after a change in control, then the bonus is an amount equal to two (2) times the larger of the Chief Executive Officer's (x) prior year annual bonus and (y) target annual bonus for the year of termination. The Chief Executive Officer is also entitled to COBRA premium payments for the 24 month severance period.

The Company also has employment agreements with some of its other executive officers, including the Company's Chief Scientific Officer, Chief, Strategic Development and General Counsel and Chief Financial Officer, that govern the terms and conditions of their employment. These agreements were amended during 2011. Under these agreements as amended, if the Company terminates the employment of any of the executive officers for reasons other than cause, or if any of the executive officers terminates his or her employment for good reason, the Company must (i) make severance payments equal to the base salary the executive would have received during the twelve month period immediately following the date of termination, plus (ii) a bonus equal to the executive officer's target cash bonus for the year of termination, prorated based on the number of days in the calendar year elapsed as of the termination date. If the termination occurs within 18 months after a change in control, then the severance payment is 24 months of base salary and is paid in a lump sum, and the bonus is an amount equal to two (2) times the executive officer's target cash bonus for the year of termination. The executive officers are also entitled to COBRA premium payments for the relevant severance period.

The Company also has a change in control agreement with its Chief Medical Officer. Under this agreement, if the Company terminates the employment of the Chief Medical Officer for reasons other than cause within twelve months following a change in control, or if the Chief Medical Officer terminates his employment for good reason within six months following a change in control, the Company must pay the Chief Medical Officer (i) a lump sum equal to the base salary the Chief Medical Officer would have received during the 24 month period immediately following the date of termination, plus (ii) a bonus equal to two times the Chief Medical Officer's target cash bonus for the year of termination. The Chief Medical Officer is also entitled to COBRA premium payments for the severance period.

#### *Other*

In August 2012, the Company received a letter from PRF alleging that it breached specified covenants and representations in the PRF agreement and purporting to exercise the put option. The letter also includes an allegation that PRF has suffered injuries beyond what is covered by their purported exercise of the put option, although it does not specify or quantify those injuries. The Company believes that the allegations are without merit and that the put option has not been validly exercised. Although the letter from PRF does not include a purported calculation of the put option price, if it were validly exercised, the Company estimates that the



incremental cost in excess of amounts already accrued to PRF at December 31, 2012 would be no more than approximately \$2.5 million.

On December 2, 2011, Apotex filed suit against the Company in the U.S. District Court for the Southern District of New York. In that suit, Apotex alleged, among other claims, that the Company engaged in anticompetitive behavior and false advertising in connection with the development and marketing of Zanaflex Capsules, including that the citizen petition the Company filed with the FDA delayed FDA approval of Apotex's generic tizanidine capsules. On January 26, 2012, the Company moved to dismiss or stay Apotex's suit. On February 3, 2012, the FDA denied the citizen petition that the Company filed and approved Apotex's ANDA for a generic version of Zanaflex Capsules. On February 21, 2012, Apotex filed an amended complaint that incorporated the FDA action, but otherwise made allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits, recovery of litigation costs, and injunctive relief. Following the Company's filing of a motion to dismiss the amended complaint, in 2013 the Court dismissed six of the seven counts in the amended complaint, including all of the antitrust claims in the amended complaint, leaving only a claim under the Lanham Act relating to alleged product promotional activities. The Company has filed a motion for reconsideration of the decision regarding the Lanham Act claim. The Company intends to defend itself vigorously in the litigation. However, the Company cannot be sure that it will prevail in its defense, as the outcome of litigation is inherently uncertain, and an adverse determination could harm it.

The Company accrues for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. While losses, if any, are possible the Company is not able to estimate any ranges of losses as of December 31, 2012. Litigation expenses are expensed as incurred.

