

ACORDA THERAPEUTICS INC  
Form 10-K  
February 28, 2012

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2011

OR

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

Commission File Number 000-50513

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation  
or organization)

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

15 Skyline Drive  
Hawthorne, New York 10532  
(914) 347-4300  
(Address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)

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

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

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

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

Large accelerated filer <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>
--	---	--	---

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

As of June 30, 2011, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was \$736,447,807. 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, 2011 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, 2012, the registrant had 39,701,072 shares of common stock, par value \$0.001 per share, outstanding. The registrant does not have any non-voting stock outstanding.

Table of Contents

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement for its 2012 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2011. 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.

Table of Contents

ACORDA THERAPEUTICS, INC.

2011 FORM 10-K ANNUAL REPORT

TABLE OF CONTENTS

	Page
<u>PART I</u>	1
<u>Item 1. Business</u>	1
<u>Item 1A. Risk Factors</u>	38
<u>Item 1B. Unresolved Staff Comments</u>	62
<u>Item 2. Properties</u>	62
<u>Item 3. Legal Proceedings</u>	63
<u>Item 4. Mine Safety Disclosures</u>	63
<u>PART II</u>	64
<u>Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	64
<u>Item 6. Selected Financial Data</u>	66
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	68
<u>Item 7A. Quantitative and Qualitative Disclosures about Market Risk</u>	92
<u>Item 8. Financial Statements and Supplementary Data</u>	93
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</u>	93
<u>Item 9A. Controls and Procedures</u>	93
<u>Item 9B. Other Information</u>	96
<u>PART III</u>	96
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	96
<u>Item 11. Executive Compensation</u>	96
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	96
<u>Item 13. Certain Relationship and Related Transactions, and Director Independence</u>	96
<u>Item 14. Principal Accounting Fees and Services</u>	96
<u>PART IV</u>	97
<u>Item 15. Exhibits and Financial Statement Schedules</u>	97

SIGNATURES

i

---

Table of Contents

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 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 any acquired or in-licensed programs; 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; 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.

---

Table of Contents

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 \$210.5 million for the year ended December 31, 2011.

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.

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. 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). To date, Biogen Idec has launched Fampyra in Germany, the United Kingdom, Denmark, Norway and Iceland. Launch in most of the remaining EU countries is expected by the end of 2012. Also, in May 2011, Fampyra was approved for use in Australia by the Australian Therapeutic Goods Administration, and has been launched there. In November 2011, Biogen Idec received approval from the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), and in February 2012 Biogen Idec received approval from Health Canada. Biogen Idec plans to submit regulatory filings for Fampyra in more than 20 countries in 2012.

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. On February 6, 2012, we launched tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules, under our agreement with Watson Pharma, Inc., a subsidiary of Watson Pharmaceuticals, Inc., following the launch by Apotex, Inc. of its generic tizanidine hydrochloride capsules.

We are developing a pipeline of novel neurological therapies. We are studying dalfampridine to improve a range of functional impairments, in addition to walking disability, caused by MS, as well as its use in other neurological conditions, including cerebral palsy and chronic stroke. In addition, we are developing our clinical stage compound AC105 for acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and SCI.

---



## Table of Contents

Additional preclinical programs include rHlgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in SCI.

On February 15, 2012, we entered into an agreement to acquire Neuronex, Inc., a privately-held development stage pharmaceutical company. Neuronex is preparing a 505(b)(2) type New Drug Application, or NDA, for a proprietary nasal spray formulation of Diazepam, or DZNS, as a rescue treatment for certain epilepsy patients. The NDA will provide pharmacokinetic data with the nasal spray and reference older investigations on efficacy and safety for Diastat AcuDial (diazepam rectal gel), a rectally-administered diazepam formulation. This acquisition would bring us a near-term commercial opportunity in neurology that would leverage our experience in developing neurological products and, if the DZNS product is approved for sale, our existing commercial infrastructure. Completion of the acquisition is subject to specified conditions and termination rights.

Our goal is to continue to grow as a fully-integrated biopharmaceutical company focused on innovative therapies in neurology by commercializing our FDA approved products, developing our product candidates and advancing our research and development programs for underserved markets. We will also look to build long-term value by acquiring and in-licensing 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 \$210.5 million for the year ended December 31, 2011, with approximately 19,000 new patients trying Ampyra therapy in 2011. Approximately 30% of all eligible MS patients have tried Ampyra since the 2010 launch. As of December 31, 2011, 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 received a sixth refill. Compliance rates for Ampyra are approximately 90%, with patients currently taking an average of 1.8 tablets per day, compared to the approved dosing of 2 tablets per day. We are also 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. We plan to begin a Phase 2 proof-of-concept clinical study of dalfampridine in chronic stroke patients in the second half of 2012. Investigator-initiated studies are exploring potential additional therapeutic applications of dalfampridine.
- **Ampyra Patents:** In August 2011, the U.S. Patent and Trademark Office, or USPTO, issued one of our Ampyra patent applications and allowed another. The USPTO determined that the issued patent will extend into 2027 with final patent term adjustment calculation. The patent that issues from the allowed patent application is expected to expire in 2025 plus any additional term determined by the final patent term adjustment calculation by the USPTO, which may extend the term of the patent into 2026. In June 2011, the European Patent Office, or EPO, issued a patent from our EPO patent application that corresponds to our patent application allowed by the USPTO in August 2011.
- **Fampyra/Biogen:** 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). To date, Biogen Idec has launched Fampyra in Germany, the United Kingdom, Denmark, Norway and Iceland. Launch in most of the remaining EU countries is expected by the end of 2012. In May 2011, Fampyra was approved for use in Australia by the Australian Therapeutic Goods Administration, and has been launched there. In November 2011, Biogen Idec received approval from the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), and in February 2012 Biogen Idec received approval from Health Canada. Biogen Idec plans to submit regulatory filings for Fampyra in more than 20 countries in 2012.

Table of Contents

- Zanaflex Capsules and Zanaflex tablets: Our Zanaflex Capsules, which we launched in April 2005, and Zanaflex tablets, which we also sell, are FDA-approved as short-acting drugs for the management of spasticity, a symptom of many CNS disorders, including MS and SCI. These products contain tizanidine hydrochloride, one of the two leading drugs used to treat spasticity. In February 2012, the FDA approved an Abbreviated New Drug Application, or ANDA, filed by Apotex Corp. and Apotex Inc. (“Apotex”) with respect to a generic version of tizanidine hydrochloride capsules. On February 6, 2012, Apotex launched generic tizanidine hydrochloride capsules, and we launched an authorized generic version of Zanaflex Capsules under our agreement with Watson Pharma, Inc., a subsidiary of Watson Pharmaceuticals, Inc.
- Research and Development Programs: We have three ongoing research and development programs – neuregulins, remyelinating antibodies and chondroitinase – focused on novel approaches to limit and repair damage to components of the CNS. In addition, in 2011, we in-licensed a clinical-stage program, AC105, to develop an acute treatment for neurological trauma.
  - o Neuregulins: GGF2 is our lead product candidate for our neuregulins program. We commenced a Phase 1 clinical trial of GGF2 in heart failure patients in December 2010, and the clinical trial is ongoing. We plan to announce initial study results in the second half of 2012. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product either by entering into a partnership, most likely with a cardiovascular-focused company, or by developing it on our own. We also are continuing with research on potential neurology indications for GGF2.
  - o Remyelinating Antibodies: rHlgM22 is the lead antibody in our remyelinating antibody program, and we are developing it as a potential therapeutic for MS. We expect to file an IND for rHlgM22 for the treatment of MS in the first half of 2012, and to begin a Phase 1 clinical trial by the end of 2012. 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.
  - o 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 plan to study AC105 as an acute treatment for patients who have suffered neurological trauma, such as SCI and traumatic brain injury, or TBI, and we expect to begin a Phase 2 clinical trial in patients with acute SCI in the second half of 2012. 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.
- Neuronex Merger Agreement: On February 15, 2012, we entered into a merger agreement with Neuronex, Inc., a privately-held development stage pharmaceutical company. Neuronex is preparing a 505(b)(2) type New Drug Application, or NDA, for a proprietary nasal spray formulation of Diazepam, or DZNS, as a rescue treatment for certain epilepsy patients. The NDA will provide pharmacokinetic data with the nasal spray and reference older investigations on efficacy and safety for Diastat AcuDial (diazepam rectal gel), a rectally-administered diazepam formulation. Completion of the acquisition is subject to specified conditions and termination rights. This acquisition would provide a near-term commercial opportunity in neurology that would leverage our experience in developing neurological products and, if the DZNS product is approved for sale, our existing commercial infrastructure. Under the terms of the merger agreement, we made an upfront payment of \$2.0 million and paid \$500,000 of a pre-closing research funding commitment of up to \$1.2 million to prepare for a DZNS pre-NDA meeting with the FDA. Following the pre-NDA meeting, we can, at our option, complete the acquisition by paying an additional \$6.8 million. If the acquisition is completed, we will assume oversight and financial responsibility for all future development and regulatory programs for DZNS. We expect that these expenses would not exceed \$8

million in 2012. If we complete the acquisition, there are potential earnout payments to the former owners of Neuronex of up to \$18 million based upon the

## Table of Contents

achievement of specified regulatory and manufacturing-related milestones. If we complete the acquisition and DZNS is approved by the FDA, the former owners of Neuronex will also be entitled to receive milestone and royalty-like earnout payments from us based on net sales. Also, there are potential payments to SK Biopharmaceuticals Co., Ltd., or SK – the company that licenses the patent and other rights related to the DZNS product to Neuronex – and if we complete the acquisition we will be responsible for these payments. These payments include up to \$8 million upon the achievement of specified development milestones (including \$1 million upon FDA acceptance of the first NDA for the DZNS product), up to \$3 million upon the achievement of specified sales milestones, and a tiered, mid-single digit royalty based on net sales. The structure of the deal enables us to make measured investments in the DZNS product through its development and regulatory review phases, with the majority of milestone payments to follow approval, if obtained.

- **Corporate Headquarters:** In June 2011, we announced that we signed an agreement to lease approximately 138,000 square feet of office and laboratory space within the Ardsley Park life science campus in Ardsley, N.Y. for a 15 year period expected to begin in June 2012. We also announced that we plan to relocate our corporate headquarters, and all employees currently based at our Hawthorne, N.Y. location, to the Ardsley facility. We have grown substantially over the last several years, and the new facility will provide state-of-the art office and laboratory space that will accommodate our current needs and allow for future growth.
- **Corporate Update:** In January 2012, General Counsel Jane Wasman, J.D., was named Chief, Strategic Development. In this new role, Ms. Wasman will assume additional responsibilities for overseeing the development and execution of our long-range strategic plans and objectives. She will continue to serve as our General Counsel. Also, in October 2011, Enrique Carrazana, M.D., joined us as our Chief Medical Officer.

## Our Strategy

Our strategy is to continue to grow as a fully-integrated biopharmaceutical company and to become a leading neurology company focused on the identification, development and commercialization of a range of nervous system therapeutics. We are using our scientific, clinical and commercial expertise in MS and SCI as strategic points of access to additional nervous system markets, including stroke and TBI. For 2012, we are focused on making disciplined investments in growing Ampyra sales, expanding the Ampyra franchise, and expanding our pipeline. Key aspects of our strategy are:

- Continue to invest in growing Ampyra sales, with focus in 2012 on sales and marketing programs that increase awareness and use in patients with earlier stages of walking disability who can benefit from Ampyra. We also plan to continue to focus on educating prescribers of the value of Ampyra to earlier-stage patients, and to expand 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 chronic stroke.
- 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 2012 in particular: advance GGF2 through its ongoing Phase 1 trial; advance AC105 into a Phase 2 clinical trial in patients with acute SCI; and advance rHIgM22

into a Phase 1 clinical trial.

- Expand our pipeline through the potential in-licensing and/or acquisition of select products and technologies in neurology, with our focus through 2012 on commercial or near commercial opportunities.

4

---

Table of Contents

## Our Products and Product Pipeline

Commercial Products	Indication	Status	Marketing Rights
Ampyra	MS	FDA-approved and marketed in the U.S.	Acorda (U.S.)
Fampyra	MS	Approved in EU (conditional), Australia, Canada, and New Zealand; launched in Germany, U.K. and a number of other EU countries and in Australia	Biogen Idec (outside U.S.)
Zanaflex Capsules	Spasticity	FDA-approved	Acorda (U.S.)
Zanaflex tablets	Spasticity	FDA-approved	Acorda (U.S.)
Research and Development Programs	Proposed Therapeutic Area(s)	Stage of Development	Marketing Rights
Dalfampridine	Cerebral Palsy	Phase 2 proof-of-concept clinical trial commenced December 2011	Acorda (U.S.)
Dalfampridine	Chronic Stroke	Phase 2 proof-of-concept clinical trial expected to begin H2 2012	Acorda (U.S.)
AC105	SCI and TBI	Acute SCI Phase 2 clinical trial expected to begin in H2 2012	Acorda/Worldwide
Neuregulin Program	Heart failure*	GGF2 Phase 1 clinical trial ongoing; initial results expected H2 2012	Acorda/Worldwide
Remyelinating Antibodies Program	MS	rHIgM22 IND filing expected H1 2012; Phase 1 clinical trial expected to begin in H2 2012	Acorda/Worldwide
Chondroitinase Program	SCI	Research	Acorda/Worldwide

\*The company is also continuing with 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



## Table of Contents

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. 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.

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

## 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

## Table of Contents

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 chronic stroke. Current treatments for chronic stroke include physical and occupational therapy, but there are no pharmacologic therapies indicated specifically to improve function. A majority of those living with chronic stroke 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 muscle itself, 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 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 is he or she considered to have epilepsy. EEGs and brain scans are common diagnostic test for epilepsy.

It is estimated that epilepsy affects approximately 2.2 million people in the US. Seizures are generally classified as either partial onset, or focal, seizures, or generalized onset seizures. Approximately one third of

## Table of Contents

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.

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

We also have patents and pending patent applications covering Ampyra and its uses. In August 2011, the U.S. Patent and Trademark Office, or USPTO, issued one of our Ampyra patent applications and allowed an Ampyra application. The USPTO determined that the issued patent will extend into 2027 based on a final patent term adjustment calculation. The patent that issues from the allowed patent application is expected to expire in 2025 plus any additional term determined by the final patent term adjustment calculation by the USPTO, which may extend the term of the patent into 2026. In June 2011, the European Patent Office, or EPO, issued a patent from our EPO patent application that corresponds to our USPTO patent application allowed by the USPTO in August 2011.

We have an exclusive license from Alkermes (originally with Elan, but transferred to Alkermes as part of its acquisition of Elan's Drug Technologies business) to another U.S. patent directed to methods of treatment using Ampyra that currently expires in July 2013. In March 2010, we filed an application for patent term extension for this patent under the Hatch-Waxman law that allows for a patent to be extended for up to five additional years to compensate for regulatory delays stemming from the FDA approval process. We have requested an extension for the full five year period for this patent. The FDA has finalized its determination of the regulatory review period in the patent term extension proceeding. We now await a notice of final determination from the USPTO confirming the

length of the patent term extension and issuance of a patent term extension certificate from the USPTO.

In January 2010, Biogen Idec announced that it submitted a centralized Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Ampyra, which is known outside the U.S. as Fampyra. 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). To date, Biogen Idec has launched Fampyra in Germany, the United Kingdom, Denmark, Norway and Iceland. Launch in most of the remaining EU countries is expected by the end of 2012. In May 2011, Fampyra

## Table of Contents

was approved for use in Australia by the Australian Therapeutic Goods Administration, and has been launched there. In November 2011, Biogen Idec received approval from the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), and in February 2012 Biogen received approval from Health Canada. Biogen Idec plans to submit regulatory filings for Fampyra in more than 20 countries in 2012.

We are working with external parties on a potential once-daily formulation of dalfampridine. We also are exploring potential new indications both within MS and 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. Also, we plan to begin a Phase 2 proof-of-concept trial of dalfampridine in chronic stroke in the second half of 2012. This study is expected to enroll patients who have experienced a stroke and who have stabilized with chronic neurologic deficits, which may include walking impairment and arm weakness. 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. This trial will target 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.

## 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



## Table of Contents

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. The 5 mg efficacy study is in progress. 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 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

Our lead research and development programs include three distinct biologic 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 our research and development 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 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.

The first 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. In December 2010, we enrolled the first patient in a Phase 1 clinical trial exploring the safety and tolerability of GGF2 in patients with heart failure, and we are continuing preclinical studies of potential neurology indications for GGF2. This clinical trial is ongoing, and we plan to announce initial study results in the second half of 2012.

The second program comprises a series of IgM antibodies. We are developing the lead antibody

## Table of Contents

(rHIgM22) as a potential therapeutic for MS, and we expect to file an IND for rHIgM22 for the treatment of MS in the first half of 2012. In preparation for a filing, we worked with a contract manufacturer to complete the scale up manufacturing and purification processes, and we have completed formal preclinical safety and toxicity studies. 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.

The third program is in the research stage and is focused on developing chondroitinase as a therapeutic to break down inhibitory factors in the scar tissue that develops as a result of an injury to the CNS. Published research has demonstrated that this scar tissue is partly responsible for limiting the regeneration of nerve fibers in the CNS and restricting their ability to modify existing neural connections.

