ACORDA THERAPEUTICS INC
Form 10-K
February 27, 2015

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, 2014

OR

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

For the transition period from to

Commission File Number 000-50513

ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	13-3831168
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
420 Saw Mill River Road, Ardsley, New York	10502
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (914) 347-4300

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

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

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

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

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

As of June 30, 2014, the aggregate market value (based on the closing price on that date) of the registrant's voting stock held by non-affiliates was $830,937,207. For purposes of this calculation, shares of common stock held by directors, officers and stockholders whose ownership exceeds five percent of the common stock outstanding at June 30, 2014 were excluded. Exclusion of shares held by any person should not be construed to indicate that the person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that the person is controlled by or under common control with the registrant.

As of February 17, 2015, the registrant had 42,575,393 shares of common stock, par value $0.001 per share, outstanding. The registrant does not have any non-voting stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a proxy statement for its 2015 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2014. 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.

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This Annual Report on Form 10-K contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties, including: The ability to realize the benefits anticipated from the Civitas Therapeutics, Inc. transaction and to successfully integrate Civitas's operations into our operations; our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including CVT-301, Plumiaz, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; 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; 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 failure to comply with regulatory requirements could result in adverse action by regulatory agencies. 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 and our subsidiaries 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,” “Zanaflex Capsules,” “Qutenza” and “ARCUS.” 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 (e.g., “Plumiaz”) in the U.S. and worldwide for potential product names or for disease awareness activities. Third party trademarks, trade names, and service marks used in this report are the property of their respective owners.

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PART I

Item 1. Business.

Company Overview

We are a biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that restore neurological function and improve the lives of people with neurological disorders. We market three FDA-approved therapies, including Ampyra (dalfampridine) Extended Release Tablets, 10mg, a treatment to improve walking in patients with multiple sclerosis, or MS, as demonstrated by an increase in walking speed. We also market Zanaflex Capsules and tablets, FDA-approved as short-acting drugs for the management of spasticity, and Qutenza, an FDA-approved dermal patch for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain.

We have one of the leading pipelines in the industry of novel neurological therapies. We are currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders, including chronic post-stroke walking deficits (PSWD), Parkinson's disease, epilepsy, heart failure, MS, and spinal cord injury. Our goal is to help patients to a better future, while building a leading neurology company with a portfolio of innovative products.

Ampyra is the first product for which we completed clinical development. Ampyra, an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), was approved by the FDA in January 2010. Ampyra demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). 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, and had net revenue of $366.2 million for the year ended December 31, 2014. Since the March 2010 launch of Ampyra, more than 100,000 people with MS in the U.S. have tried Ampyra. We believe that Ampyra is now viewed as the standard of care in MS for people who have walking difficulties.

In 2014, one new U.S. Ampyra patent was issued. We now have five Orange Book-listed patents providing protection up to 2027. Ampyra also has Orphan Drug designation, which gives it marketing exclusivity in the U.S. until January 2017. In 2014, we received eight Paragraph IV Certification Notice Letters from generic drug manufacturers advising that they had submitted Abbreviated New Drug Applications, or ANDAs, to the FDA requesting permission to manufacture and market a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to these filings, we filed lawsuits against all of these companies alleging multiple counts of patent infringement. As a result of our filing these lawsuits, there is a statutory stay that restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date. On February 10 and 27, 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. We will oppose the requests to institute these two IPRs, and if they are allowed to proceed, we will oppose the full proceedings. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

We believe there may be potential for dalfampridine to be applied to neurological conditions in addition to MS. In December 2014, we announced that the first patient has been enrolled in a Phase 3 clinical trial of dalfampridine to

evaluate the use of dalfampridine administered twice daily (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke. Also, we have been exploring a once-daily (QD) formulation of dalfampridine for use in the chronic post-stroke clinical program. Based on the results of an in-vitro alcohol dose dumping study and a subsequent fed-fasted study in

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2014, we determined that the initial QD formulation that we had been developing with an external partner was not practical for further testing. We are working with different external partners to develop a new QD formulation that could be included in future post-stroke studies.

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec International GmbH, or Biogen Idec, under a license and collaboration agreement that we entered into in June 2009. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen Idec anticipates making Fampyra commercially available in additional markets in 2015. We recorded $10.0 million of royalty revenue and $9.1 million of amortized license revenue in 2014 related to Fampyra.

In October 2014, we acquired Civitas Therapeutics, Inc., a privately-held pharmaceutical company with global rights to CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease, or PD. CVT-301 is a novel, self-administered inhaled therapy for the treatment of OFF episodes in Parkinson's disease which is further described below. OFF episodes are characterized by a re-emergence of Parkinson's disease symptoms such as tremor, muscle stiffness and impaired ability to move. In December 2014, we announced that the first patient has been enrolled in a Phase 3 study of CVT-301 for the treatment of OFF episodes in Parkinson's disease. We are projecting that, if approved, annual peak sales of CVT-301 in the U.S. alone could exceed $500 million. Our acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which we believe has potential applications in multiple disease areas, and a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities.