## **(12) Intangible Assets**

### *Zanaflex*

The Company acquired all of Alkermes' U.S. sales, marketing and distribution rights to Zanaflex Capsules and Zanaflex tablets in July 2004 for \$2.0 million plus \$675,000 for finished goods inventory. The Company was also responsible for up to \$19.5 million in future contingent milestone payments based on cumulative gross sales of Zanaflex tablets and Zanaflex Capsules. As of December 31, 2009, the Company made \$19.5 million of these milestone payments which were recorded as intangible assets in the consolidated financial statements.

The Company had sued Apotex Corp. and Apotex Inc. (collectively, "Apotex") for patent infringement related to Apotex Inc.'s submission of an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In September 2011, the the U.S. District Court for the District of New Jersey ruled against the Company in that litigation. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid as not enabled and not infringed by Apotex. In June 2012, the U.S. Court of Appeals for the Federal Circuit affirmed the decision. We did not seek any further appeals of the decision. The Company believes that the intangible asset associated with Zanaflex Capsules was fully impaired based on estimated undiscounted cash flows and the associated fair value of this asset and therefore the Company recorded an asset impairment charge of approximately \$13.0 million to write-off the remaining carrying value of this asset during the three-month period ended September 30, 2011 to cost of sales.

### *Ampyra*

On January 22, 2010, the Company received marketing approval from the FDA for Ampyra triggering two milestone payments of \$2.5 million to Alkermes, \$750,000 to Rush-Presbyterian St. Luke's Medical Center (Rush) and an additional \$2.5 million payable to Alkermes two years from date of approval. The Company made milestone payments totaling \$3.25 million which were recorded as intangible assets in the consolidated financial statements during the three-month period ended March 31, 2010. An additional milestone payment to Alkermes was paid during the three-month period ended March 31, 2012 with an additional \$2.5 million recorded as an intangible asset.

In April 2011 the Company announced the United States Patent and Trademark Office (USPTO) allowed U.S. Patent Application No. 11/010,828 entitled “Sustained Release Aminopyridine Composition.” The claims of the patent application relate to methods to improve walking in patients with multiple sclerosis (MS) by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent that issued from this application was accorded an initial patent term adjustment by the USPTO of 298 days, initially extending its term to early October 2025. In August 2011 the USPTO issued the Company’s Patent Application No. 11/010,828 as U.S. Patent No. US 8,007,826 entitled “Sustained Release Aminopyridine Composition.” The patent, which is listed in the FDA Orange Book, expires in May 2027. The estimated remaining useful life of this asset is presented in the table below.

In August 2003, the Company entered into an Amended and Restated License Agreement with the Canadian Spinal Research Organization (CSRO). Under this agreement, the Company was 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 required the Company to pay to CSRO royalties based on a percentage of net sales of any product incorporating the licensed rights, including royalties on the sale of Ampyra and on the sale of dalfampridine for any other indication. During the three-month period ended March 31, 2010, the Company purchased CSRO’s rights to all royalty payments under the agreement with CSRO for \$3.0 million. This payment was recorded as an intangible asset in the consolidated financial statements. The estimated remaining useful life of this asset is presented in the table below.

### Websites

Intangible assets also include certain website development costs which have been capitalized. The Company has developed several websites, each with its own purpose, including the general corporate website, product information websites and websites focused on the MS community. In June 2012 the Company received an untitled letter from the FDA stating that one of its Ampyra promotional videos did not comply with applicable law and was misleading because it overstated the efficacy of and minimized important safety information associated with Ampyra. In compliance with the untitled FDA letter, the Company discontinued use of the video, and in light of the FDA letter we also evaluated and discontinued the use of some other promotional materials. Much of the promotional material was available on one of the Company’s websites and, as a result of its compliance with the FDA, portions of its website were permanently impaired. A charge of approximately \$664,000 was recorded for this impairment and was recorded in selling, general and administrative expenses.

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its intangible assets may warrant revision or that the carrying value of these assets may be impaired. As of December 31, 2012, the Company does not believe that there are any facts or circumstances that would indicate a need for changing the estimated remaining useful life of the Company’s other intangible assets.