The fourth program is based on a magnesium formulation with a polymer such as polyethylene glycol, which we refer to as AC105. AC105 is being developed as an acute treatment for patients who have suffered neurological trauma, such as SCI and TBI. AC105 has been shown to reduce lesion size and enhance recovery in animal models of SCI. We acquired this program from Medtronic, Inc. and one of its affiliates in 2011 pursuant to a license agreement, which is further described below. We expect to begin a Phase 2 clinical trial in patients with acute SCI in the second half of 2012.

### Neuregulins/GGF2

Neuregulins form a family of growth factors related to epidermal growth factor. These molecules bind to erbB receptors, which translate the growth factor signal to the cell and cause changes in cell growth, protein production and gene expression. Neuregulins have been shown in published studies to have a range of effects in protection and repair of cells both in the nervous system and in the heart. In 2002, we obtained from CeNeS Pharmaceuticals plc., or CeNeS, an exclusive worldwide license to its neuregulin patents and related technology, including GGF2, our lead molecule from the neuregulin family.

Neuregulins covered in the portfolio from CeNeS have a number of potential applications. Neuregulins and their erbB receptors are essential for cardiac development. 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.

In March 2010 we filed an IND application for GGF2 as a therapy for the treatment of heart failure, and the IND became effective in April 2010. In December 2010, we enrolled the first patient in a Phase 1 clinical trial exploring the safety and tolerability of GGF2 in patients with heart failure, and the clinical trial is ongoing. We plan to announce initial study results in the second half of 2012. 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 either by entering into a partnership, most likely with a cardiovascular-focused company, or developing it on our own.

We and Vanderbilt University received a \$1 million Cardiac Translational Research Implementation Program, or C-TRIP, grant from the National Heart, Lung and Blood Institute, or NHLBI, to support research on GGF2 separate from the Phase 1 clinical trial.

#### Antibodies/Remyelinating Antibodies Program

Our remyelinating antibodies program is based on our research collaboration with Mayo Foundation for

## Table of Contents

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 expect to file an IND for rHIgM22 for the treatment of MS in the first half of 2012, and Phase 1 clinical trials are expected to begin by the end of 2012. In preparation for a filing, we worked with a contract manufacturer to complete the scale up manufacturing and purification processes, and we have completed formal preclinical safety and toxicity studies. The manufacturing data, clinical plans and preclinical safety profile will be subject to FDA review in connection with the filing of an IND.

### Chondroitinase Program

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

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

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, which has been funded in part by federal and state grants, to develop second generation approaches to overcoming the proteoglycan matrix. Our research is currently focused on SCI but we are also looking at other neurotraumatic indications. The approaches we are developing include novel enzyme molecules

and alternative approaches to blocking matrix formation. We are exploring the possibility of obtaining additional research grants from the National Institutes of Health, or NIH, as well as potential partnerships with other companies to support completion of our preclinical program in chondroitinase. In 2003, we obtained an exclusive worldwide license to certain patents and technology from Cambridge University Technical Services Limited (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.

Table of Contents

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 plan to study AC105 as an acute treatment for patients who have suffered neurological trauma, such as SCI and TBI, and we expect to begin a Phase 2 clinical trial in patients with acute SCI in the second half of 2012. 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 failed to show that significant magnesium levels reach the CNS and have also failed to show benefit. 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.

Agreement and Plan of Merger with Neuronex, Inc.

On February 15, 2012, we and our wholly owned subsidiary ATI Development Corp., or ATI, entered into a merger agreement with Neuronex, Inc., a privately-held development stage pharmaceutical company. Neuronex is developing Diazepam nasal spray, or DZNS, under Section 505(b)(2) of the Food, Drug and Cosmetic Act as a rescue treatment for certain seizures. Pursuant to the merger agreement, upon the closing of the transactions contemplated thereby, ATI would merge with and into Neuronex, with Neuronex continuing as the surviving corporation and our wholly owned subsidiary (the "Merger").

In accordance with the terms and conditions of the merger agreement, upon execution of the merger agreement, we made an initial payment of \$2 million to Neuronex. We also paid Neuronex \$500,000 of a pre-closing research funding commitment of up to \$1.2 million. Upon closing of the Merger, we will pay an additional \$6.8 million in cash consideration for the Merger, subject to adjustment in accordance with the provisions of the merger agreement. We used cash on hand to fund the initial \$2 million payment and also intend to use cash on hand to fund the pre-closing research and development payments and the closing consideration.

Under the terms of the merger agreement, after closing of the Merger, 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 DZNS product, and up to \$105 million upon the achievement of specified sales milestones with respect to the DZNS 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 DZNS 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 the patent and other intellectual property and other rights relating to the DZNS 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 DZNS product (including a \$1 million payment upon the FDA's acceptance for review of the first NDA for the DZNS product), and up to \$3 million upon the achievement of specified sales milestones with respect to the DZNS product. Also, Neuronex is



## Table of Contents

obligated to pay SK a tiered, mid-single digit royalty on net sales of DZNS products. Upon closing of the Merger, we will be responsible for these milestone payments and royalties, in addition to the earnout payments described above.

Consummation of the Merger is subject to certain conditions, including (i) our receipt of the official minutes, or (the “FDA Minutes”) from a meeting contemplated by the merger agreement to be held among us, Neuronex, and the U.S. Food and Drug Administration with respect to the DZNS product and a contemplated filing of the New Drug Application for the product, (ii) consent of SK to the transactions contemplated by the merger agreement, and (iii) other conditions customary for a transaction of this type.

Consummation of the Merger is also subject to the parties not exercising their rights to terminate the merger agreement. Under the merger agreement, (i) we have the right to terminate the merger agreement at any time prior to closing, even if the closing conditions have been satisfied, and Neuronex can terminate the merger agreement after a specified time period has elapsed after receipt of the FDA Minutes, and (ii) both we and Neuronex have termination rights in the event of certain breaches of representations or covenants by the other party. In the event the merger agreement is terminated prior to the closing date for any reason other than by us because of a breach by Neuronex, Neuronex shall retain all amounts previously paid by us under the merger agreement as a break-up fee and we shall have no further obligations to Neuronex.

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

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

We expect that Neuronex will not have any employees at the time of the Merger, if it is completed.

## 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 93 sales representatives in the field calling on a priority target list of approximately 7,000 physicians.

- **Specialty Sales Force.** We employ a field-based team of highly experienced sales professionals to call primarily on neurologists and on other specialists and prescribers treating patients with MS, as well as other conditions that involve spasticity.
- **Managed Markets Team.** We employ a field-based team responsible for payer strategy, as well as contracting and account management of managed care organizations, pharmacy benefit managers, Medicaid agencies, specialty pharmacies, wholesale drug distribution customers, the Veterans Affairs institutions and the DOD military treatment facilities.

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

## Table of Contents

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, since 2008, Acorda has been a national sponsor of the National Multiple Sclerosis Society's Walk MS program. This sponsorship allowed us to engage thousands of people with MS, as well as their families, physicians and caregivers, in a discussion about the impact of walking impairment on their lives. Acorda has also developed the "I Walk Because" program to give a voice to the community that participates in the Walk MS events. Acorda takes its "I Walk Because" event booth to select Walk MS events across the country. Walkers are invited to decorate t-shirts with the reasons why they are walking for MS, and they are also invited to film a short video to share with friends and family. In addition to these efforts, we have implemented a comprehensive series of educational and promotional programs to support Ampyra.

Pursuant to our REMS approved by the FDA, 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 Amerisource Specialty Distribution Healthcare, which is the exclusive specialty pharmacy distributor for 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. As of February 2012, our authorized generic version of tizanidine hydrochloride capsules is marketed under our agreement with Watson Pharma, Inc., a subsidiary of 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 and SCI. We also have consultants who are experts in heart failure, given our research in this area with GGF2. Depending on their expertise, these advisors provide assistance in trial design, conduct clinical trials, keep us apprised of the latest scientific advances and help us identify and evaluate business development opportunities.

## Collaborations, Alliances and License Agreements

Biogen Idec

In 2009, we entered into the Collaboration Agreement with Biogen Idec, pursuant to which we and Biogen Idec have agreed to collaborate on the development and commercialization of products containing aminopyridines, including Ampyra, initially directed to the treatment of MS (licensed products). The Collaboration Agreement includes a sublicense of our rights under an existing license agreement with 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

Table of Contents

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.

In January 2010, Biogen Idec announced that it submitted a centralized Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) and a New Drug Submission (NDS) to Health Canada for Ampyra, which is known outside the U.S. as Fampyra. In January 2011, the EMA's Committee for Medicinal Products for Human Use (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). To date, Biogen Idec has launched Fampyra in Germany, United Kingdom, Denmark, Norway and Iceland. Launch in most of the remaining EU countries is expected by the end of 2012. In May 2011, Fampyra was approved for use in Australia by the Australian Therapeutic Goods Administration, and has been launched there. In November 2011, Biogen Idec received approval from the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), and in February 2012 Biogen received approval from Health Canada. Biogen plans to submit regulatory filings for Fampyra in more than 20 countries in 2012.

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, as described above. 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 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

Table of Contents

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,



Table of Contents

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 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. The FDA approval of Ampyra triggered a milestone of \$2.5 million to Elan that we paid in 2010.

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 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.

Table of Contents

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) 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. For more information, refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Financing Arrangements."

Rush-Presbyterian St. Luke's Medical Center

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

We agreed to pay Rush a license fee, milestone payments of up to \$850,000 and royalties based on net

Table of Contents

sales of the product for neurological indications. We have made or accrued an aggregate of \$850,000 in milestone payments and \$6.9 million in royalties under this agreement through December 31, 2011. 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).

Canadian Spinal Research Organization

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

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

Our agreement with CSRO remains in effect although we have fully satisfied our royalty payment obligations. We have the right to terminate the CSRO agreement at any time by written notice. In addition, the CSRO agreement may be terminated by either party following an uncured material breach by the other party. The CSRO agreement may also be terminated by either party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of assets, by the other party. Subject to the early termination provisions, the CSRO agreement will expire upon the termination of all royalty or other payment obligations on a country-by-country basis. This expiration is based on when royalty payments would have been payable, which is the earlier of the expiration of the last to expire licensed patent in a country or ten years from the date of the first commercial sale of the product in a country. We expect the agreement to terminate in Canada in 2012, and in the U.S. and certain foreign countries other than Canada in 2013, when the respective patents covered by the agreement expire.

Cornell Research Foundation, Inc.

In February 2003, we entered into a license agreement with Cornell Research Foundation, Inc. pursuant to which we were granted an exclusive license under a patent for the use of dalfampridine in the treatment of anterior horn cell diseases. In 2011, we exercised our right to terminate this license agreement.

Cambridge Enterprise Limited (formerly)Cambridge University Technical Services Limited and King's College London

In December 2003, we entered into a license agreement with Cambridge Enterprise Limited (formerly Cambridge University Technical Services Limited) and King's College London, pursuant to which we were granted an exclusive worldwide license, including the right to sublicense, under a U.S. patent application, from which a U.S. patent issued in 2010, and its foreign (U.K.) counterpart to develop and commercialize products related to enzymatic methods, including chondroitinase, of treating CNS disorders. We were also granted a non-exclusive worldwide license, including the right to sublicense, under the same U.S. and foreign patent applications to develop and commercialize products related to small molecule inhibitors for use in treating CNS disorders.

Table of Contents

In consideration for these licenses, we paid an upfront license fee and are required to make payments of up to \$2.2 million upon the achievement of certain milestones. We paid the \$45,000 upfront license fee in 2009 and have not yet been obligated to make any milestone payments. We are also obligated to pay royalties on net sales and on any sublicense royalties that we receive.

The King's College license may be terminated by any party following an uncured material breach by any other party. The King's College license may also be terminated by any party if any other party ceases to carry on business, is declared by a court of competent jurisdiction to be bankrupt or upon the appointment of a liquidator of that party. Subject to the early termination provisions, the King's College license agreement will continue until the expiration of the last to expire valid claim under the licensed patent applications, which we expect to be in 2023 in the U.S. and other countries, at which time the licenses granted under the license agreement will automatically become non-exclusive, worldwide, fully paid-up and irrevocable. However, pursuant to a 2011 amendment to the license agreement, if a patent covered by the license agreement does not receive an extension, then our royalty obligation could be extended for a specified period of time depending on when commercial sales of a licensed product commence.

Mayo Foundation for Medical Education and Research

In September 2000, we entered into a license agreement with Mayo Foundation for Education and Research, or Mayo Clinic, pursuant to which we were granted an exclusive worldwide license to its patents and other intellectual property on certain antibodies. Under this agreement, we have the right to develop, make, use and sell those antibodies for nervous system disorders or injuries. We have worked closely with one of Mayo Clinic's research groups on developing and patenting this emerging technology in connection with the therapeutic use of certain antibodies, specifically myelination and remyelination in MS and SCI. Mayo Clinic has the right to continue internal research on the antibodies and, in the event it develops other applications that are related to our license, it must offer Acorda certain rights to this new subject matter before rights can be offered to a third party.

Under the Mayo Clinic agreement, we are obligated to make milestone payments of up to \$1.9 million and to pay royalties based on net sales. In 2010, we reached our first milestone under this agreement and made a \$45,000 milestone payment. The Mayo Clinic agreement may be terminated by either party following an uncured material breach by the other party. We may terminate the Mayo Clinic agreement at will upon prior written notice to Mayo Clinic. In addition, either party also has the right to terminate upon the insolvency of the other party, the filing of bankruptcy by or against the other party, or the assignment of assets to the benefit of creditors by the other party. Unless otherwise terminated, this license agreement will terminate upon the expiration of the last licensed patent in any such licensed product.

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

Paion AG (formerly CeNeS Pharmaceuticals plc)

In November 2002, we entered into two license agreements with CeNeS Pharmaceuticals plc, which has subsequently been acquired by Paion AG. The first agreement relates to an exclusive worldwide sublicense under certain patents, patent applications and know-how to make, have made, use, import, offer for sale and sell protein products composed of GGF2 or fragments thereof and non-protein products developed through the use of material covered by a valid claim in the patents. The license to these patents and the right to sub-license these patents were granted to Paion by the Ludwig Institute for Cancer Research.

Our payment obligations to Paion (as the acquiror of CeNeS Pharmaceuticals) include payment of an upfront license fee, royalties based on annual net sales of the product, if any, as well as payments of up to \$8.5



Table of Contents

million upon achieving certain milestones in connection with the development, testing and regulatory approval of any protein products. The completion of animal toxicology studies and the filing of an IND triggered milestone payments in 2010 aggregating \$1.0 million. We are obligated to make minimum royalty payments commencing in the third calendar year following the first commercial sale of any licensed product. If we fail to pay any minimum royalty, Paion will have the option to convert our license or any sublicense to a non-exclusive license. This agreement with Paion is effective until the later of November 12, 2017 or the expiration of the last-to-expire valid claim in the licensed patents. We may terminate this agreement at will upon prior written notice to Paion. In addition, this first agreement may be terminated by either party following an uncured material breach by the other party and if this agreement is terminated under that provision, we may retain the exclusive worldwide sublicense granted to us under this agreement, provided that we continue to pay royalties.

The second agreement relates to an exclusive worldwide sublicense to us under certain Paion patents, patent applications and know-how to make and have made, use and have used, sell, offer for sale, have sold and import protein products composed of one or more proteins, or fragments thereof, encoded by the growth factor gene NRG-2 and non-protein products developed through the use of material covered by a valid claim of the patents. The license previously included a sub-license of patent rights granted to Paion by the President and Fellows of Harvard College, in addition to rights owned directly by Paion, but we have returned the sublicensed rights back to Paion.

We have agreed to a timeline to achieve certain milestones relating to the research and development and the clinical testing and filing of regulatory approvals for the products. We are also required to make milestone payments of up to \$5.9 million. If we are unable to meet a milestone, Paion has agreed to negotiate in good faith with us to agree for a reasonable extension of the time to achieve the milestone up to one year. We are obligated to pay Paion a license fee and royalties based on a percentage of net sales of protein products and non-protein products covered under the agreement. We made payments of \$25,000 in connection with this agreement through December 31, 2009 and did not make any payments in 2010 or 2011.

This second agreement may be terminated by either party following an unremedied default of a material obligation by the other party. Paion may terminate this agreement upon our failure to cure a default in our obligations relating to maintenance of insurance liability or our failure to meet certain milestones. We have the right to terminate this agreement upon written notice to Paion. The license granted to us pursuant to this agreement continues after the expiration of this agreement and may continue after the termination of this agreement, depending upon the circumstances under which this agreement is terminated.

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

The Brigham and Women's Hospital, Inc.

In February 2008, we entered into a license agreement with Brigham and Women's Hospital, Inc., or Brigham, acting on its own behalf and on behalf of Beth Israel Deaconess Medical Center, or Beth Israel. Pursuant to the license agreement, we were granted a co-exclusive license in the U.S., and an exclusive license outside the U.S., to their patent rights relating to the use of GGF2 in the treatment of congestive heart failure. Under this agreement, we have

the right to develop, make, use and sell products covered by valid claims under the patent rights, with certain sublicensing rights. Brigham and Beth Israel have retained the right to use the subject matter of the license for internal research, clinical and educational purposes. If the other co-exclusive U.S. license to these patent rights (held by a third party) is terminated or expires, we have an option to negotiate an exclusive U.S. license to the patents, and Brigham and Beth Israel cannot license the patent rights to a third party unless we fail to reach agreement on an exclusive U.S. license.