Intangible assets consisted of the following:

(In thousands)	December 31, 2012	December 31, 2011	Estimated remaining useful lives as of December 31, 2012
Zanaflex Capsule patents .....	\$19,350	\$19,350	0 years
Zanaflex trade name.....	2,150	2,150	0 years
Ampyra milestones .....	5,750	5,750	14 years
Ampyra CSRO royalty buyout.....	3,000	3,000	7 years
Website development costs.....	5,841	4,028	3 years
Website development costs – in process.....	712	42	3 years
	36,803	34,320	
Less accumulated amortization.....	27,484	25,551	
	<u>\$9,319</u>	<u>\$8,769</u>	

The Company recorded \$2.6 million and \$16.2 million in amortization expense related to these intangible assets in the years ended December 31, 2012 and 2011, respectively. The expense recorded in 2012 includes a \$664,000 charge for a website impairment charge relating to the removal of promotional materials as requested by the FDA recorded during the three-month period ended December 31, 2012. The expense recorded in 2011 includes \$13.0 million for Zanaflex Capsule intangible asset impairment recorded during the three-month period ended September 30, 2011 due to the trial court decision of the Apotex patent infringement lawsuit.

Estimated future amortization expense for intangible assets subsequent to December 31, 2012 for the next five years is as follows:

(In thousands)	
2013.....	\$1,826
2014.....	1,573
2015.....	1,368
2016.....	588
2017.....	588
	<u>\$5,943</u>

### **(13) Debt**

#### *Convertible Note*

The Company is a party to an amended and restated license agreement and a supply agreement with Alkermes, which replaced two prior license and supply agreements for Ampyra. Under the license agreement, Alkermes also loaned to the Company an aggregate of \$7.5 million pursuant to two convertible promissory notes. On December 23, 2005, Alkermes transferred these promissory notes to funds affiliated with Saints Capital. One promissory note remains outstanding in the amount of \$5.0 million bears interest at a rate of 3% beginning on the first anniversary of the issuance of the note (See Note 9).

#### *Sale of Revenue Interest*

On December 23, 2005, the Company entered into an agreement with an affiliate of Paul Royalty Fund (PRF), under which the Company received \$15 million in cash. In exchange the Company has assigned PRF revenue interest in Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all Zanaflex net revenues (as defined in the agreement) generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, the Company entered into an amendment to the revenue interest assignment agreement with PRF. Under the terms of the amendment, PRF paid the Company \$5.0 million in November 2006. An additional \$5.0 million was due to the Company if net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone was met and the receivable was reflected in the Company's December 31, 2006 financial statements. Under the terms of the amendment, the Company repaid PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010 since the net revenues milestone was met. Under the agreement and the amendment to the agreement, PRF is entitled to the following portion of Zanaflex net revenues:

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

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

In connection with the transaction, the Company recorded a liability, referred to as the revenue interest liability. The Company imputes interest expense associated with this liability using the effective interest rate method and records a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. The Company currently estimates that the imputed interest rate associated with this liability will be approximately 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. The Company recorded approximately \$1.7 million, \$3.4 million and \$3.8 million in interest expense related to this agreement in 2012, 2011 and 2010, respectively. Through December 31, 2012, \$45.7 million in payments have been made to PRF as a result of Zanaflex sales levels and milestones reached.