Under this agreement, we paid a license fee of \$25,000 in 2008 and we are obligated to make milestone payments of up to \$1.4 million and to pay royalties based on net sales. Our IND for GGF2 filed in 2010 triggered

Table of Contents

our first milestone payment of \$150,000. We have agreed to a timeline to achieve certain milestones relating to the research, development, clinical testing, and filing of regulatory approvals for a product covered by the agreement. If we fail to timely meet these milestones, Brigham and Beth Israel could, in certain cases, terminate the agreement subject to our right to present a plan to achieve the missed milestone within a reasonable period of time.

The agreement may be terminated by us at will upon prior written notice to Brigham and Beth Israel. In addition, the agreement may be terminated by Brigham and Beth Israel following our uncured material breach or upon our failure to maintain agreed upon insurance, our failure to remain solvent, the filing of a bankruptcy petition against us, or an the assignment of our assets for the benefit of creditors. Subject to early termination provisions, this license agreement will terminate on a country by country basis upon the expiration of the last to expire licensed patent in a country. Based on current U.S. patents, termination in the U.S. is expected to be in 2021, and based on the current non-U.S. patent portfolio, termination is expected to be in 2020 in each country other than the U.S.

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 plan to study AC105 as an acute treatment for patients who have suffered neurological trauma, such as SCI and TBI, and we expect to begin a Phase 2 clinical trial in patients with acute SCI in the second half of 2012. 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 failed to show that significant magnesium levels reach the CNS and have also failed to show benefit. 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

## Table of Contents

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.

## 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.

## Table of Contents

### Zanaflex

We currently rely on Alkermes to supply us with Zanaflex Capsules (and for the supply of our authorized generic Zanaflex capsules being marketed by Watson Pharma) under our 2004 Supply Agreement. The initial term of the agreement expired in 2009, but is subject to two automatic two-year renewal terms. Either party may terminate the agreement by notifying the other party at least 12 months prior to the expiration of the initial term or any renewal term. In addition, either party may terminate the agreement if the other party commits a material breach that remains uncured. If a failure to supply occurs under the agreement, other than a force majeure event, or if we terminate the supply agreement for cause, 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. Also, in June 2011, we received FDA approval for Farmak to also be our supplier of tizanidine hydrochloride for 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 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 GLP safety and toxicology and is now being evaluated in our GGF2 Phase 1 clinical trial.

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

#### rHIgM22

We have contracted for testing and manufacturing development activities for rHIgM22 to be performed by outside contractors. In 2009, we signed a Master Vendor Agreement with Biovest International Inc. to produce rHIgM22 under cGMPs. In 2009, we also contracted with CMC Biologics to develop methods and purify under cGMPs the rHIgM22 produced at Biovest. Acorda and CMC Biologics are working to develop analytical and characterization assays to support the manufacture of rHIgM22. cGMP material produced at Biovest and CMC



## Table of Contents

Biologics has been used in GLP safety and toxicology studies. We expect to file an IND for rHIgM22 for the treatment of MS in the first half of 2012. In preparation for a 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. The manufacturing data, clinical plans and preclinical safety profile will be subject to FDA review in connection with the filing of an IND.

## Intellectual Property

There are six major families of subject matter in our patent portfolio: Ampyra, Zanaflex Capsules, neuregulins, remyelinating antibodies, chondroitinase and AC105. 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. Two of these patents in the U.S. relate to sustained release formulations, including formulations of monoaminopyridines, such as 4-aminopyridine (dalfampridine), and methods of treatment of relevant neurological conditions. In March 2010, we filed patent term extension requests with the U.S. Patent and Trademark Office, or USPTO, under the Hatch Waxman law on these two U.S. patents. The length of such an extension can be up to five additional years and depends on factors such as the amount of time taken by the FDA to review the first marketing approval application of the drug covered by the patent. As only one patent can be extended, we chose to proceed with the extension for the patent which, absent such an extension, is set to expire in July 2013. We have requested an extension for the full five-year period for this patent, which relates to methods of treatment. The other patent, which relates to sustained release formulations, expired in December 2011. 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.

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. In August 2011, the USPTO issued our patent relating to methods to improve walking in patients with multiple sclerosis, or MS, by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent will extend into 2027 based on the USPTO’s final patent term adjustment calculation, and has been listed in the FDA Orange Book.

Also, in August 2011, the USPTO allowed our U.S. patent application 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. The patent that issues from this application, which will be 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, which may extend the term of the patent into 2026.

In June 2011, the European Patent Office, or EPO, granted a European Patent with “composition for use” and other use claims directed to sustained release aminopyridine compositions for, among other things, increasing walking speed, improving lower extremity muscle strength, or improving lower extremity muscle tone, in patients with MS. This patent corresponds to the U.S. patent application, referred to above, that was allowed by the USPTO in August 2011. The European patent is currently set to expire in April 2025. We have also applied for Supplementary Protection Certificates or “SPCs” in various European countries based on this granted European Patent.

We have pending patent applications filed during 2010 and 2011 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 2031, respectively.

## Table of Contents

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 to broaden our intellectual property portfolio on dalfampridine and explore additional therapeutic indications for Ampyra, as well as provide access to pre-clinical compounds that may have utility in nervous system disorders. Under the terms of the purchase agreement, we were assigned two key licensing and research agreements relating to the use of aminopyridines in peripheral neuropathies and to two early stage development candidates. We also acquired NRI's pre-clinical and clinical data, regulatory filings (including Orphan Drug designations), copyrights, trademarks and domain names relating to the three products. Two Phase 2 studies of the aminopyridine compound Ampydin® (IR) for the treatment of chronic functional motor and sensory deficits resulting from Guillain-Barre Syndrome, 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, 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 relating to multiparticulate tizanidine compositions, including those sold by us as Zanaflex Capsules. On September 7, 2011, we announced that the U.S. District Court for the District of New Jersey had ruled against us 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. We are appealing the decision. On December 2, 2011, Apotex filed suit against us in the U.S.

District Court for the Southern District of New York. Apotex characterized the suit in its complaint as a “civil antitrust action” and “an action for false advertising” relating to Zanaflex Capsules. Among other allegations, Apotex claimed that our filing of a citizen petition with the FDA had “delayed FDA approval of Apotex’s generic tizanidine capsules.” We intend to defend ourself vigorously.

## Table of Contents

### 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 a central or peripheral nervous system injury associated with demyelination and 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, including two foreign patents granted in 2011.

### 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 ABC1, to reduce inflammation in patients with central nervous system diseases, spinal cord injury or multiple sclerosis and certain chondroitinase ABC1 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.

## Table of Contents

### 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 therefor, 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.

### 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. BioMarin has announced that it will be working to determine the regulatory path for approval in the U.S. for LEMS, as well as exploring developing the product for use in other indications, which may include MS. In the EU, and the U.S., if this product is successfully developed and approved, physicians might prescribe it instead of Ampyra, even if it were not approved for MS.

In certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis, which is referred to as compounding. We are aware that at present compounded dalfampridine is used by some people with MS, 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



## Table of Contents

with these current treatments because they have been accepted and regularly prescribed to people with MS by physicians, or because they are being promoted to improve walking or other neurological functions.

### Spasticity

Tizanidine hydrochloride, the active pharmaceutical ingredient in Zanaflex Capsules, Zanaflex tablets and generic tizanidine hydrochloride tablets, is one of the two leading FDA-approved treatments for spasticity, a symptom suffered by, 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, the U.S. District Court for the District of New Jersey recently ruled against us in litigation with Apotex relating to the ANDA filed by Apotex for the approval of a generic version of Zanaflex Capsules, holding 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. We are appealing the decision. However, 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 Watson Pharmaceuticals, Inc. In addition, several companies have reported that they are working on potential new delivery formulations of tizanidine hydrochloride. The launch of generic tizanidine hydrochloride capsules into the marketplace will likely cause our revenues from the sale of Zanaflex Capsules to decline significantly.

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.

### 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:

Table of Contents

- 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 at least two adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use(s);
- FDA review of whether each facility in which the product is manufactured, processed, packed or held meets standards designed to assure the product's continued quality; and
- submission to the FDA of 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.

## Table of Contents

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. 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

## Table of Contents

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. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory

requirements. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

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



## Table of Contents

exist in the form of a notice of inspectional observations, or Form FDA 483. The observations may be more or less significant. If we receive a notice of inspectional observations, we likely will be required to respond in writing, and may be required to undertake corrective and preventive actions in order to address the FDA's concerns.

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

The FDA's policies may change and additional government regulations may be enacted which could impose additional burdens or limitations on our ability to market products after approval. Moreover, increased attention to the containment of 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 should not affect Ampyra's orphan drug designation, as it was granted prior to the increase in diagnoses above 200,000.

Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, and reduced filing fees for marketing applications. If a product that has an orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity for that use. This means that, subsequent to approval, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. FDA may approve a subsequent application from another person if 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

## Table of Contents

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 Community, or EC, 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 EC 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

## Table of Contents

Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, as amended, the False Claims Act, also as amended, and are affected by the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act, 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. 2009 legislative changes 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 if ongoing legal challenges to these legislative changes are not successful. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

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

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

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

## 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

Table of Contents

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

The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) 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, the increased use and funding for comparative effectiveness research 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, Thompson Micromedex, DrugDex, or Clinical Pharmacology. Another commonly cited compendium, for example under Medicaid, is the DrugDex Information System.

Different pricing and reimbursement schemes exist in other countries. For example, in the 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



## Table of Contents

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 17, 2012, we had 328 employees. Of the 328 employees, 71 perform research and development activities, including preclinical programs, clinical trials, regulatory affairs, biostatistics, and drug safety, and 257 work in sales, marketing, managed markets, business development, manufacturing, medical affairs, communications, and general and administrative.

## CORPORATE INFORMATION

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 15 Skyline Drive, Hawthorne, New York 10532. Our telephone number is (914) 347-4300. Our website is [www.acorda.com](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 2012 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2011 proxy statement within 120 days after the end of our 2011 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 2012 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 2011, we may not be able to sustain profitability.

As of December 31, 2011, we had an accumulated deficit of approximately \$409.5 million. Although we had net income of \$30.6 million for the year ended December 31, 2011, we had net losses of \$11.8 million and \$83.9 million for the years ended December 31, 2010 and 2009, respectively. Prior to 2011, we had operating

Table of Contents

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 neurological conditions such as cerebral palsy and chronic stroke
- continuing to advance clinical development of our AC105 and GGF2 programs, and advance rHlgM22 into clinical trials;
  - 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 in-licensing and/or acquisition of additional products and technologies.

If we are not successful in executing our business plan, we may not sustain profitability.

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

We currently derive substantially all of our revenue from the sale of Ampyra, Zanaflex Capsules and Zanaflex tablets. We believe that sales of Ampyra will continue to constitute a significant and growing portion of our total revenue for the foreseeable future. We expect that net revenue from Zanaflex Capsules, which declined in 2011 compared to 2010, will decline significantly in 2012, due to competition from a generic version of tizanidine hydrochloride capsules, following approval by the FDA of Apotex' ANDA for a generic version in February 2012. Although we have entered into an agreement with Watson Pharma to market an authorized generic version of Zanaflex Capsules, royalty income from the sale of this product is expected to only partially offset the expected decline in Zanaflex Capsules revenue.

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;

Table of Contents

- 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.

In addition, forecasting revenue is difficult, especially when the product is the first product approved for a particular indication. We may, therefore, experience significant fluctuations in sales of Ampyra from period.

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

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

We rely exclusively on 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 certain 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 to supply dalfampridine, the active pharmaceutical ingredient in Ampyra.

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

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. 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 and Zanaflex capsules.

We rely on a single manufacturer, Patheon, for the manufacture of Zanaflex tablets. Also, we rely on Farmak a.s. as the 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

Table of Contents

the required manufacturing technology to that supplier.

Our dependence on others to manufacture our marketed products and clinical trial materials may adversely affect our ability to develop and commercialize our products on a timely and competitive basis. Any such failure may result in decreased product sales and lower product revenue, which would harm our business.

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

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

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

Ampyra was approved with an indicated use limited to improving walking 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.

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

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

- sales of Ampyra may be significantly decreased from projected sales;
- regulatory approvals for Ampyra may be restricted or withdrawn;
- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals;



Table of Contents

- 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.

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

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

Our success in 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 certain risks, including, but not limited to, risks that these specialty pharmacies will:

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

- cease operations.

In late 2010 and early 2011, we learned that two of the specialty pharmacies that dispense Ampyra failed 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. Because the specialty pharmacies did not report these adverse events to us in a timely manner, while we reported them to the FDA, we did not report them in a timely manner. To our knowledge, no regulatory action has been taken against us or the specialty pharmacies involved by the FDA. However, if these

Table of Contents

specialty pharmacies continue to experience problems with adverse event reporting, and even if they do not, the FDA could take regulatory action against us and/or the specialty pharmacies. During an FDA inspection focused on our adverse event reporting system that began in July 2011, reporting of adverse events by our specialty pharmacies was reviewed. Issues were identified on a Form 483 (discussed below in these risk factors) and we have responded and are awaiting official FDA feedback.

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

Physicians may prescribe drug products for uses that are not described in the product’s labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician’s choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies may not promote drugs for off-label uses. Accordingly, without FDA approval of Ampyra for use in any indications other than improving walking ability in people with MS, we may not promote Ampyra in the U.S. for these indications. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

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

We are dependent on our collaboration with Biogen Idec to commercialize Ampyra outside of the U.S. (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 in a timely manner, or at all;

- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

Table of Contents

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- the collaborations may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates; and
  - collaborators may experience financial difficulties.

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

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

In order to market our products in the EU and many other foreign jurisdictions, separate regulatory approvals must be obtained and numerous and varying regulatory requirements must be complied with. Approval procedures vary among countries and can involve additional clinical and nonclinical testing. The time required to obtain approval may differ from that required to obtain FDA approval. We and our partner may fail to obtain foreign regulatory approvals on a timely basis, if at all. In addition, individual countries, within the EU or elsewhere, may require additional steps after regulatory approval to gain access to national markets, such as agreements with pricing authorities and other agencies, that may affect the ability of us or our partner to market and sell products outside the U.S. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Inability to obtain necessary regulatory approvals to commercialize Ampyra or other product candidates in foreign markets could materially harm our business prospects.

Under the Collaboration Agreement, Biogen Idec has the right to develop and commercialize Ampyra in the EU and other markets outside the U.S. In January 2010, Biogen Idec submitted a centralized Marketing Authorization Application, or MAA, to the European Medicines Agency (EMA) for Ampyra, known outside the U.S. as 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, Fampridine (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 Ampyra or other product candidates could also produce findings that are inconsistent with the trial results we have previously submitted to the FDA, in which case we would be obligated to report those findings to the FDA.

Table of Contents

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

Two of our active research and development programs – remyelinating antibodies and chondroitinase – have not advanced to clinical trials. Our future success depends, in part, on our ability to select successful product candidates, complete preclinical development of these product candidates and advance them to clinical trials. These product candidates will require significant development, preclinical studies and clinical trials, regulatory clearances and substantial additional investment before they can be commercialized.

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; however, given the complex nature of the drug discovery and development process, it is difficult to predict accurately if and when we will achieve these goals. For example, in the case of our remyelinating antibodies program, we plan to advance rHlgM22 into a Phase 1 clinical trial during 2012. However, we may not be able to successfully initiate this clinical trial on time or at all, and if we do initiate the clinical trial it may not be successful. 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, chronic stroke, 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. We are currently conducting a Phase 1 clinical trial for our neuregulin Glial Growth Factor 2. We expect to begin a Phase 2 clinical trial for our AC105 program in the second half of 2012 and to begin a Phase 1 clinical trial for our rHlgM22 by the end of 2012.

Clinical development of any product candidate that we determine to take into clinical trials, such as our neuregulin Glial Growth Factor 2, our AC105 program, or rHlgM22, 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;



Table of Contents

- 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 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

Table of Contents

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 our clinical trials, the resulting data from the clinical trial may not be usable or we, an institutional review board or the FDA may suspend or terminate 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 an 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 has provided the FDA with formal responses to the inspectional observations as well as to the verbal comments and is in the process of implementing specific actions to address the FDA's concerns and enhance our overall pharmacovigilance process. We have met each of our obligations on time through the end of 2011. Nevertheless, the FDA may decide that our responses and corrective actions are not adequate and may decide to issue a written warning letter or take other enforcement action. In addition, although Ampyra was approved by the FDA on January 22, 2010, the FDA has not inspected our third-party suppliers' drug product manufacturing sites in connection with that approval. The process validation efforts and manufacturing process at these sites could be inspected at a later date and the FDA might find what it considers to be deficiencies in the manufacturing process or process validation efforts, which could negatively impact the availability of product supply.

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

## Table of Contents

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, thereby limiting our potential to generate revenue.