The agreement also contains put and call options whereby the Company may repurchase the revenue interest at its option or can be required by PRF to repurchase the revenue interest, contingent upon certain events. If the Company experiences a change of control, undergoes certain bankruptcy events, transfers any of their interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfers all or substantially all of its assets, or breaches certain of the covenants, representations or warranties made under the agreement, PRF has the right, which the Company refers to as PRF's put option, to require the Company to repurchase the rights sold to PRF at the "put/call price" in effect on the date such right is exercised. If the Company experiences a change of control it has the right, which the Company refers to as the Company's call option, to repurchase the rights sold to PRF at the "put/call price" in effect on the date such right is exercised. If the Company's call option becomes exercisable as a result of this trigger, the Company will have a period of 180 days during which to exercise the option. The Company does not currently intend to exercise its call option if it becomes exercisable as a result of such a transaction but may reevaluate whether it would exercise the option during the 180-day period. The put/call price on a given date is the greater of (i) 150% of all payments made by PRF as of such date, less all payments received by PRF as of such date, and (ii) an amount that would generate an internal rate of return to PRF of 25% on all payments made by PRF as of such date, taking into account the amount and timing of all payments received by PRF as of such date. The Company has determined that PRF's put option and the Company's call option meet the criteria to be considered an embedded derivative and should be accounted for as such. The Company recorded a net liability of \$329,000 as of December 31, 2012 related to the put/call option to reflect its current estimated fair value. This liability is revalued as needed to reflect any changes in the fair value and any gain or loss resulting from the revaluation is recorded in earnings. For the year ended December 31, 2012, a gain of \$701,000 has been recorded as a result of the change in the fair value of the net put/call liability balance from December 31, 2011.

#### **(14) Fair Value Measurements**

The Company defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. The Company bases fair value on the assumptions market participants would use when pricing the asset or liability.

The Company utilizes a fair value hierarchy which requires it to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company primarily applies the market approach for recurring fair value measurements. The standard describes three levels of inputs that may be used to measure fair value:

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

### Recurring

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2012, and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value. During the three-month period ended June 30, 2012 the Company reclassified its US Treasury bonds in short-term and long-term investments from Level 1 to Level 2 assets.

(In thousands)	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>2012</b>			
<b>Assets Carried at Fair Value:</b>			
Cash equivalents .....	\$27,932	\$—	\$—
Short-term investments .....	—	191,949	—
Long-term investments .....	—	99,363	—
<b>Liabilities Carried at Fair Value:</b>			
Put/call liability.....	—	—	329
<b>2011</b>			
<b>Assets Carried at Fair Value:</b>			
Cash equivalents .....	\$38,340	\$—	\$—
Short-term investments .....	—	237,953	—
Long-term investments .....	—	—	—
<b>Liabilities Carried at Fair Value:</b>			
Put/call liability.....	—	—	1,030

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

(In thousands)	<u>Year ended December 31, 2012</u>	<u>Year ended December 31, 2011</u>
<b>Put/call liability:</b>		
Balance, beginning of period.....	\$1,030	\$391
Total realized and unrealized (gains) losses included in selling, general and administrative expenses:.....	(701)	639
Balance, end of period .....	<u>\$329</u>	<u>\$1,030</u>

The Company estimates the fair value of its put/call liability using a discounted cash flow valuation technique. Using this approach, historical and expected future cash flows are calculated over the expected life of the PRF agreement, are discounted, and then exercise scenario probabilities are applied. Some of the more significant assumptions made in the valuation include (i) the estimated Zanaflex revenue forecast and (ii) the likelihood of put/call exercise trigger events such as bankruptcy and change of control. The valuation is performed periodically when the significant assumptions change. Realized gains and losses are included in sales, general and administrative expenses.

The put/call liability has been classified as a Level 3 liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market due to the lack of trading in the security. If different assumptions were used for the various inputs to the valuation approach including, but not limited to, assumptions involving the estimated Zanaflex revenue forecast and the likelihood of trigger events, the estimated fair value could be significantly higher or lower than the fair value we determined. The Company may be required to record losses in future periods, which may be significant.

*Assets Measured and Recorded at Fair Value on a Nonrecurring Basis*

Our non-financial assets, such as intangible assets and property, plant and equipment are only recorded at fair value if an impairment charge is recognized. The tables below present non-financial assets that were measured and recorded at fair value on a nonrecurring basis and the total impairment losses recorded during 2012 and 2011.