Market acceptance of our products and product candidates depends on the benefits of our products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness and our ability to demonstrate these benefits to physicians and patients. We believe market acceptance also depends on the pricing of our products and the reimbursement policies of government and third-party payers, as well as on the effectiveness of our sales and marketing activities. Physicians may not prescribe our products, and patients may determine, for any reason, that our products are not useful to them. For example, physicians may not believe that the benefits of Zanaflex Capsules outweigh their higher cost in relation to Zanaflex tablets or generic tizanidine hydrochloride tablets, or that the benefits of Ampyra are meaningful for patients. 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 governmental authorities can delay commercialization by one year or more. Even if reimbursement is available, reimbursement policies may harm our ability or that of our partners, such as Biogen Idec, to sell our products on a profitable basis.

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

- rate of adoption by healthcare practitioners;
- rate of a product's acceptance by the target population,

- timing of market entry relative to competitive products,
  - availability of alternative therapies,
  - perceived advantages of alternative therapies,
  - price of product relative to alternative therapies,

Table of Contents

- extent of marketing efforts,
- unavailability of adequate reimbursement by third parties, and
- side effects or unfavorable publicity concerning the products or similar products.

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

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

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

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

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

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

reimbursement under government programs, criminal fines and imprisonment.

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Service Act pharmaceutical pricing program, which requires us to sell our products to certain customers at prices lower than we otherwise might be able to charge. If products are



Table of Contents

made available to authorized users of the Federal Supply Schedule, additional pricing laws and requirements apply. Pharmaceutical companies have been prosecuted under federal and state false claims laws for manipulating information submitted to the Medicaid Rebate Program or for knowingly submitting or using allegedly inaccurate pricing information in connection with federal pricing and discount programs.

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

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

In March 2010, Congress enacted legislation known as the Patient Protection and Affordable Care Act (Affordable Care Act), which substantially changes the way that 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 use of comparative effectiveness research 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.

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

Beginning in 2011, the law required 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 March 2013, pharmaceutical manufacturers will be required to report payments or other transfers of value made to healthcare providers during the preceding calendar year. These reports will be placed on a public database. Similarly, beginning in April 2012, pharmaceutical manufacturers will be required to report samples of prescription drugs requested by and distributed to healthcare providers during the preceding calendar year. The law does not state whether these disclosures will be made publicly available. If we fail to provide these reports, or if the reports we provide are not accurate, we could be subject to significant penalties. In addition, the federal government has been given additional enforcement authority.

The federal anti-kickback statute was also amended as a part of the Affordable Care Act to provide that a

Table of Contents

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

Our 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 Zanaflex Capsules. Our business would 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 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. For both Ampyra and Zanaflex Capsules, we expect increasing pressure to offer larger discounts or discounts to a greater number of third-party payers to maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary. There is no guarantee that we would be able to negotiate agreements with third-party payers at price levels that are profitable to us, or at all. A number of third-party payers also require prior authorization for, or even refuse to provide, reimbursement for Ampyra, and others may do so in the future. Similarly, a number of third-party payers require prior authorization for, or refuse to provide, reimbursement for Zanaflex Capsules, and other third-party payers may do so in the future. Patients who cannot meet the conditions of prior authorizations are often prevented from obtaining the prescribed medication, because they cannot afford to pay for the medication without reimbursement. If we are unsuccessful in maintaining reimbursement for our products at acceptable levels, or if reimbursement for our products by third-party payers is subject to overly restrictive prior authorizations, our business will be 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 has been in effect since 2006. The benefit is provided primarily through private entities, which attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations increase pressure to lower prescription drug prices or increase rebate payments to offset price. While the law specifically prohibits the U.S. government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress 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

Table of Contents

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. For example, we are aware that BioMarin is developing a 3,4 diaminopyridine product that may compete with Ampyra. In certain circumstances, pharmacists are not prohibited from formulating certain drug compounds to fill prescriptions on an individual patient basis. We are aware that at present compounded dalfampridine is used by some people with MS and it is possible that some people will want to continue to use compounded formulations even though Ampyra is commercially available. Several companies are engaged in developing products that include novel immune system approaches and cell 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 our preclinical candidates.

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, in February 2012, the FDA approved an Abbreviated New Drug Application, or ANDA, filed by Apotex Corp. and Apotex Inc. (“Apotex”) with respect to a generic version of tizanidine hydrochloride capsules. On February 6, 2012, Apotex launched generic tizanidine hydrochloride capsules and we launched an authorized generic version of Zanaflex Capsules under our agreement with Watson Pharma. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. All of these products will compete with Zanaflex Capsules and, as a result, we expect our net revenue from Zanaflex Capsules to decline significantly.

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.

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

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

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;

Table of Contents

- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
  - difficulties in assimilating the operations of the acquired companies;
  - diverting our management's attention away from other business concerns;
  - entering markets in which we have limited or no direct experience; and
- potential loss of our key employees or key employees of the acquired companies or businesses.

We cannot assure you that any acquisition or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions and in-licenses. Any acquisition might distract resources from and otherwise 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.





Table of Contents

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 and reauthorized by the 2007 FDA Amendments Act (FDAAA) 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 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 studies. 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 commitment, including a court-imposed injunction to conduct studies.

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

In addition, the research, manufacturing, distribution, sale and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, the Federal Trade Commission, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the

Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, as amended, the False Claims Act, as amended, and are affected by the privacy provisions of the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended (VHCA). If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements

Table of Contents

apply. Under the VHCA, we are required to offer certain drugs at a reduced price to a number of federal agencies including the Veterans Administration and the Department of Defense (DOD), the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. 2009 legislative changes 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 if ongoing legal challenges to these legislative changes are not successful. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

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

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

Several states have also enacted legislation regarding promotional and other activities conducted by

Table of Contents

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 formal compliance infrastructure and standard operating procedures to comply with such laws, but we cannot eliminate the risk created by these uncertainties. Unless we are in full compliance with these laws, we could face enforcement action, fines and other penalties, including government orders to stop selling drugs into a state until properly licensed, and could receive adverse publicity.

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, 2011, we had approximately \$295.9 million in cash, cash equivalents and short-term investments. We have several product candidates in various stages of development, and all will require significant further investment to develop, test and obtain regulatory approval prior to commercialization. We may need to seek additional equity or debt financing or strategic collaborations to complete our product development activities, and could require substantial funding to commercialize any products that we successfully develop. We may not be able to raise additional capital on favorable terms or at all. To the extent that we are able to raise additional capital through the sale of equity securities, the issuance of those securities would result in dilution to our stockholders. Holders of such new equity securities may also have rights, preference or privileges that are senior to yours. If additional capital is raised through the incurrence of indebtedness, we may become subject to various restrictions and covenants that could limit our ability to respond to market conditions, provide for unanticipated capital investments or take advantage of business opportunities. To the extent funding is raised through collaborations or intellectual property-based financings, we may be required to give up some or all of the rights and related intellectual property to one or more of our products, product candidates or preclinical programs. If we are unable to obtain sufficient financing on favorable terms when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs or devote less resources to marketing Ampyra.

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

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

Table of Contents

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

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

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

Our success depends on the continuing contributions of our management team and scientific personnel, and maintaining relationships with our scientific and medical network and the network of centers in the 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 \$9 million of liability in excess of the general liability policy's \$2 million limit. This amount of insurance coverage may not be adequate to cover all liabilities or defense costs we might incur. In addition, the cost of compliance with environmental and health and safety regulations may be substantial.



Table of Contents

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 six major families of subject matter in our patent portfolio, including Ampyra, Zanaflex Capsules, neuregulins, remyelinating antibodies, chondroitinase, and AC105, 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

Table of Contents

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.

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc., advising that it had submitted an ANDA to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In response, 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 relating to multiparticulate tizanidine compositions, including those sold by us as Zanaflex Capsules. Apotex answered our complaint asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. On September 7, 2011, we announced that the U.S. District Court for the District of New Jersey had ruled against us in the 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. We are appealing the decision. However, the FDA approved Apotex's ANDA, and Apotex launched generic tizanidine hydrochloride capsules on February 6, 2012. Other third parties may bring claims similar to those of Apotex and may also seek approval from the FDA for generic tizanidine hydrochloride capsules. Zanaflex Capsules will face significant competition from generic tizanidine hydrochloride capsules, including from our own authorized generic version that is being sold under our agreement with Watson Pharma, and this competition will likely cause significant declines in our Zanaflex Capsules net revenue and profit margin.

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.

Table of Contents

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 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;

Table of Contents

- 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, 2012, we had outstanding 39,701,072 shares of voting common stock. Also, options to acquire 4,796,816 shares of common stock were outstanding as of February 15, 2012, exercisable at an average exercise price of \$21.33 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, 2011, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 48.6% 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.



Table of Contents

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our principal executive offices are located in an approximately 52,785 square foot facility in Hawthorne, NY. The current annual rent for this facility is 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

Table of Contents

laboratory space in Ardsley, New York. We plan to relocate 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 will provide state-of-the art office and laboratory space that will accommodate our current needs and allow for future growth.

We anticipate taking possession of the new space in June 2012, subject to completion of certain improvements to the facility prior to our occupancy. The commencement of the term would be deferred in the case of certain delays in the completion of those improvements. 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 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 will initially be \$3.4 million per year, and will be 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 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 relating to multiparticulate tizanidine compositions, including those sold by us as Zanaflex Capsules. The patent expires in 2021.

In November 2007, Apotex answered our complaint, asserting patent invalidity and non-infringement. Apotex also counterclaimed, seeking a declaratory judgment of patent invalidity and non-infringement. We denied those counterclaims. A bench trial was held in May 2011. On September 7, 2011, we announced that the Court had ruled against us in the 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. We are appealing 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 alleges, 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 makes allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits, recovery of litigation costs, and injunctive relief. We plan to file a timely response to the

amended complaint. We intend to defend ourself vigorously in the litigation.

Item 4. Mine Safety Disclosures.

Not applicable.

63

---

Table of Contents

## PART II

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

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

	High	Low
Fiscal Year Ended December 31, 2011		
Fourth Quarter	\$24.08	\$18.36
Third Quarter	\$32.66	\$19.77
Second Quarter	\$33.48	\$20.90
First Quarter	\$31.67	\$20.43
	High	Low
Fiscal Year Ended December 31, 2010		
Fourth Quarter	\$33.39	\$24.99
Third Quarter	\$37.29	\$28.53
Second Quarter	\$40.48	\$30.66
First Quarter	\$36.83	\$25.05

Registrar and Transfer Company is the transfer agent and registrar for our common stock. As of February 15, 2012, 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 12/31/2006 and its relative performance is tracked through 12/31/2011.

Table of Contents

	12/06	12/07	12/08	12/09	12/10	12/11
Acorda Therapeutics, Inc	100.00	138.64	129.48	159.09	172.10	150.51
NASDAQ Composite	100.00	110.26	65.65	95.19	112.10	110.81
NASDAQ Biotechnology	100.00	102.53	96.57	110.05	117.19	124.54

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 three-month period ended December 31, 2011. Acorda has not announced any plans or programs for the repurchase of its Common Stock.

Table of Contents

Item 6. Selected Financial Data.

The following unaudited selected consolidated financial data for each of the five years in the period ended December 31, 2011 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.

Table of Contents

	Year Ended December 31,				
	2011	2010	2009	2008	2007
	(in thousands, except per share data)				
<b>Statement of Operations</b>					
<b>Data:</b>					
<b>Revenues:</b>					
Net revenue	\$256,271	\$181,545	\$49,959	\$47,728	\$39,426
Milestone revenue	25,000	—	4,714	—	—
License revenue	9,057	9,428	—	—	—
Royalty revenue	1,909	32	—	—	—
Grant revenue	—	—	—	99	60
Total net revenue	292,237	191,005	54,673	47,827	39,486
<b>Costs and expenses:</b>					
Cost of sales	64,183	35,518	11,059	11,355	8,356
Cost of milestone and license revenue	2,384	660	330	—	—
Research and development	42,108	30,600	34,611	36,604	22,410
Selling, general and administrative	148,508	132,657	89,930	73,307	48,168
Total operating expenses	257,183	199,435	135,930	121,266	78,934
Operating income (loss)	35,054	(8,430 )	(81,257 )	(73,439 )	(39,448 )
<b>Other income (expense):</b>					
Interest and amortization of debt discount expense	(3,570 )	(3,922 )	(4,415 )	(5,591 )	(2,664 )
Interest income	552	575	1,750	4,682	4,087
Other income (expense)	(18 )	8	(18 )	8	51
Total other income (expense)	(3,036 )	(3,339 )	(2,683 )	(901 )	1,474
Income (loss) before income taxes	\$32,018	\$(11,769 )	\$(83,940 )	\$(74,340 )	\$(37,974 )
Provision for income taxes	(1,413 )	—	—	—	—
Net income (loss)	\$30,605	\$(11,769 )	\$(83,940 )	\$(74,340 )	\$(37,974 )
<b>Net income (loss) per share</b>					
—basic	\$0.78	\$(0.31 )	\$(2.22 )	\$(2.19 )	\$(1.45 )
—diluted	\$0.76	\$(0.31 )	\$(2.22 )	\$(2.19 )	\$(1.45 )
<b>Weighted average shares of common stock outstanding used in computing net income (loss) per share —basic</b>					
	39,000	38,355	37,735	33,939	26,237
<b>Weighted average shares of common stock outstanding used in computing net income (loss) per share —diluted</b>					
	40,064	38,355	37,735	33,939	26,237





Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

As of December 31,  
2009  
(in thousands)

	2011	2010	2009	2008	2007
<b>Consolidated Balance Sheet</b>					
<b>Data:</b>					
Cash and cash equivalents	\$57,954	\$34,641	\$47,314	\$29,613	\$16,810
Short term investments	237,953	205,389	224,778	216,435	78,310
Working capital	273,599	217,274	220,380	207,445	71,770
<b>Total assets</b>	<b>379,488</b>	<b>342,101</b>	<b>319,471</b>	<b>281,501</b>	<b>127,306</b>
Deferred product revenue—Zanaflex tablets	9,967	9,526	9,215	7,867	7,914
Deferred product revenue—Zanaflex Capsules	20,632	21,770	21,489	16,436	13,924
Current portion of deferred license revenue	9,057	9,429	9,429	—	—
Non-current portion of deferred license revenue	77,742	86,429	95,857	—	—
Current portion of revenue interest liability—PRF transaction	1,001	1,297	6,179	6,181	1,785
Put/call option liability—PRF transaction	1,030	391	638	338	463
Non-current portion of revenue interest liability—PRF transaction	1,898	3,586	5,631	12,498	17,444
Long term convertible notes payable	5,230	6,186	7,112	6,905	6,703
<b>Total stockholders' equity</b>	<b>205,209</b>	<b>151,261</b>	<b>137,333</b>	<b>207,157</b>	<b>63,433</b>

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 MS, spinal cord injury, 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 \$210.5 million for the year ended December 31, 2011 and \$133.1 million for the year ended December 31, 2010. Approximately 30% of all eligible MS patients have tried Ampyra since the 2010 launch. As of December 31, 2011, 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 received a sixth refill. Compliance rates for Ampyra are approximately 90%, with patients currently taking an average of 1.8 tablets per day, compared to the approved dosing of 2 tablets per day.

## Table of Contents

Ampyra is marketed in the United States through our own specialty sales force and commercial infrastructure. We currently have approximately 93 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Regional Scientific Managers, Regional Reimbursement Directors, and Managed Markets account managers who provide information and assistance to payers and physicians on Ampyra.

Pursuant to our REMS approved by the FDA, 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 Amerisource Specialty Distribution Healthcare, which is the exclusive specialty pharmacy distributor for the U.S. Department of Veterans Affairs, or VA. All of these customers are contractually obligated to hold no more than 30 days of inventory.

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.

As of December 31, 2011, approximately 75% of commercially insured individuals had no or limited prior authorizations, or PAs, for Ampyra. We define limited PAs as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. As of December 31, 2011, approximately 24% of commercially insured individuals were subject to more restrictive PAs, which may include requirements for multiple timed walk tests and/or Expanded Disability Status Scale score requirements to initiate therapy. Such restricted PAs may also include requirements of objective measures of ambulation improvement to reauthorize Ampyra therapy. We estimate that, as of December 31, 2011, approximately 1% of commercially insured individuals were blocked from receiving reimbursement for Ampyra. Access figures were calculated based on the number of pharmacy lives reported by commercial healthcare plans.

As of August 1, 2011, three of the largest national health plans in the U.S. – Aetna, United Healthcare and Cigna – listed Ampyra in the lowest branded co-pay tier of their commercial preferred drug list or formulary.

## License and Collaboration Agreement with Biogen Idec

In July 2011, Biogen Idec received conditional approval from the European Commission for Fampyra, which triggered a \$25 million milestone payment to us under our License and Collaboration Agreement with Biogen Idec. Pursuant to our worldwide license and supply agreement with Elan (which has been transferred to Alkermes in connection with Alkermes' 2011 acquisition of Elan's Drug Technologies business), we directed 7% of this milestone payment to Elan. To date, Biogen Idec has launched Fampyra in Germany, the United Kingdom, Denmark, Norway and Iceland. Launch in most of the remaining EU countries is expected by the end of 2012. Also, in May 2011, Fampyra was approved for use in Australia by the Australian Therapeutic Goods Administration, and has been launched there. In November 2011, Biogen received approval from the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), and in February 2012 Biogen Idec received approval from Health Canada. Biogen Idec plans to submit regulatory filings for Fampyra in more than 20 countries in 2012. 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 is 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

## Table of Contents

of dalfampridine in adults with cerebral palsy. Also, we plan to begin a Phase 2 proof-of-concept trial of dalfampridine in chronic stroke in the second half of 2012. This study is expected to enroll patients who have experienced a stroke and who have stabilized with chronic neurologic deficits, which may include walking impairment and arm weakness. 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. This trial will target 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.

### Patent Update Related to Ampyra

On August 30, 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 claims of the patent relate to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. The patent, which is eligible for listing in the FDA Orange Book, will extend into 2027 with final patent restoration.

On August 10, 2011, we announced that the United States Patent and Trademark Office, or USPTO, had allowed U.S. Patent Application No. 11/102,559 entitled "Method of Using Sustained Release Aminopyridine Compositions." The claims of the patent application relate 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. The patent that issues from this application, which will be 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, which may extend the term of the patent into 2026. The European Patent Office, or EPO, issued a corresponding patent in June 2011.

### Zanaflex

Zanaflex Capsules and Zanaflex tablets 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. Combined net revenue of Zanaflex Capsules and Zanaflex tablets was \$45.8 million for the year ended December 31, 2011 and \$48.5 million for the year ended December 31, 2010. The commercial launch of generic tizanidine hydrochloride capsules in February 2012 by Apotex and potentially others, including our own authorized generic product being marketed by Watson Pharma, will likely cause the Company's net revenue from Zanaflex Capsules to decline significantly in 2012 and beyond.

The Company believes that the intangible assets associated with Zanaflex Capsules are now fully impaired based on estimated undiscounted cash flows and associated fair value of this asset. We made this decision based on a September 2011 ruling by the U.S. District Court for the District of New Jersey in litigation with Apotex that our patent relating to Zanaflex Capsules is invalid as not enabled (refer to Item 3 of this report for more information on this litigation). For the three-month period ended September 30, 2011, the Company recorded an asset impairment charge of approximately \$13.0 million to write-off the remaining carrying value of this asset. In connection with the outcome of the Apotex litigation, during the three-month period ended September 30, 2011, the Company also recorded a loss on our put/call liability resulting from a change in its fair market value of \$1.1 million related to the PRF revenue interest agreement as well as an inventory reserve of approximately \$1.3 million consisting of a \$1.0 million charge for commercial inventory and a \$336,000 charge for sample inventory. As of December 31, 2011, there have been no accruals for loss contingencies aside from payments related to the litigation itself.

### Other Internal Research Programs

We have three ongoing research and development programs focused on novel approaches to limit and repair damage to components of the CNS: neuregulins, remyelinating antibodies and chondroitinase. We believe

70

---

## Table of Contents

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 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 are conducting a Phase 1 clinical trial of GGF2 in heart failure patients and expect to announce preliminary trial results in the second half of 2012. 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 expect to file an IND for one of the remyelinating antibodies, rHIgM22, for the treatment of MS in the first half of 2012 and expect to begin a Phase 1 clinical trial by the end of 2012. In preparation for the 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. The manufacturing data, clinical plans and preclinical safety profile will be subject to FDA review as part of our IND filing.

### Chondroitinase Program

We are continuing research, which has been funded in part by federal and state grants, 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. We are exploring the possibility of obtaining additional research grants from the National Institutes of Health, or NIH, as well as potential partnerships with other companies to support our efforts.

### Acquisition from Medtronic of AC 105

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 expect to begin enrollment in a Phase 2 clinical trial in patients with acute SCI in the second half of 2012.

### Ardsley Lease

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. Base rent will initially be \$3.4 million per year, subject to a 2.5% annual increase. We have options to extend the lease term for three additional five-year periods, and 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. We anticipate taking possession of the new space in June 2012, subject to completion of certain improvements that must be finished prior to our occupancy.





## Table of Contents

### Outlook for 2012

#### Financial Guidance for 2012

We are providing the following guidance with respect to our 2012 financial performance. The following does not reflect any potential expenditures related to the Neuronex transaction described below.

- We expect 2012 net revenue from the sale of Ampyra to range from \$255 million to \$275 million.
- We expect combined net revenues from sales of Zanaflex Capsules (including from sales of authorized generic tizanidine hydrochloride under our agreement with Watson Pharma) and Zanaflex tablets, and royalty revenue from sales by Biogen Idec of Fampyra outside the U.S., of at least \$25 million.
- Research and development expenses are expected to range from \$50 million to \$60 million, excluding share-based compensation charges. These expenses will include post-marketing studies for Ampyra, Phase 2 proof-of-concept studies in cerebral palsy and chronic stroke, and sponsorship of investigator-initiated studies of Ampyra.
- Selling, general and administrative expenses are expected to range from \$145 million to \$160 million, excluding share-based compensation charges. The principal factors affecting SG&A will be commercial and administrative costs related to Ampyra.
  - We expect to be cash flow positive in 2012.

The range of SG&A and R&D expenditures for 2012 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 2012 Initiatives and Expected Developments

Our key initiatives and expected developments during 2012 are as follows:

##### Biogen Idec

Biogen Idec plans to submit regulatory filings for Fampyra in more than 20 countries in 2012. To date, Biogen Idec has launched Fampyra in Germany, the United Kingdom, Denmark, Norway and Iceland, and it is expected that Fampyra will be available in the remaining EU countries by the end of 2012. Also, in May 2011, Fampyra was approved for use in Australia by the Australian Therapeutic Goods Administration, and has been launched there. In November 2011, Biogen Idec received approval from the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE), and in February 2012 Biogen Idec received approval from Health Canada.



## Table of Contents

### Targeted Development Milestones

Our goals with respect to our development pipeline in 2012 are as follows:

- Our Phase 2 proof-of-concept clinical trial of dalfampridine in adults with cerebral palsy, which was commenced in December 2011, is expected to continue throughout 2012.
- We plan to submit an IND for rHIgM22 with the FDA in the first half of 2012, and to begin a Phase 1 clinical trial by the end of 2012.
- Initial study results from our ongoing GGF2 Phase 1 clinical trial are expected to be announced in the second half of 2012.
- A Phase 2 proof-of-concept clinical trial of dalfampridine in chronic stroke patients is expected to begin in the second half of 2012.
  - A Phase 2 clinical trial of AC105 in patients with acute SCI is expected to begin in the second half of 2012.
- Funding of investigator-initiated studies of Ampyra in MS, focused on a range of neurological functions and other neurological disorders, will be ongoing in 2012.

### Neuronex Acquisition Agreement and Development of DZNS

On February 15, 2012, we entered into a merger agreement with Neuronex, Inc., which is preparing a 505(b)(2) type NDA for a proprietary nasal spray formulation of Diazepam, or DZNS, as a rescue treatment for certain epilepsy patients. We made an upfront payment of \$2 million upon signing the agreement and will fund up to \$1.2 million (of which we paid \$500,000 on signing) in research and development costs prior to closing.

The closing is subject to a number of conditions including our satisfaction with the results of a meeting to be held with the FDA regarding Neuronex's expected NDA filing. Following the pre-NDA meeting, we can, at our option, complete the acquisition by paying an additional \$6.8 million in merger consideration. If we do not complete the transaction, other than as a result of a breach by Neuronex, Neuronex is entitled to retain all amounts previously paid by us as a break-up fee and we have no further obligations to Neuronex.

If we consummate the acquisition and the Neuronex product is approved by the FDA, additional potential payments would include up to \$18 million to the former Neuronex equity holders in earnout payments upon the achievement of specified regulatory and manufacturing-related milestones and up to \$105 million upon the achievement of specified sales milestones. The former Neuronex equity holders would also be entitled to receive milestone and royalty-like earnout payments from us based on worldwide net sales, ranging from the upper single digits to lower double digits.

In addition to the potential payments to former Neuronex equity holders, if we consummate the acquisition, we would be obligated to pay certain amounts to SK Biopharmaceuticals Co., Ltd. ("SK"), the licensor of the patent and other intellectual property and other rights relating to the DZNS product, under its license agreement with Neuronex. Pursuant to this license, Neuronex is obligated to pay SK up to \$8 million upon the achievement of specified development milestones with respect to the DZNS product (including \$1 million upon the FDA's acceptance of the NDA for the DZNS product), and up to \$3 million upon the achievement of specified sales milestones with respect to the DZNS product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of DZNS products.

If the acquisition is completed, we will assume oversight and financial responsibility for Neuronex's development and regulatory programs for diazepam nasal spray. We expect that these expenses would not exceed

## Table of Contents

\$8 million in 2012.

We expect that Neuronex will not have any employees at the time of the acquisition, if it is completed.

### Ardasley Lease

We expect to move into our new facility in Ardsley, New York in June 2012, subject to completion of certain improvements, which are being funded in part by us and in part by the owner of the facility.

### Results of Operations

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. 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 consists 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. We expect net revenues from the sale of Zanaflex Capsules to decline substantially during the year ended December 31, 2012.

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

## Table of Contents

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 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 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.

## Table of Contents

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 rHlgM22 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.

## Table of Contents

### 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 a 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.

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

#### Net Revenue

##### Ampyra

We recognize product sales of Ampyra following shipment of product to a network of specialty pharmacy providers, Kaiser and the specialty distributor to the VA. We recognized net revenue from the sale of Ampyra of \$133.1 million for the year ended December 31, 2010.

Discounts and allowances which are included as an offset in net revenue consists 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.

##### 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 \$48.5 million for the year ended December 31, 2010, as compared to \$50.0 million for the year ended December 31, 2009. The decrease was due to a decrease in both shipments and prescriptions due to increasing managed care pressure, among other factors, partially offset by a 15% price

## Table of Contents

increase for Zanaflex Capsules effective February 1, 2010 and a 9% price increase for Zanaflex Capsules and tablets effective November 1, 2010.

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.

### License Revenue

The Company recognized \$9.4 million and \$4.7 million in license revenue for the years ended December 31, 2010 and 2009, respectively related to the \$110.0 million received from Biogen Idec in 2009 as part of our collaboration agreement. The increase was due to recognition of a full year of revenue in 2010 versus a half year of recognition in 2009.

### Cost of Sales

#### Ampyra

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

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

#### Zanaflex

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



## Table of Contents

### Cost of License Revenue

We recorded cost of license revenue of \$660,000 and \$330,000 for the years ended December 31, 2010 and 2009, respectively. 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. The increase in cost of license revenue represents a full year of recognition for 2010 versus a partial year for 2009.

### Research and Development

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

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

### Selling, General and Administrative

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

General and administrative expenses for the year ended December 31, 2010 were \$44.9 million compared to \$32.0 million for the year ended December 31, 2009, an increase of approximately \$12.9 million, or 40%. The increase was the result of an increase in general and administrative staff and compensation and other expenses of \$5.3 million related to supporting the overall growth of the organization, an increase in medical affairs expenses including educational programs of \$4.2 million, and an increase in costs related to Ampyra post-approval regulatory, safety and



technical operations support expenses of \$3.4 million.

## Table of Contents

### Other Expense

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

### 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 2011 and, at December 31, 2011, we had \$295.9 million of cash, cash equivalents and short-term investments, compared to \$240.0 million at December 31, 2010. We believe that we have sufficient cash, cash equivalents and short-term investments on hand, in addition to cash expected to be generated from operations, to fund our 2012 business plan, including our currently anticipated development pipeline activities in 2012 and our anticipated payment commitments to Neuronex.

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, 2011, \$6.4 million of these promissory notes was outstanding, which amount includes accrued interest. The first of seven annual payments on this note were due and paid on the one year anniversary after Ampyra approval on January 22, 2011 and will continue to be paid annually until paid in full.

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.

## Table of Contents

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, 2011, referred to as the revenue interest liability, of approximately \$2.9 million. We impute interest expense associated with this liability using the effective interest rate method and record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 5.7%. Payments made to PRF as a result of Zanaflex sales levels will reduce the accrued interest liability and the principal amount of the revenue interest liability.

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 \$1.0 million as of December 31, 2011 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, 2011, cash and cash equivalents and short-term investments were approximately \$295.9 million, as compared to \$240.0 million at December 31, 2010. 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

Table of Contents

deposits and investments in a Treasury money market fund and high-quality government bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. As of December 31, 2011, our cash and cash equivalents were \$58.0 million, as compared to \$34.6 million as of December 31, 2010. 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 \$238.0 million as of December 31, 2011, as compared to \$205.4 million as of December 31, 2010.

Net Cash Provided by/(Used in) Operations

Net cash provided by (used in) 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.

Cash used in operations for the year ended December 31, 2010 was primarily attributable to an increase in inventory held by the Company of \$31.7 million due to the purchase of Ampyra launch stock and additional Ampyra inventory to meet demand which was launched in 2010, an increase in accounts receivable of \$16.5 million resulting from an increase in gross product sales for Ampyra which was launched in 2010, a net loss of \$11.8 million, and a decrease in the non-current portion of deferred license revenue of \$9.4 million due to the amortization of the upfront collaboration payment received during the three-month period ended September 30, 2009. Cash used in operations for the year ended December 31, 2010 also included a net increase of \$23.5 million due to changes in other working capital items. Cash used in operations was partially offset by a non-cash share-based compensation expense of \$17.8 million, amortization of net premiums and discounts on short-term investments of \$4.5 million, and depreciation and amortization of \$4.0 million.

Net Cash Used in Investing

Net used in investing activities for the year ended December 31, 2011 was \$45.0 million, primarily due to \$266.7 million in purchases of short-term investments, purchases of intangible assets of \$3.6 million, and purchases of property and equipment of \$2.2 million partially offset by \$227.5 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, 2011 was \$2.0 million, primarily due to \$4.0 million in net proceeds from the issuance of common stock and exercise of stock options partially offset by \$2.0 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

Table of Contents

significant contractual obligations at December 31, 2011 and the effect such obligations are expected to have on our liquidity and cash flow in future periods.

(In thousands)	Total	Payments due by period (1)		
		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)	20,371	2,275	10,589	7,507
Inventory purchase commitments (4)	12,442	12,442	—	—
Total	\$38,534	\$15,861	\$14,022	\$8,651

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

(2) Represents the remaining 6 annual payments of principal and interest to be made on the convertible note payable to Saints Capital.

(3) Represents payments for Hawthorne, NY lease through June 2012, then for Ardsley, NY lease thereafter.

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

Under certain license agreements, we are also required to pay license fees and milestones for the use of technologies and products in our R&D activities and in the commercialization of products. We have committed to make potential future milestone payments to third parties of up to approximately \$63.0 million as part of our various collaborations, including licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones had not occurred as of December 31, 2011, 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.

## Table of Contents

### 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, 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 30 days of inventory.

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

Based on 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 will accept returns of Ampyra for two months prior to and six months after its expiration date but, once our product is prescribed, it cannot be returned. We will provide a credit to our customers for returned products but we do not exchange product from inventory for the returned product.

#### 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

Table of Contents

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 \$1.3 million and \$386,000 for the years ended December 31, 2011 and 2010, respectively. A 10% change in this expense estimate would have had an approximate \$130,000 and \$39,000 effect on the Company's cost of sales for the years ended December 31, 2011 and 2010, 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 being 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, 2011 we received approximately \$3.4 million in recall returns which was charged directly against deferred revenue. Under the terms of our agreement with

## Table of Contents

Alkermes, they are responsible for the cost of replacing the inventory and any reasonable and actual costs and expenses that we incur 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 the Company's allowances and accruals requiring critical estimates, and the specific considerations it uses in estimating their amounts are as follows:

**Government Chargebacks and Rebates:** The Company contracts with Medicaid and other government agencies such as the Federal Supply Schedule which commits us to providing those agencies with our most favorable pricing. This ensures that our products remain eligible for purchase or reimbursement under these government-funded programs. 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. The Company's chargebacks and rebate accruals were \$3.1 million and \$2.8 million at December 31, 2011 and December 31, 2010, respectively. A 10% change in the Company's chargebacks and rebate allowances would have had an approximate \$998,000 and \$493,000 effect on the Company's net revenue for the years ended December 31, 2011 and December 31, 2010, respectively.

**Managed Care Contract Rebates:** The Company contracts 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 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. The Company's managed care contract rebate accruals were \$273,000 and \$222,000 at December 31, 2011 and December 31, 2010, respectively. A 10% change in the Company's managed care contract rebate allowances would have had an approximate \$146,000 and \$33,000 effect on the Company's net revenue for the years ended December 31, 2011 and December 31, 2010, respectively.

**Copay Mitigation Rebates:** The Company offers copay mitigation to commercially insured patients who have coverage for Ampyra (and do not reside in states excluded from receiving copay mitigation) 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. The Company's copay mitigation rebate accruals were \$135,000 and \$31,000 at December 31, 2011

and December 31, 2010, respectively. A 10% change in the Company's managed care contract rebate allowances would have had an approximate \$489,000 and \$296,000 effect on the Company's net revenue for the years ended December 31, 2010 and December 31, 2010, respectively.