(in thousands)	Net Carrying Value as of December 31, 2012	Fair Value Measured and Recorded Using			Impairment Losses December 31, 2012
		Level 1	Level 2	Level 3	
Websites	\$2,292	\$2,292	\$—	\$—	\$664
<b>Total impairment losses</b>					<b>\$664</b>

(in thousands)	Net Carrying Value as of December 31, 2011	Fair Value Measured and Recorded Using			Impairment Losses December 31, 2011
		Level 1	Level 2	Level 3	
Zanaflex intangible asset (1)	\$—	\$—	\$—	\$—	\$13,038
<b>Total impairment losses</b>					<b>\$13,038</b>

(1) \$962,000 in intangible amortization recorded during the nine-month period ended September 30, 2011.

Intangible assets also include certain website development costs which have been capitalized. The Company has developed several websites, each with its own purpose, including the general corporate website, product information websites and websites focused on the MS community. In June 2012 the Company received an untitled letter from the FDA stating that one of its Ampyra promotional videos did not comply with applicable law and was misleading because it overstated the efficacy of and minimized important safety information associated with Ampyra. In compliance with the untitled FDA letter, the Company discontinued use of the video, and in light of the FDA letter we also evaluated and discontinued the use of some other promotional materials. Much of the promotional material was available on one of the Company's websites and, as a result of its compliance with the FDA request, portions of our website were permanently impaired. A charge of approximately \$664,000 was recorded for this impairment.

The Company had sued Apotex Corp. and Apotex Inc. (collectively, "Apotex") for patent infringement related to Apotex Inc.'s submission of an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. On September 7, 2011, the Company announced that the U.S. District Court for the District of New Jersey had ruled against it in that litigation. The Court held that the claims of U.S. Patent No. 6,455,557 covering use of multiparticulate tizanidine compositions are invalid as not enabled and not infringed by Apotex. Following the Company's appeal, in June 2012 the U.S. Court of Appeals for the Federal Circuit affirmed the decision. The Company did not seek any further appeal of the decision. The Company believes that the intangible asset associated with Zanaflex Capsules was fully impaired based on estimated undiscounted cash flows and the associated fair value of this asset and therefore the Company recorded an asset impairment charge of approximately \$13.0 million to write-off the remaining carrying value of this asset during the three-month period ended September 30, 2011. See Note 12.

The Company estimated the fair value of its Zanaflex intangible asset using judgment. Based on what a market participant would pay, the Company made the significant assumption that since the Apotex trial court decision ruled that the underlying Zanaflex patent was invalid as not enabled, there is no market to sell the intangible asset and that the fair value is zero. The realized loss is included in cost of sales. This has been classified as a Level 3 asset as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market due to the lack of trading in the security. If different assumptions were used, the estimated fair value of these investments could be significantly higher than the fair value we determined.

**(15) Quarterly Consolidated Financial Data (unaudited)**

(In thousands, except per share amounts)

	<b>2012</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Total net revenues .....	\$71,248	\$75,656	\$77,437	\$81,473
Gross profit .....	58,625	61,922	62,517	65,109
Net income —basic and diluted.....	7,846	4,545	9,594	132,973
Net income per share—basic .....	\$0.20	\$0.12	\$0.24	\$3.36
Net income per share—diluted .....	0.19	0.11	0.24	3.27
	<b>2011</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Total net revenues .....	\$61,286	\$65,276	\$93,031	\$72,644
Gross profit .....	49,236	53,228	66,380	59,210
Net income (loss)—basic and diluted .....	(672)	(285)	18,867	12,694
Net income (loss) per share—basic .....	\$(0.02)	\$(0.01)	\$0.48	\$0.32
Net income (loss) per share—diluted .....	(0.02)	(0.01)	0.47	0.32

**(b) Exhibits.**

The following Exhibits are incorporated herein by reference or are filed with this Annual Report on Form 10-K as indicated below. All exhibits incorporated herein by reference have been filed under the Company's SEC File Number 000-50513.