Table of Contents

**Cash Discounts:** The Company sells Ampyra directly to its 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 provides invoice discounts for prompt payment. The Company estimates its 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. The Company's cash discounts and allowances accruals were \$303,000 and \$324,000 at December 31, 2011 and December 31, 2010, respectively. A 10% change in the Company's cash discounts and allowances would have had an approximate \$336,000 and \$258,000 effect on the Company's net revenue for the years ended December 31, 2011 and December 31, 2010, respectively.

**Product Returns:** Our specialty pharmacies have 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 has been prescribed, it is no longer eligible for return. When specialty pharmacies return product, they will be given a credit against amounts owed. The Company does not replace returned product with new product. As of the year ended December 31, 2011, the Company has not received any product returns of Ampyra. Ampyra has been granted orphan drug status, meaning that the product should not be subject to generic competitors for at least seven years post approval. While we do not have the benefit of our own historical data for a product similar to Ampyra, we compared reserve rates employed by companies with similar selling models or products (i.e. other specialty pharmaceutical products). Based on our specialty distribution model (sales to only a limited number of specialty pharmacies, Kaiser, and the specialty distributor to the VA), the data we receive from our specialty pharmacies, the returns experience of other specialty products with similar selling models and the fact that the specialty pharmacies, Kaiser, and the specialty distributor to the VA have contractually agreed to hold no more than 30 days' worth of product stock, we expect the returns rate for Ampyra will be low, similar to other specialty distribution models. We consider the past buying patterns our specialty pharmacies, Kaiser, and the specialty distributor to the VA, the estimated remaining shelf life of product previously shipped, the expiration dates of product currently being shipped, our own price changes and those of competitive products, and introductions of generic products as applicable to determine our return rate. The Company's returns accrual was \$480,000 and \$353,000 at December 31, 2011 and December 31, 2010, respectively. A 10% change in the Company's returns allowance would have had an approximate \$13,000 and \$35,000 effect on the Company's net revenue for the years ended December 31, 2011 and December 31, 2010, 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:** The Company has 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 the Company, as well as indirectly through Ampyra Patient Support Services (APSS), which in turn provides data to the Company. A data fee is paid by the Company 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. The Company pays a fee for service to certain wholesalers on contractually determined rates for distribution, inventory management and data reporting services. The Company estimates its fee for service accruals and allowances based on sales to each wholesaler and the applicable contracted rate. The Company's 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. The Company's data fee and fee for service accruals were \$998,000 and \$1.2 million at December 31, 2011 and December 31, 2010, respectively. A 10% change in the Company's data fee and fee for service





Table of Contents

allowances would have had an approximate \$466,000 and \$375,000 effect on the Company's net revenue for the years ended December 31, 2011 and 2010, respectively.

The Company has adjusted its allowances in the past based on actual experience, and the Company will likely be required to make adjustments to these allowances and accruals in the future. The historical adjustments have not been significant to operations. The Company continually monitors its allowances and accruals and makes adjustments when the Company believes 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 2011, 2010 and 2009:

(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
Balance at December 31, 2008	572	-	-	258	-	620	1,450
Allowances for sales 2009	3,383	-	-	1,576	-	2,889	7,848
Allowances for prior year sales	468	-	-	-	-	(7 )	461
Actual credits for sales during 2009	(2,228 )	-	-	(1,434 )	-	(2,154 )	(5,816 )
Actual credits for prior year sales	(430 )	-	-	(168 )	-	(586 )	(1,184 )
Balance at December 31, 2009	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 )

Balance at December 31, 2010	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 )
Balance at December 31, 2011	\$ 3,099	\$ 273	\$ 135	\$ 303	\$ 480	\$ 998	\$ 5,288

### 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, 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 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.

## Table of Contents

### 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. As of December 31, 2011 we estimated 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.

### Ampyra Inventory

Prior to regulatory approval of Ampyra in the three-month period ended March 31, 2010, the Company 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, the Company 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 the Company's agreement with Alkermes and well as the capitalization of a milestone achievement with the Canadian Spinal Research Organization (CSRO) during the three months ended March 31, 2010, packaging costs, freight and required inventory stability testing costs. The Company's 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 net selling price pertaining to a prior quarter. At the end of each quarter, the Company performs 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 the Company's balance sheet and is required to be paid within 45 days of the quarter end. In the event the Company has sold any inventory purchased from Alkermes during that respective quarter, the Company 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 the Company to purchase up to 25% of its 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 the Company's balance sheet.

## Table of Contents

### 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, intangible write-off expense when necessary, 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

Research and development expenses include the costs associated with our internal research and development activities including, employee compensation and benefits, occupancy costs, and research and development conducted for us by third parties, such as contract research organizations (CROs), sponsored university-based research, clinical trial vendors, contract manufacturing for our preclinical program, costs of materials used in clinical trials, depreciation of capital resources used to develop our products and regulatory consulting to support our products. In addition, research and development expenses include expenses related to grant revenue and the cost of clinical trial drug supply shipped to our clinical study vendors. 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 have three ongoing research and development programs – neuregulins, remyelinating antibodies and chondroitinase – focused on novel approaches to limit and repair damage to components of the CNS. A clinical trial is ongoing for our lead product candidate for our neuregulins program, GGF2. We plan to file an IND for our lead antibody in our remyelinating antibody program, rHIgM22, in the first half of 2012, and to begin a Phase 1 clinical trial by the end of the year. Our chondroitinase program is still in the research phase. In addition, in 2011, we in-licensed a clinical-stage program, AC105, to develop an acute treatment for neurological trauma. 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 in-licensing 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.

With respect to previously established clinical study accruals in prior periods and for the twelve-month period ended December 31, 2011 we did not make any significant adjustments to our clinical study costs.



## Table of Contents

### 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 and the cost of Ampyra and Zanaflex sales and marketing initiatives.

### 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 investments. Interest expense consists of interest expense related to our revenue interest liability and accrued interest on our convertible notes.

### Income Taxes

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

We recorded a \$1.4 million provision for income taxes for the year ended December 31, 2011. We did not record any tax provision or benefit for the years ended December 31, 2010 or 2009. We have provided a valuation allowance for the full amount of our gross deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carryforwards cannot be sufficiently assured at December 31, 2011.

As of December 31, 2011, we had available federal net operating loss carry-forwards of approximately \$230.4 million and state net operating loss carry-forwards of approximately \$205.9 million which may be available to offset future taxable income, if any. The federal losses are expected to expire between 2022 and 2030 while the state losses are expected to expire between 2012 and 2030. We also have research and development tax credit carry-forwards of approximately \$4.0 million for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2019. Since our inception, we have incurred substantial losses and may incur substantial and recurring losses in future periods. The Internal Revenue Code of 1986, as amended, the Code, provides for a limitation of the annual use of net operating loss and research and development tax credit carry-forwards (following certain ownership changes, as defined by the Code) that could significantly limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Code, as a result of past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry-forwards may be applied against future taxes we may not be able to take full advantage of these attributes for federal income tax purposes.

### Share-Based Compensation



We account for stock options and restricted stock granted to employees and non-employees by recognizing the costs resulting from all share-based payment transactions in the financial statements at their fair

Table of Contents

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:

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

Of these assumptions, the expected term of the option and expected volatility of our common stock are the most difficult to estimate since they are based on the exercise behavior of the employees and expected performance of our common stock. Increases in the term and the volatility of our common stock will generally cause an increase in compensation expense. As we acquire more historical data for our stock's volatility over the expected term of the options, we will weight our stock's volatility heavier versus our peers in the expected volatility assumption.

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

Our financial instruments consist of cash and cash equivalents, short-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, 2011.

We have cash equivalents and short-term investments at December 31, 2011, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the short-term nature of our investments in money market funds and US Treasury bonds, the carrying value of our cash equivalents and short-term investments approximate their fair value at December 31, 2011. At December 31, 2011, we held \$295.9 million in cash and cash equivalents and short-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.



Table of Contents

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 2011 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, 2011, 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, 2011 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 2011 (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, 2011, 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, 2011. This attestation report appears below.

Table of Contents

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, 2011, 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, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Acorda Therapeutics, Inc. and subsidiaries as of December 31, 2011, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year then ended, and our report dated February 28, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
February 28, 2012

95

---



Table of Contents

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 2012 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 2012 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 2012 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 2012 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 2012 Proxy Statement under the caption for the proposal relating to the “Ratification of Independent Auditors” and is incorporated herein by this reference.



Table of Contents

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

Report of KPMG LLP, Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2011 and 2010

Statements of Operations for the years ended December 31, 2011, 2010 and 2009

Statements of Changes in Stockholders' Equity for the years ended December 31, 2011, 2010 and 2009

Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009

Notes to Financial Statements

Table of Contents

INDEX TO FINANCIAL STATEMENTS

	PAGE
Consolidated Financial Statements of Acorda Therapeutics, Inc. and Subsidiaries:	
Reports of Independent Registered Public Accounting Firms	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Operations	F-5
Consolidated Statements of Changes in Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-8

F-1

---

Table of Contents

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, 2011 and 2010 and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These consolidated 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 as of December 31, 2011 and 2010 and the results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue recognition as a result of the adoption of the amendments to the FASB Accounting Standards Codification resulting from Accounting Standards Update No. 2010-17, Revenue (Topic 605): Milestone Method of Revenue Recognition (EITF Issue 08-9; ASC 605), effective January 1, 2011.

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, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 28, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

MetroPark, New Jersey  
February 28, 2012

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated statements of operations, changes in stockholders' equity, and cash flows of Acorda Therapeutics, Inc. and subsidiaries (the Company) for the year ended December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, Acorda Therapeutics, Inc. and subsidiaries results of operations and cash flows for the year ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Short Hills, New Jersey  
February 26, 2010

Table of Contents

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

(In thousands, except share amounts)

	December 31,	
	2011	2010
Assets		
Current assets:		
Cash and cash equivalents	\$57,954	\$34,641
Restricted cash	303	302
Short-term investments	237,953	205,389
Trade accounts receivable, net of allowances of \$879 and \$289, as of December 31, 2011 and 2010, respectively	22,828	22,272
Prepaid expenses	6,534	6,413
Finished goods inventory held by the Company	27,256	36,232
Finished goods inventory held by others	1,126	2,186
Other current assets	6,988	3,734
Total current assets	360,942	311,169
Property and equipment, net of accumulated depreciation	3,858	3,203
Intangible assets, net of accumulated amortization	8,769	21,336
Non-current portion of deferred cost of license revenue	5,442	6,050
Other assets	477	343
Total assets	\$379,488	\$342,101
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$21,393	\$16,961
Accrued expenses and other current liabilities	24,149	33,769
Deferred product revenue—Zanaflex tablets	9,967	9,526
Deferred product revenue—Zanaflex Capsules	20,632	21,770
Current portion of deferred license revenue	9,057	9,429
Current portion of revenue interest liability	1,001	1,297
Current portion of convertible notes payable	1,144	1,144
Total current liabilities	87,343	93,896
Non-current portion of deferred license revenue	77,742	86,429
Put/call liability	1,030	391
Non-current portion of revenue interest liability	1,898	3,586
Non-current portion of long-term convertible notes payable	5,230	6,185
Other non-current liabilities	1,036	353
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at December 31, 2011 and 2010; issued and outstanding 39,328,495 and 38,779,370 shares, including those held in treasury, as of December 31, 2011 and 2010, respectively	39	39
Treasury stock at cost (12,420 shares)	(329)	(329)
Additional paid-in capital	614,914	591,649
Accumulated deficit	(409,481)	(440,086)

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

Accumulated other comprehensive income (loss)	66	(12)
Total stockholders' equity	205,209	151,261
Total liabilities and stockholders' equity	\$379,488	\$342,101

See accompanying Notes to Consolidated Financial Statements

F-4

---



Table of Contents

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(In thousands, except per share data)

	Year ended December 31, 2011	Year ended December 31, 2010	Year ended December 31, 2009
<b>Revenues:</b>			
Net revenue	\$256,271	\$181,545	\$49,959
Milestone revenue	25,000	—	—
License revenue	9,057	9,428	4,714
Royalty revenue	1,909	32	—
Total net revenues	292,237	191,005	54,673
<b>Costs and expenses:</b>			
Cost of sales	64,183	35,518	11,059
Cost of milestone and license revenue	2,384	660	330
Research and development	42,108	30,600	34,611
Selling, general and administrative	148,508	132,657	89,930
Total operating expenses	257,183	199,435	135,930
Operating income (loss)	35,054	(8,430 )	(81,257 )
<b>Other expense:</b>			
Interest and amortization of debt discount expense	(3,570 )	(3,922 )	(4,415 )
Interest income	552	575	1,750
Other income (expense)	(18 )	8	(18 )
Total other expense	(3,036 )	(3,339 )	(2,683 )
Income (loss) before taxes	\$32,018	\$(11,769 )	\$(83,940 )
Provision for income taxes	(1,413 )	—	—
Net income (loss)	\$30,605	\$(11,769 )	\$(83,940 )
Net income (loss) per share—basic	\$0.78	\$(0.31 )	\$(2.22 )
Net income (loss) per share—diluted	\$0.76	\$(0.31 )	\$(2.22 )
Weighted average common shares outstanding used in computing net income (loss) per share—basic	39,000	38,355	37,735
Weighted average common shares outstanding used in computing net income (loss) per share—diluted	40,064	38,355	37,735

See accompanying Notes to Consolidated Financial Statements

Table of Contents

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Changes in Stockholders' Equity

(In thousands)

	Common stock					Accumulated other comprehensive income	Total stockholders' equity
	Number of shares	Par value	Treasury stock	Additional paid-in capital	Accumulated deficit		
Balance at December 31, 2008	37,613	\$38	\$0	\$550,683	\$(344,377)	\$813	\$207,157
Compensation expense for issuance of stock options to employees	—	—	—	9,690	—	—	9,690
Compensation expense for issuance of restricted stock to employees	128	—	—	2,588	—	—	2,588
Exercise of stock options	194	—	—	2,542	—	—	2,542
Comprehensive loss				—			
Unrealized loss on investment securities	—	—	—	—	—	(704)	(704)
Net loss	—	—	—	—	(83,940)	—	(83,940)
Total comprehensive loss							(84,644)
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
Comprehensive loss							

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

Unrealized loss on investment securities	—	—	—	—	—	(121)	(121)
Net loss	—	—	—	—	(11,769)	—	(11,769)
Total comprehensive loss							(11,890)
Balance at December 31, 2010	38,779	\$39	\$(329)	\$591,649	\$(440,086)	\$(12)	\$151,261
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
Comprehensive income							
Unrealized gain on investment securities	—	—	—	—	—	78	78
Net income	—	—	—	—	30,605	—	30,605
Total comprehensive income							30,683
Balance at December 31, 2011	39,328	\$39	\$(329)	\$614,914	\$(409,481)	\$66	\$205,209

See accompanying Notes to Consolidated Financial Statements

Table of Contents

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

(In thousands)

	Year ended December 31, 2011	Year ended December 31, 2010	Year ended December 31 2009
Cash flows from operating activities:			
Net income (loss)	\$30,605	\$(11,769)	\$(83,940)
Adjustments to reconcile net loss to net cash provided by/(used in) operating activities:			
Share-based compensation expense	19,303	17,777	12,278
Amortization of net premiums and discounts on short-term investments	6,750	4,473	4,931
Amortization of revenue interest issuance cost	104	96	93
Depreciation and amortization expense	4,625	3,951	2,762
Intangible asset impairment	13,038	—	—
(Gain) loss on put/call liability	639	(246)	300
Gain on disposal of property and equipment	—	—	(15)
Changes in assets and liabilities:			
Increase in accounts receivable	(556)	(16,533)	(1,116)
Increase in prepaid expenses and other current assets	(3,375)	(1,892)	(3,320)
Decrease (increase) in inventory held by the Company	8,976	(31,735)	(619)
Decrease in inventory held by others	1,060	209	78
Decrease (increase) in non-current portion of deferred cost of license revenue	608	660	(6,710)
(Decrease) increase in other assets	(237)	1	6
(Decrease) increase in accounts payable, accrued expenses, other current liabilities	(6,108)	24,706	2,024
(Decrease) increase in revenue interest liability interest payable	(23)	(76)	200
(Decrease) increase in current portion of deferred license revenue	(371)	—	9,428
(Decrease) increase in non-current portion of deferred license revenue	(8,686)	(9,428)	95,857
Increase in other non-current liabilities	682	—	—
Increase in deferred product revenue—Zanaflex tablets	441	311	1,348
(Decrease) increase in deferred product revenue—Zanaflex Capsules	(1,138)	281	5,053
Restricted cash	(1)	(1)	(4)
Net cash (used in)/provided by operating activities	66,336	(19,215)	38,634
Cash flows from investing activities:			
Purchases of property and equipment	(2,192)	(2,446)	(1,148)
Purchases of intangible assets	(3,595)	(6,998)	(1,279)

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

Purchases of short-term investments	(266,736)	(310,955)	(310,378)
Proceeds from maturities of short-term investments	227,500	325,750	296,400
Net cash (used in)/provided by investing activities	(45,023)	5,351	(16,405)
Cash flows from financing activities:			
Proceeds from issuance of common stock and option and warrant exercises	3,962	8,370	2,542
Purchase of treasury stock	—	(329)	—
Repayments of revenue interest liability	(1,962)	(6,850)	(7,070)
Net cash provided by/(used in) financing activities	2,000	1,191	(4,528)
Net increase (decrease) in cash and cash equivalents	23,313	(12,673)	17,701
Cash and cash equivalents at beginning of period	34,641	47,314	29,613
Cash and cash equivalents at end of period	\$57,954	\$34,641	\$47,314
Supplemental disclosure:			
Cash paid for interest	\$3,404	\$3,781	\$4,040
Cash paid for taxes	1,176	—	—

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

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 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.

Short-Term Investments

Short-term investments consist of US Treasury bonds with maturities greater than three months. The Company classifies its short-term investments as available-for-sale. Available-for-sale securities are recorded at fair value of the investments based on quoted market prices.

F-8

---

## Table of Contents

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.

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

Prior to regulatory approval of Ampyra, the Company incurred expenses for the manufacture of bulk, unpackaged product 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 there was no alternative future use prior to regulatory approval. 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, the Company began capitalizing the commercial inventory costs associated with manufacturing with Alkermes plc (Alkermes), formerly Elan Corporation, plc (Elan) and its second manufacturer, Patheon.

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 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 three to five 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.

F-9

---

## Table of Contents

### 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. Based on this evaluation, the Company believes that, as of each of the balance sheet dates presented, none of the Company's long-lived assets were impaired.

### 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

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. The Company has no reserves for uncertain tax positions.

F-10

---

## Table of Contents

### 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 Amerisource Specialty Distribution Healthcare, which is the exclusive specialty pharmacy distributor for 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, 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 30 days of inventory.

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, 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.

Based on the Company's specialty distribution model where it sells to only specialty pharmacies, Kaiser and the specialty distributor to the VA, the inventory and prescription data it receives from these distributors, and returns experience of other specialty products with similar selling models, the Company has been able to make a reasonable estimate for product returns. The Company will accept returns of Ampyra for two months prior to and six months after the product expiration date. The Company will provide a credit for such returns to customers with whom we have a direct relationship. Once product is prescribed, it cannot be returned. The Company does not exchange product from inventory for the returned product.

#### 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 was

F-11

---

## Table of Contents

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 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.

### 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 and cash equivalents, restricted cash and accounts receivable. The Company maintains cash and cash equivalents and restricted cash 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

F-12

---

Table of Contents

excess of FDIC insured limits. The Company performs periodic evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any institution.

The Company is substantially dependent upon Alkermes for several activities related to the development and commercialization of Ampyra. The Company and Alkermes rely on a single third-party manufacturer to supply dalfampridine, the active pharmaceutical ingredient in Ampyra. Under the Company's supply agreement with Alkermes, the Company is obligated to purchase at least 75% of its yearly supply of Ampyra from Alkermes, and the Company is required to make compensatory payments if it does not purchase 100% of its requirements from Alkermes, subject to 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 currently relies on Alkermes to supply it with Zanaflex Capsules (and for the supply of its authorized generic Zanaflex capsules being marketed by Watson Pharma) under its 2004 Supply Agreement. The initial term of the agreement expired in 2009, but is subject to two automatic two-year renewal terms. Either party may terminate the agreement by notifying the other party at least 12 months prior to the expiration of the initial term or any renewal term. In addition, either party may terminate the agreement if the other party commits a material breach that remains uncured. If a failure to supply occurs under the agreement, other than a force majeure event, or if the Company terminates the supply agreement for cause, Alkermes must use commercially reasonable efforts to assist the Company in transferring production of Zanaflex Capsules to it or a third-party manufacturer, provided that such third party is not a technological competitor of Alkermes. If the Company needs to transfer production, Alkermes has agreed to grant it 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 proprietary technology for specified purposes. The Company has 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 the Company to preserve the continuity of supply of products, including the possibility of transferring manufacturing of Zanaflex Capsules to it or a third party manufacturer. Patheon manufactures Zanaflex tablets for us.

Farmak a.s. is the Company's supplier of tizanidine hydrochloride, the active pharmaceutical ingredient, or API, in Zanaflex Capsules. Also, in June 2011, the Company received FDA approval for Farmak to also be its supplier of tizanidine hydrochloride for Zanaflex tablets.

If Alkermes, Patheon or Farmak experiences any disruption in their operations, a delay or interruption in the supply of its Zanaflex products could result until the affected supplier cures the problem or the Company locates an alternate source of supply. The Company may not be able to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements. The Company could experience substantial delays before it is able to qualify any new supplier and transfer the required manufacturing technology to that supplier. If the Company cannot manufacture enough of its Zanaflex products to meet demand, its sales would suffer.

The Company's principal direct customers as of December 31, 2011 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.





## Table of Contents

### Allowance for Cash Discounts

An allowance for cash discounts are 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 \$3.4 million and \$2.6 million for the years ended December 31, 2011 and 2010, respectively. The Company's accruals for cash discount allowances were \$303,000 and \$324,000 as of December 31, 2011 and 2010 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 \$600,000 as of December 31, 2011. The Company did not recognize an allowance as of December 31, 2010, as management believed all outstanding accounts receivable were fully collectible as of that date.

### 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 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

Net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding. The difference between basic and diluted shares is that diluted shares include the dilutive effect of the assumed exercise of outstanding securities. The Company has certain common share equivalents, which are described more fully in Note 7, which have not been used in the calculation of diluted net income (loss) per share for prior years because to do so would be anti-dilutive. As such, the numerator and the denominator used in computing both basic and diluted net income (loss) per share for prior years are equal.

Share-based Compensation

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

F-14

---

## Table of Contents

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 for the expected term of the stock options, expected volatility of its common stock, prevailing interest rates, and an estimated forfeiture rate.

## Segment Information

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

## Comprehensive Income

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

## Reclassification

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

## Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, "Comprehensive Income (Topic 220): Presentation of Comprehensive Income" (ASU 2011-05). 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 provisions of this new disclosure standard are effective January 1, 2012. The Company does not believe this accounting standard update will have a material effect on its financial statements.

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. The Company does not believe this accounting standard update will have a material effect on its 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 other than those disclosed in Note 15.

Table of Contents

## (3) Short-Term Investments

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

(In thousands)	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
December 31, 2011				
US Treasury bonds	\$237,887	\$72	\$(6)	\$237,953
December 31, 2010				
US Treasury bonds	\$205,401	\$6	\$(18)	\$205,389

The Company's short-term investments consist of US Treasury bonds with original maturities greater than three months and less than one year. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value. 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, 2011.

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 \$38.3 million and \$23.5 million as of December 31, 2011 and 2010, respectively.

## (4) Property and Equipment

Property and equipment consisted of the following:

(In thousands)	December 31, 2011	December 31, 2010	Estimated useful lives used
Leasehold improvements	\$3,240	\$3,178	Remaining lease term
Computer equipment	5,859	4,699	3 years
Laboratory equipment	2,534	2,223	5 years
Furniture and fixtures	760	760	5 years
Capital in Progress	1,093	449	3 years
	13,486	11,309	
Less accumulated depreciation	(9,628)	(8,106)	
	\$3,858	\$3,203	

Depreciation and amortization expense on property and equipment was \$1.5 million and \$1.1 million for the years ended December 31, 2011 and 2010, respectively.



Table of Contents

## (5) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	December 31, 2011	December 31, 2010
Bonus payable	\$4,725	\$4,291
Ampyra and Zanaflex discount and allowances accruals	4,680	4,426
Ampyra milestone	2,500	—
Accrued inventory	2,464	9,665
Royalties payable	1,977	2,066
Sales force commissions and incentive payments payable	1,893	6,717
Commercial and marketing expense accruals	1,811	721
Vacation accrual	1,171	1,220
Legal accruals	898	1,024
Research and development expense accruals	640	1,880
Other accrued expenses	1,390	1,759
	\$24,149	\$33,769

## (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, 2011 is 8,366,663 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 2011, 2010 and 2009. Upon the exercise of options in the future, the Company intends to issue new shares.





Table of Contents

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,		
	2011	2010	2009
Employees and directors:			
Estimated volatility	62.80%	66.31%	75.96%
Expected life in years	5.47	5.50	5.56
Risk free interest rate	2.23%	2.57%	2.15%
Dividend yield	—	—	—

The Company estimated volatility for purposes of computing compensation expense on its employee and non-employee options using a combination of the volatility of the Company's stock price since October 1, 2006 and the volatility of public companies that the Company considered comparable. As we acquire more historical data for our stock's volatility over the expected term of the options, we will weight our stock's volatility heavier versus our peers in the expected volatility assumption. The expected life used to estimate the fair value of employee options is 5.47 years. The Company based this assumption on the historical life of our options in 2011. Prior to 2011 this assumption was based on the 50th percentile of comparable peer companies' choices for expected lives.

The weighted average fair value per share of options granted to employees and directors for the years ended December 31, 2011, 2010 and 2009 amounted to approximately \$13.02, \$19.29, and \$14.33, respectively. No options were granted to non-employees for the years ended December 31, 2011, 2010 and 2009.

During the year ended December 31, 2011, the Company granted 1,540,550 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 \$23.62 per share. 1,000 of these options vested immediately, 85,000 of these options vest over a one-year vesting schedule and 1,152,930 will vest over a four-year vesting schedule. 25,000 of the restricted stock awards granted in 2011 vest over a three-year vesting schedule, 276,620 restricted stock awards 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 \$20.5 million, of which \$5.1 million was recognized during the year ended December 31, 2011.

Compensation costs for options and restricted stock granted to employees and directors amounted to \$19.3 million, \$17.8 million, and \$12.3 million, for the years ended December 31, 2011, 2010 and 2009, 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,		
	2011	2010	2009
Research and development	\$5,801	\$5,247	\$3,662
Selling, general and administrative	13,502	12,530	8,616
Total	\$19,303	\$17,777	\$12,278

F-18

---

Table of Contents

A summary of share-based compensation activity for the year ended December 31, 2011 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, 2008	3,284	\$13.55		
Granted	826	21.97		
Forfeited and expired	(205)	16.94		
Exercised	(193)	13.15		
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	6.7	\$23,129
Vested and expected to vest at December 31, 2011	4,713	\$21.25	6.7	\$23,032
Vested and exercisable at December 31, 2011	2,987	\$18.45	5.6	\$21,043

Range of exercise price	Options Outstanding			Options Exercisable	
	Outstanding as of December 31, 2011 (In thousands)	Weighted- average remaining contractual life	Weighted- average exercise price	Exercisable as of December 31, 2011 (In thousands)	Weighted- average exercise price
\$2.45-\$16.88	1,064	3.42	\$ 7.45	1,064	\$ 7.45
\$17.52-\$21.52	1,008	6.49	20.17	737	19.97
\$21.61-\$22.13	1,062	8.11	22.07	418	22.09
\$22.24-\$31.67	966	8.01	28.00	483	28.07
\$31.71-\$37.48	693	8.23	33.80	285	33.89
	4,793	6.73	\$21.31	2,987	\$18.45

Unrecognized compensation cost for unvested stock options and restricted stock awards as of December 31, 2011 totaled \$32.1 million and is expected to be recognized over a weighted average period of approximately 2.4 years.

Table of Contents

## Restricted Stock Activity

	Number of Shares (In thousands)
Restricted Stock	
Nonvested at December 31, 2008	150
Granted	208
Vested	(128)
Forfeited	(26)
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

## (7) Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2011, 2010 and 2009:

(In thousands, except per share data)	Year ended December 31, 2011	Year ended December 31, 2010	Year ended December 31, 2009
Basic and diluted			
Net income (loss)	\$30,605	\$(11,769)	\$(83,940)
Weighted average common shares outstanding used in computing net income (loss) per share—basic	39,000	38,355	37,735
Plus: net effect of dilutive stock options and restricted common shares	1,064	—	—
Weighted average common shares outstanding used in computing net income (loss) per share—diluted	40,064	38,355	37,735
Net income (loss) per share—basic	\$0.78	\$(0.31)	\$(2.22)
Net income (loss) per share—diluted	\$0.76	\$(0.31)	\$(2.22)

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.

F-20

---

Table of Contents

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, 2011	Year ended December 31, 2010	Year ended December 31, 2009
Denominator			
Dilutive stock options and restricted common shares	4,106	4,408	3,916
Convertible note	67	67	67

## (8) Income Taxes

The Company had available federal net operating loss (NOL) carry-forwards of approximately \$230.4 million and \$266.9 million and state NOL carry-forwards of approximately \$205.9 million and \$261.0 million as of December 31, 2011 and 2010, respectively, which may be available to offset future taxable income, if any. The federal losses are expected to expire between 2022 and 2030 while the state losses are expected to expire between 2012 and 2030. The Company also has research and development tax credit carry-forwards of approximately \$4.0 million and \$3.7 million as of December 31, 2011 and 2010, for federal income tax reporting purposes that may be available to reduce federal income taxes, if any, and expire in future years beginning in 2019. The Company is no longer subject to federal or state income tax audits for tax years prior to 2006 however, such taxing authorities can review any net operating losses utilized by the Company in years subsequent to 1999. The Company also has Alternative Minimum Tax credit carry-forwards of \$1.1 and \$0.2 million as of December 31, 2011 and 2010, respectively. Such credits can be carried forward indefinitely and have no expiration date.

The difference between tax expense and the amount computed by applying the statutory federal income tax rate (35% for 2011 and 34% for 2010 and 2009) to income before income taxes is as follows:

(In thousands)	December 31, 2011	December 31, 2010	December 31, 2009
Statutory rate applied to pre-tax income (loss)	\$11,206	\$(4,017)	\$(28,448)
Add (deduct):			
Meals and entertainment	274	254	232
Stock options and restricted stock	278	(154)	2,064
State tax	325	(387)	(1,361)
Other	214	(163)	(233)
Increase (decrease) to valuation allowance (net)	(6,479)	6,627	27,746
Increase in statutory tax rate	(4,118)	—	—
Research and development credit	(287)	(2,160)	—
Income taxes	\$1,413	\$—	\$—

Table of Contents

The tax effect of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2011 and 2010 are presented below:

(In thousands)	December 31, 2011	December 31, 2010
Net operating loss carry-forwards	\$74,774	\$82,914
State NOL net of federal benefit	942	1,601
Research and development tax credit	4,025	3,738
Property and equipment	(532)	146
Intellectual property	7,399	2,608
Stock options and restricted stock	13,910	13,134
Deferred revenue	38,958	40,248
Revenue interest liability	1,504	1,939
Medtronic acquisition	1,110	—
NRI acquisition	760	795
Other temporary differences	4,746	6,703
	147,596	153,826
Less valuation allowance	(147,596)	(153,826)
Net deferred tax assets	\$—	\$—

Changes in the valuation allowance for the years ended December 31, 2011 and 2010 amounted to approximately a \$6.2 million decrease and a \$6.6 million increase, respectively. A tax benefit of \$5.9 million associated with the exercise of stock options will be recorded in additional paid-in capital when the associated net operating loss is recognized. Since inception, the Company has incurred substantial losses and may incur substantial losses in future periods. The Tax Reform Act of 1986 (the Act) provides for a limitation of the annual use of NOL and research and development tax credit carry-forwards (following certain ownership changes, as defined by the Act) that could significantly limit the Company's ability to utilize these carry-forwards. The Company has experienced various ownership changes, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carry-forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry-forwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes. Because of the above mentioned factors, the Company has not recognized its gross deferred tax assets as of and for all periods presented. As of December 31, 2011, management believes that it is more likely than not that the net deferred tax assets will not be realized based on future operations and reversal of deferred tax liabilities. Accordingly, the Company has provided a full valuation allowance against its gross deferred tax assets and no tax benefit has been recognized relative to its pretax losses.

On January 1, 2007, the Company adopted FIN 48, which was later superseded by ASC 740-10, which clarifies the accounting for income taxes by prescribing the minimum threshold a tax position is required to meet before being recognized in the financial statements as well as guidance on de-recognition, measurement, classification and disclosure of tax positions. There were no uncertain tax positions at December 31, 2011.

Table of Contents

(9) License and 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 unpaid principal is convertible into 67,476 shares of common stock. Principal and interest are repayable, if not converted, ratably over a seven-year period beginning one year after the Company receives certain regulatory approval for the products to be developed, subject to limitations related to gross margin on product sales. 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.

F-23

---

## Table of Contents

### 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.

### 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. 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.

F-24

---

Table of Contents

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 and \$9.4 million in license revenue, a portion of the \$110.0 million received from Biogen Idec, and \$634,000 and \$660,000 in cost of license revenue, a portion of the \$7.7 million paid to Alkermes, during the twelve-month periods ended December 31, 2011 and 2010, respectively.

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 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 and \$660,000 in cost of license revenue, which represents the amortized portion of the \$7.7 million paid to Alkermes in 2009, for the twelve-month periods ended

F-25

---

Table of Contents

December 31, 2011 and 2010, respectively. 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.

## (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 \$1.1 million, \$1.0 million and \$757,000 for the years ended December 31, 2011, 2010, and 2009, respectively.