<b>Exhibit No.</b>	<b>Description</b>
2.1*	Agreement and Plan of Merger, dated as of February 15, 2012, among the Registrant, ATI Development Corp., Neuronex, Inc., and Moise A. Khayrallah, Ph.D., solely as the Stockholders' Representative as set forth therein. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2012.
3.1	Amended and Restated Certificate of Incorporation of the Registrant. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, No. 333-138842, filed on November 20, 2006.
3.2	Bylaws of the Registrant, as amended on December 15, 2011. Incorporated herein by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
4.1	Specimen Stock Certificate evidencing shares of common stock. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.1**	Acorda Therapeutics 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.2**	Amendment to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.3**	Amendment No. 2 to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.4**	Acorda Therapeutics 2006 Employee Incentive Plan. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.5**	Acorda Therapeutics 2006 Employee Incentive Plan, as amended as of January 13, 2006. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 18, 2006.
10.6**	Forms of Equity Award Documents. Incorporated herein by reference to Exhibit 10.58 to Registrant's Annual Report on Form 10-K filed on March 1, 2011.
10.7**	Employment Agreement, dated August 11, 2002, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.8**	Amendment to August 11, 2002 Employment Agreement, dated September 26, 2005, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.9**	Amendment to August 11, 2002 Employment Agreement, dated May 10, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.



<b>Exhibit No.</b>	<b>Description</b>
10.10**	Amendment to August 11, 2002 Employment Agreement dated December 28, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.52 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.
10.11**	Amendment to August 11, 2002 Employment Agreement dated June 21, 2011, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.61 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.12**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.13**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.14**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.67 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.15**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.16**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.17**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.68 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.18**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.19**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.20**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.69 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.21**	Employment Offer Letter, dated October 20, 2008, by and between the Registrant and Thomas C. Wessel. Incorporated herein by reference to Exhibit 10.53 to Registrant's Annual Report on Form 10-K filed on March 2, 2009.
10.22**	Consulting Agreement effective as of October 1, 2011, by and between the Registrant and Thomas C. Wessel. Incorporated herein by reference to Exhibit 10.65 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.23**	Separation Agreement and General Release dated November 21, 2011, by and between the Registrant and Thomas C. Wessel. Incorporated herein by reference to Exhibit 10.71 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.

<b>Exhibit No.</b>	<b>Description</b>
10.24**	Employment Offer Letter, dated January 22, 2010, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.57 to Registrant's Quarterly Report on Form 10-Q filed on May 10, 2010.
10.25**	Letter agreement dated November 7, 2011, by and between the Registrant and Lauren Sabella. Incorporated herein by reference to Exhibit 10.70 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.26**	Employment Offer Letter, dated August 18, 2011, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.64 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.27**	Letter agreement dated October 19, 2011, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.66 to the Registrant's Annual Report on Form 10-K filed on February 28, 2012.
10.28	Letter agreement dated September 4, 2012, by and between the Registrant and Enrique Carrazana. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed November 8, 2012.
10.29	Lease, dated as of June 23, 2011, by and between the Registrant and BMR-Ardsley Park LLC. Incorporated herein by reference to Exhibit 10.62 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.30	Limited Recourse Convertible Promissory Note issued to Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.31	Note Modification and Amendment, dated as of December 23, 2005, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.32	Revenue Interests Assignment Agreement, dated as of December 23, 2005, between the Registrant and King George Holdings Luxembourg IIA S.à.r.l., an affiliate of Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.33	First Amendment to Revenue Interests Assignment Agreement and to Guaranty, dated November 28, 2006 by and among the Registrant, King George Holdings Luxembourg IIA S.à.r.l. and Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.45 to Registrant's Current Report on Form 8-K filed on November 29, 2006.
10.34	License Agreement, dated September 8, 2000, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.35*	Side Letter Agreement, dated June 1, 2005, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.36	License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.22 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.37*	License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