## (11) Commitments and Contingencies

During 1998, the Company entered into a lease agreement for its corporate office. During November 2000, May 2001, February 2007, July 2008 and February 2009, the Company entered into amendments of the lease for its facility. Under the amendments, the Company increased the total leased space and extended the lease term for its original leased space. The lease for this facility was previously scheduled to expire in December 2012. However, in connection with the Company entering into a lease for a new headquarters facility, 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 anticipates taking possession of the new space in June 2012, subject to completion of certain improvements to the facility prior to its occupancy. The commencement of the term would be deferred in the case of certain delays in the completion of those improvements. 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 will initially be \$3.4 million per year, and will be subject to a 2.5% annual increase.

Future minimum commitments under all non-cancelable leases required subsequent to December 31, 2011 are as follows:

(In thousands)

2012	\$2,275
2013	3,443
2014	3,529
2015	3,617
2016	3,707
Later years	25,994
	\$42,565

Rent expense under these operating leases during the years ended December 31, 2011, 2010 and 2009 was \$1.1 million, \$1.1 million, and \$1.0 million, respectively.

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

F-26

---

Table of Contents

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 \$53 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 accrued at December 31, 2011 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.

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 or her employment for good reason within six months following a change in control, the Company must pay the Chief

F-27

---

## Table of Contents

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.

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. The Company is appealing the decision.

On December 2, 2011, Apotex filed suit against the Company in the U.S. District Court for the Southern District of New York. Apotex characterized the suit in its complaint as a "civil antitrust action" and "an action for false advertising" relating to Acorda's Zanaflex Capsules. Among other allegations, Apotex claims Acorda's filing of a citizen petition with the U.S. Food and Drug Administration has "delayed FDA approval of Apotex's generic tizanidine capsules". Apotex is seeking monetary damages, disgorgement of Acorda profits, recovery of litigation costs, injunctive relief, and such other relief as the Court deems proper. The Company intends to defend itself vigorously. However, we cannot be sure that we will prevail in our defense, as the outcome of litigation is inherently uncertain, and an adverse determination could harm us. The Company accrues for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. As of December 31, 2011 there have been no accruals for legal matters aside from payments related to the litigation itself.

### (12) Intangible Assets

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.

In connection with this transaction, the Company acquired the rights to the trade name "Zanaflex®", one issued U.S. patent and two patent applications related to Zanaflex Capsules, and the remaining tablet inventory on hand with Alkermes. Additionally, the Company assumed Alkermes' existing contract with Novartis to manufacture Zanaflex tablets and entered into a separate contract with Alkermes to manufacture Zanaflex Capsules. The Company separately launched Zanaflex Capsules in April 2005. The Company did not acquire any receivables, employees, facilities or fixed assets. The Company allocated, on a relative fair value basis, the initial and milestone payments made to Alkermes to the assets acquired, principally the Zanaflex trade name and the capsulation patent. There is no expected residual value of these intangible assets. The Company amortizes the allocated fair value of the trade name and patent over their estimated future economic benefit to be achieved. The Zanaflex trade name was fully amortized as of December 31, 2008.

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. The Company is appealing 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

F-28

---

Table of Contents

cost of sales. See Note 14.

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 accrued at December 31, 2011 with an additional \$2.5 million recorded as an intangible asset.

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, the Company had made an aggregate of \$850,000 in milestone payments under this agreement. As of December 31, 2011, the Company made or accrued royalty payments totaling \$6.9 million.

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.

On April 19, 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, described below, was accorded an initial patent term adjustment by the USPTO of 298 days, initially extending its term to early October 2025. The Company re-evaluated the useful life of the Ampyra milestones and Ampyra CSRO royalty buyout intangible assets during the three-month period ended June 30, 2011 and the revised estimated remaining useful lives of the assets are presented in the table below.

On August 30, 2011 the United States Patent and Trademark Office (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 eligible for listing in the FDA Orange Book, is now expected to expire in May 2027, including patent term adjustment. The final patent life issuance did not have a material impact on the amortization expense for the current or future periods.

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.

F-29

---

Table of Contents

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 noted above, the Company evaluated the value and remaining useful lives of the Zanaflex Capsule patents as of September 30, 2011 and recorded a charge of approximately \$13.0 million to fully impair this asset. As of December 31, 2011, 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 intangible assets related to Ampyra.

Intangible assets consisted of the following:

(In thousands)	December 31, 2011	December 31, 2010	Estimated remaining useful lives as of December 31, 2011
Zanaflex Capsule patents	\$19,350	\$19,350	0 years
Zanaflex trade name	2,150	2,150	0 years
Ampyra milestones	5,750	3,250	15 years
CSRO royalty buyout	3,000	3,000	8 years
Website development costs	4,028	2,975	0-3 years
Website development costs – in process	42	—	3 years
	34,320	30,725	
Less accumulated amortization	25,551	9,389	
	\$8,769	\$21,336	

The Company recorded \$16.2 million and \$2.8 million in amortization expense related to these intangible assets in the years ended December 31, 2011 and 2010, respectively. 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, 2011 for the next five years is as follows:

(In thousands)	
2012	\$1,579
2013	1,136
2014	870
2015	588
2016	588
	\$4,761

## (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).

F-30

---

Table of Contents

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 \$3.4 million, \$3.8 million and \$4.2 million in interest expense related to this agreement in 2011, 2010 and 2009, respectively. Through December 31, 2011, \$43.3 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

F-31

---

Table of Contents

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 \$1.0 million as of December 31, 2011 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, 2011, a loss of \$639,000 has been recorded as a result of the change in the fair value of the net put/call liability balance from December 31, 2010.

## (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, 2011, and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

(In thousands)	Level 1	Level 2	Level 3
2011			
Assets Carried at Fair Value:			
Cash equivalents	\$38,340	\$—	\$—
Short-term investments	237,953	—	—
Liabilities Carried at Fair Value:			
Put/call liability	—	—	1,030
2010			
Assets Carried at Fair Value:			
Cash equivalents	\$23,529	\$—	\$—
Short-term investments	205,389	—	—
Liabilities Carried at Fair Value:			

Put/call liability	—	—	391
--------------------	---	---	-----

F-32

---

Table of Contents

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)	Balance as of December 31, 2010	Realized loss included in net income	Unrealized gains included in other comprehensive income/loss	Balance as of December 31, 2011
<b>Liabilities Carried at Fair Value:</b>				
Put/call liability	\$391	\$639	\$—	\$1,030

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

The put/call liability 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 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 of these investments 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 table below presents non-financial assets that were measured and recorded at fair value on a nonrecurring basis and the total impairment losses recorded during 2011. There were no non-financial assets that were measured and recorded at fair value on a non-recurring basis in 2010 or 2009.

(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.

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. The Company is

appealing 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

F-33

---

Table of Contents

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) Subsequent Events

Apotex received FDA approval of its ANDA and launched generic tizanidine hydrochloride capsules in February 2012. Also, the Company has entered into an agreement with Watson Pharma, Inc., a subsidiary of Watson Pharmaceuticals, Inc., to market tizanidine hydrochloride capsules, an authorized generic version of Zanaflex Capsules in February 2012. The launch of generic tizanidine hydrochloride capsules into the marketplace will likely cause the Company's net revenue from Zanaflex Capsules to decline significantly.

On February 15, 2012, we entered into a merger agreement with Neuronex, Inc., a privately-held development stage pharmaceutical company. Neuronex is preparing a 505(b)(2) type New Drug Application, or NDA, for a proprietary nasal spray formulation of Diazepam, or DZNS, as a rescue treatment for certain epilepsy patients. Under the terms of the merger agreement, we made an upfront payment of \$2.0 million and paid \$500,000 of up to \$1.2 million in research funding to prepare for diazepam nasal spray pre-NDA meeting with the U.S. Food and Drug Administration, or FDA. Following the pre-NDA meeting, we can, at our option, complete the acquisition by paying an additional \$6.8 million. If the acquisition is completed, we will assume oversight and financial responsibility for all future development and regulatory programs for diazepam nasal spray. There are potential payments to Neuronex and other parties of \$1 million for the completion and acceptance of an NDA by the FDA, and up to \$25 million following regulatory approvals in the U.S. and Europe. If we complete the acquisition and the medication is approved by the FDA, the former owners of Neuronex will also be entitled to receive milestone and royalty-like earnout payments from us based on net sales.

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

(In thousands, except per share amounts)

	2011			
	March 31	June 30	September 30	December 31
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

	2010			
	March 31	June 30	September 30	December 31
Total net revenues	\$17,747	\$42,836	\$63,622	\$66,800
Gross profit	14,671	35,004	51,956	53,856
Net income (loss)—basic and diluted	(21,115)	(6,763)	12,437	3,671
Net income (loss) per share—basic	\$(0.56)	\$(0.18)	\$0.32	\$0.10
Net income (loss) per share—diluted	(0.56)	(0.18)	0.31	0.09

F-34

---

Table of Contents

## (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 by reference have been filed under the Company's SEC File Number 000-50513.

Exhibit No.	Description
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.
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	Sixth Amended and Restated Registration Rights Agreement, dated March 3, 2004, by and among the Registrant and certain stockholders named therein. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.7**	Employment Agreement, dated August 11, 2002, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.8**	Amendment to August 11, 2002 Employment Agreement, dated September 26, 2005, by and between the Registrant and Ron Cohen. Incorporated herein by reference to



Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

10.9\*\* Letter Agreement, dated November 30, 2004, by and between the Registrant and Mark Pinney. Incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

---

Table of Contents

Exhibit No.	Description
10.10**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.11**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Mary Fisher. Incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.12**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.13**	Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.14	Amended and Restated License Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.14 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A filed on July 20, 2011.
10.15*	Supply Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006
10.16	License Agreement, dated September 26, 2003, by and between the Registrant and Rush-Presbyterian-St. Luke's Medical Center. Incorporated herein by reference to Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.17	Side Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.18*	Payment Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.19*	Amendment No. 1 to the Payment Agreement, dated as of October 27, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to

Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-K

Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A,  
No. 333-128827, filed on January 25, 2006.

10.20\*

Amended and Restated License Agreement, dated August 1, 2003, by and between the Registrant and Canadian Spinal Research Organization. Incorporated herein by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006

---

Table of Contents

Exhibit No.	Description
10.21*	License Agreement, dated February 3, 2003, by and between the Registrant and Cornell Research Foundation, Inc. Incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.22	License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.22 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.23*	License Agreement, dated November 12, 2002, by and between the Registrant and CeNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.24	License Agreement, dated September 8, 2000, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.25*	Side Letter Agreement, dated June 1, 2005, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.26*	Asset Purchase Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.27*	Zanaflex Supply Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.28*	Assignment and Assumption Agreement, dated as of July 21, 2004, by and among the Registrant, Elan Pharmaceuticals, Inc., and Novartis Pharma AG. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.29*	License Agreement, dated April 17, 1991, by and between Sandoz Pharma, now Novartis Pharma AG and Athena Neurosciences, Inc., now Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.30	Patent Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1, No. 333-128827,

filed on October 5, 2005.

- 10.31 Trademark License Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
- 10.32 Agreement Relating to Additional Trademark, dated as of July 2005, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
-

Table of Contents

Exhibit No.	Description
10.33	Domain Name Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.34	Bill of Sale and Assignment and Assumption Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.35	Limited Recourse Convertible Promissory Note issued to Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.36	Full Recourse Convertible Promissory Note issued to Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.37	Note Modification and Amendment, dated as of December 23, 2005, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.
10.38*	Fampridine Tablet Technical Transfer Program Proposal for Commercial Registration, dated February 26, 2003, by and between the Registrant and Patheon, Inc. Incorporated herein by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.39	Securities Amendment Agreement, dated September 26, 2003, by and among the Registrant, Elan Corporation plc and Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.
10.40*	Syndicated Sales Force Agreement, dated as of August 1, 2005, between the Registrant and Cardinal Health PTS, LLC. Incorporated herein by reference to Exhibit 10.40 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.
10.41	License Agreement, dated as of December 19, 2003, by and among the Registrant, Cambridge University Technical Services Limited, and King's College London. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Amendment No. 1 to its Quarterly Report on Form 10-Q/A filed on July 20, 2011.
10.42	Promissory Note issued to General Electric Capital Corporation. Incorporated herein by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

10.43

Revenue Interests Assignment Agreement, dated as of December 23, 2005, between the Registrant and King George Holdings Luxembourg IIA S.à.r.l., an affiliate of Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

---

Table of Contents

Exhibit No.	Description
10.44	Securities Purchase Agreement, dated as of October 3, 2006, by and among the Registrant and the purchasers listed on Exhibit A thereto. Incorporated herein by reference to Exhibit 10.44 of the Registrant's Current Report on Form 8-K filed on October 5, 2006.
10.45	First Amendment to Revenue Interests Assignment Agreement and to Guaranty, dated November 28, 2006 by and among the Registrant, King George Holdings Luxembourg IIA S.à.r.l. and Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.45 to Registrant's Current Report on Form 8-K filed on November 29, 2006.
10.46**	Amendment to August 11, 2002 Employment Agreement, dated May 10, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.47**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.48**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Mary Fisher. Incorporated herein by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.49**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.50**	Amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.
10.51	Registration Rights Agreement, dated as of February 1, 2008, by and among the Registrant and Edward A. Labry III. Incorporated herein by reference to Exhibit 10.51 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.
10.52**	Amendment to August 11, 2002 Employment Agreement dated December 28, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.52 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.
10.53**	Employment Offer Letter, dated October 20, 2008, by and between the Registrant and Thomas C. Wessel. Incorporated herein by reference to Exhibit 10.53 to Registrant's Annual Report on Form 10-K filed on March 2, 2009.
10.54*	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.



10.55\*

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.

---

Table of Contents

Exhibit No.	Description
10.56	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.
10.57**	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.
10.58**	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.
10.59*	Development and Supplemental Agreement between Elan Pharma International Limited and the Registrant dated January 14, 2011. Incorporated by reference to Exhibit 10.59 to Registrant's Quarterly Report on Form 10-Q filed on May 9, 2011.
10.60*	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 by reference to Exhibit 10.60 to Registrant's Quarterly Report on Form 10-Q filed on May 9, 2011.
10.61**	Amendment to August 11, 2002 Employment Agreement dated June 21, 2011, by and between the Registrant and Ron Cohen. Incorporated by reference to Exhibit 10.61 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.62	Lease, dated as of June 23, 2011, by and between the Registrant and BMR-Ardsley Park LLC. Incorporated by reference to Exhibit 10.62 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.63*	License Agreement, dated as of June 27, 2011, by and between the Registrant and Medtronic, Inc. and Warsaw Orthopedic, Inc. Incorporated by reference to Exhibit 10.63 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2011.
10.64**	Employment Offer Letter, dated August 18, 2011, by and between the Registrant and Enrique Carrazana.
10.65**	Consulting Agreement effective as of October 1, 2011, by and between the Registrant and Thomas C. Wessel.
10.66**	Letter agreement dated October 19, 2011, by and between the Registrant and Enrique Carrazana.
10.67**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Andrew R. Blight.
10.68**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and David Lawrence.

10.69\*\* Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Jane Wasman.

10.70\*\* Letter agreement dated November 7, 2011, by and between the Registrant and Lauren Sabella.

10.71\*\* Separation Agreement and General Release dated November 21, 2011, by and between the Registrant and Thomas C. Wessel.

21 List of Subsidiaries of the Registrant.

---

Table of Contents

Exhibit No.	Description
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
23.2	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32.1	Certification 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

---

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

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

\*\*\*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.”

Table of Contents

## 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 28th day of February 2012.

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.

Signature	Title	Date
/s/ Ron Cohen, M.D. Ron Cohen, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2012
/s/ David Lawrence, M.B.A. David Lawrence, M.B.A.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 28, 2012
/s/ Barry Greene Barry Greene	Director	February 28, 2012
/s/ Peder K. Jensen Peder K. Jensen	Director	February 28, 2012
/s/ John P. Kelley John P. Kelley	Director	February 28, 2012
/s/ Sandra Panem, Ph.D. Sandra Panem, Ph.D.	Director	February 28, 2012
/s/ Lorin J. Randall Lorin J. Randall	Director	February 28, 2012
/s/ Steven M. Rauscher, M.B.A. Steven M. Rauscher, M.B.A.	Director	February 28, 2012
/s/ Ian Smith Ian Smith	Director	February 28, 2012



Table of Contents

## EXHIBIT INDEX

Number	Description
3.2	Bylaws of the Registrant, as amended on December 15, 2011.
10.64**	Employment Offer Letter, dated August 18, 2011, by and between the Registrant and Enrique Carrazana, M.D.
10.65**	Consulting Agreement effective as of October 1, 2011, by and between the Registrant and Thomas C. Wessel.
10.66**	Letter agreement dated October 19, 2011, by and between the Registrant and Enrique Carrazana, M.D.
10.67**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Andrew R. Blight.
10.68**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and David Lawrence.
10.69**	Amendment to December 19, 2005 Employment Agreement, dated November 7, 2011, by and between the Registrant and Jane Wasman.
10.70**	Letter agreement dated November 7, 2011, by and between the Registrant and Lauren Sabella.
10.71**	Separation Agreement and General Release dated November 21, 2011, by and between the Registrant and Thomas C. Wessel.
21	List of Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
23.2	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
31.1	Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.

32.1	Certification 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

---

\*\* 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.”