<b>Exhibit No.</b>	<b>Description</b>
10.38*	Amendment #1 to the License Agreement, dated March 15, 2012, by and between the Registrant and Paion Holdings UK Ltd (formerly CeNeS Pharmaceuticals, plc). Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2012.
10.39	Amended and Restated License Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.14 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A filed on July 20, 2011.
10.40*	Supply Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.41	Side Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.42*	Payment Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.43*	Amendment No. 1 to the Payment Agreement, dated as of October 27, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.44	Securities Amendment Agreement, dated September 26, 2003, by and among the Registrant, Elan Corporation plc and Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.45	Amendment No. 1 Agreement and Sublicense Consent Between Elan Corporation, plc and the Registrant dated June 30, 2009. Incorporated herein by reference to Exhibit 10.56 to Registrant's Quarterly Report on Form 10-Q filed on August 10, 2009.
10.46	Amendment No. 2 to Amended and Restated License Agreement and Supply Agreement between the Registrant and Alkermes Pharma Ireland Limited dated March 29, 2012.
10.47*	Development and Supplemental Agreement between Elan Pharma International Limited and the Registrant dated January 14, 2011. Incorporated herein by reference to Exhibit 10.59 to Registrant's Quarterly Report on Form 10-Q filed on May 9, 2011.
10.48*	Collaboration and License Agreement Between Biogen Idec International GmbH and the Registrant dated June 30, 2009. Incorporated herein by reference to Exhibit 10.54 to Registrant's Quarterly Report on Form 10-Q filed on August 10, 2009.
10.49*	Supply Agreement Between Biogen Idec International GmbH and the Registrant dated June 30, 2009. Incorporated herein by reference to Exhibit 10.55 to Registrant's Quarterly Report on Form 10-Q filed on August 10, 2009.
10.50*	Amended and Restated License Agreement, dated August 1, 2003, by and between the Registrant and Canadian Spinal Research Organization. Incorporated herein by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.51	License Agreement, dated September 26, 2003, by and between the Registrant and Rush-Presbyterian-St. Luke's Medical Center. Incorporated herein by reference to Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.

<b>Exhibit No.</b>	<b>Description</b>
10.52*	Asset Purchase Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.53*	Zanaflex Supply Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.54*	Assignment and Assumption Agreement, dated as of July 21, 2004, by and among the Registrant, Elan Pharmaceuticals, Inc., and Novartis Pharma AG. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.55*	License Agreement, dated April 17, 1991, by and between Sandoz Pharma, now Novartis Pharma AG and Athena Neurosciences, Inc., now Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.56	Patent Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.57	Trademark License Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.58	Agreement Relating to Additional Trademark, dated as of July 2005, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.59	Domain Name Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.60	Bill of Sale and Assignment and Assumption Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.61*	License Agreement, dated February 3, 2003, by and between the Registrant and Cornell Research Foundation, Inc. Incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.62	License Agreement, dated as of December 19, 2003, by and among the Registrant, Cambridge University Technical Services Limited, and King's College London. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A filed on July 20, 2011.
10.63*	Amendment #1 to License Agreement among the Registrant, Cambridge Enterprise Limited (formerly Cambridge University Technical Services Limited), and Kings College London dated as of March 4, 2011. Incorporated herein by reference to Exhibit 10.60 to Registrant's Quarterly Report on Form 10-Q filed on May 9, 2011.
10.64*	License Agreement, dated as of June 27, 2011, by and between the Registrant and Medtronic, Inc. and Warsaw Orthopedic, Inc. Incorporated herein by reference to Exhibit 10.63 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.65*	License Agreement dated as of July 6, 2010, between SK Biopharmaceuticals Co., Ltd. (formerly SK Holdings Co., Ltd.) and Neuronex, Inc.

<b>Exhibit No.</b>	<b>Description</b>
21	List of Subsidiaries of the Registrant.
23	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification by the Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification by the Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Definition Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

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\* Portions of this exhibit were redacted pursuant to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

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

\*\*\* In accordance with Regulation S-T, the XBRL-related information in Exhibit 101 to this Annual Report on Form 10-K shall be deemed to be “furnished” and not “filed.”

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Acorda Therapeutics, Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 28 th day of February 2013.

### ACORDA THERAPEUTICS, INC.

By: /s/ RON COHEN  
Ron Cohen  
*President and Chief Executive Officer*

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ RON COHEN, M.D.</u> Ron Cohen, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2013
<u>/s/ DAVID LAWRENCE, M.B.A.</u> David Lawrence, M.B.A.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 28, 2013
<u>/s/ BARRY GREENE</u> Barry Greene	Director	February 28, 2013
<u>/s/ PEDER K. JENSEN, M.D.</u> Peder K. Jensen, M.D.	Director	February 28, 2013
<u>/s/ JOHN P. KELLEY</u> John P. Kelley	Director	February 28, 2013
<u>/s/ SANDRA PANEM, PH.D.</u> Sandra Panem, Ph.D.	Director	February 28, 2013
<u>/s/ LORIN J. RANDALL</u> Lorin J. Randall	Director	February 28, 2013
<u>/s/ STEVEN M. RAUSCHER, M.B.A.</u> Steven M. Rauscher, M.B.A.	Director	February 28, 2013
<u>/s/ IAN SMITH</u> Ian Smith	Director	February 28, 2013

## EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
10.46	Amendment No. 2 to Amended and Restated License Agreement and Supply Agreement between the Registrant and Alkermes Pharma Ireland Limited dated March 29, 2012.
10.65*	License Agreement dated as of July 6, 2010, between SK Biopharmaceuticals Co., Ltd. (formerly SK Holdings Co., Ltd.) and Neuronex, Inc.
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101.DEF***	XBRL Taxonomy Extension Definition Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

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\* Portions of this exhibit were redacted pursuant to a confidential treatment request filed with the Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

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

\*\*\* In accordance with Regulation S-T, the XBRL-related information in Exhibit 101 to this Annual Report on Form 10-K shall be deemed to be “furnished” and not “filed.”

**List of Subsidiaries of the Registrant**

**Neuronex, Inc. (Delaware)**

**Acorda Therapeutics Limited (UK)**

**MS Research & Development Corporation (Delaware)**



**Consent of Independent Registered Public Accounting Firm**

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

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 Nos. 333-164312 and 333-152826)
- (2) Registration Statement (Form S-8 Nos. 333-164626, 333-158085, 333-131846, 333-149726, 333-174785, and 333-179906)

of our reports dated February 28, 2013 with respect to the consolidated financial statements of Acorda Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Acorda Therapeutics, Inc. included in this Annual Report (Form 10-K) of Acorda Therapeutics, Inc. for the year ended December 31, 2012.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
February 28, 2013

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

I, Ron Cohen, certify that:

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

Date: February 28, 2013

/s/ RON COHEN

Ron Cohen

*Chief Executive Officer*

*(Principal Executive Officer)*

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

I, David Lawrence, certify that:

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

Date: February 28, 2013

/s/ DAVID LAWRENCE

David Lawrence

*Chief Financial Officer*

*(Principal Financial Officer)*

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

In connection with the Annual Report on Form 10-K of Acorda Therapeutics, Inc. (the “Company”) for the fiscal year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Ron Cohen, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ RON COHEN  
Chief Executive Officer  
(Principal Executive Officer)  
February 28, 2013

[A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Acorda Therapeutics, Inc and will be retained by Acorda Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.]

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

In connection with the Annual Report on Form 10-K of Acorda Therapeutics, Inc. (the “Company”) for the fiscal year ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, David Lawrence, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DAVID LAWRENCE  
Chief Financial Officer  
(Principal Financial Officer)  
February 28, 2013

[A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Acorda Therapeutics, Inc and will be retained by Acorda Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.]