We are also developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters, also known as acute repetitive seizures. In 2013, we submitted a New Drug Application (NDA) filing for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. We are continuing to work with the FDA to define the additional clinical work necessary for the re-submission of the NDA and approval of Plumiaz, and we are encouraged by the progress of our discussions. We anticipate that our current infrastructure can support sales and marketing of this product if it receives FDA approval. We believe this product, if approved, has the potential to generate peak annual sales significantly higher than $100 million.

In June 2014, we completed a public offering of $345 million aggregate principal amount of 1.75% Convertible Senior Notes due 2021, which aggregate principal amount includes the exercise of the underwriter's over-allotment option. We conducted the notes offering to raise funds for general corporate purposes, including to fund possible acquisitions of, or investments in, complementary businesses, products and technologies. The net proceeds from the offering helped fund the purchase price and other payments made in connection with the Civitas acquisition.

We are focused on continuing to grow as a fully-integrated biopharmaceutical company by commercializing our FDA-approved products, developing our product candidates and advancing our research and development programs for underserved markets. We are seeking to leverage our financial strength to invest in our pipeline of research and development programs and potentially to acquire additional products that will fit with our commercial structure and expertise in both neurology and specialty pharmaceuticals. Our goal is to create a balanced portfolio that creates significant near-term value, as well as intermediate and longer-term opportunities for further value accretion.

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

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of $366.2 million for the year ended December 31, 2014.

Since the March 2010 launch of Ampyra, more than 100,000 people with MS in the U.S. have tried Ampyra. We believe that Ampyra is now viewed as the standard of care in MS for people who have walking difficulties. As of December 2014, approximately 70% of all people with MS who were prescribed Ampyra received a first refill, and approximately 40% of all people with MS who were prescribed Ampyra have been dispensed at least six months of the medicine through refills, consistent with previously reported trends. These refill rates exclude patients who started Ampyra through our First Step trial program, which provides eligible patients with two months of Ampyra at no cost. More than 65% of new Ampyra patients currently enroll in First Step. The program is in its fourth year, and data show that First Step participants have higher compliance and persistency rates over time compared to non-First Step patients. Approximately 50% of patients who initiate Ampyra therapy with the First Step free trial program convert to paid prescriptions.

Two of the largest national health plans in the U.S. – United Healthcare and Cigna – have listed Ampyra in the lowest competitive reimbursement tier, which means that it is listed in either the lowest branded copay tier or the lowest branded specialty tier (if more than one specialty tier exists) of their commercial preferred drug list or formulary. Approximately 75% of insured individuals in the U.S. continue to have no or limited prior authorizations, or PA's, for Ampyra. We define limited PAs as those that require only an MS diagnosis, documentation of no contraindications, and/or simple documentation that the patient has a walking impairment; such documentation may include a Timed 25-Foot Walk (T25W) test. The access figure is calculated based on the number of pharmacy lives reported by health plans.

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. In a poll of more than 2,000 people with MS, 87% said they experienced some limitation to their walking ability and limited activities that involved walking. Among MS patients diagnosed within the last 5 years, 58% report experiencing mobility issues at least twice a week. Even in early stages of the disease, walking can be a significant issue; approximately 1 out of every 4 MS patients experiences walking difficulty by the time of diagnosis, according to a 2011 Harris poll sponsored by Acorda. In the European Union, over 700,000 people suffer from MS, and an additional 100,000 people in Canada are also diagnosed with this disease.

Ampyra/Fampyra Patents

We have five issued patents listed in the Orange Book for Ampyra, one of which issued in 2014. The first is U.S. Patent No. 8,007,826, with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the United States Patent and Trademark Office, or USPTO, this patent will extend into 2027. The second is U.S. Patent No. 5,540,938 ("the '938 patent"), the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In April 2013, the '938 patent received a five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the '938 patent will expire in 2018. We have an exclusive license to this patent from Alkermes (originally with Elan, but transferred to Alkermes as part of its acquisition of Elan's Drug Technologies business). The third is U.S. Patent No. 8,354,437, which includes claims relating to methods to improve walking, increase walking speed, and treat walking disability in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2026. The fourth is U.S. Patent No. 8,440,703, which includes claims directed to methods of improving lower extremity function and walking and increasing walking speed in patients with MS by administering less than 15 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2025. The fifth, which issued in 2014, is U.S. Patent No. 8,663,685 with claims relating to methods to improve walking in patients with MS by administering 10 mg of

sustained release 4-aminopyridine (dalfampridine) twice daily. Absent patent term adjustment, the patent is set to expire in 2025.

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In 2014, we received eight Paragraph IV Certification Notice Letters from generic drug manufacturers advising that they had submitted Abbreviated New Drug Applications, or ANDAs, to the FDA requesting permission to manufacture and market a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to these filings, we filed lawsuits against all of these companies alleging multiple counts of patent infringement. This litigation is further described below in Part I, Item 3 of this report. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notice Letters. As a result, a 30 month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30 month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra. This restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date.

On February 10 and 27, 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. We will oppose the requests to institute these two IPRs, and if they are allowed to proceed, we will oppose the full proceedings. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

In 2011, the European Patent Office, or EPO, granted EP 1732548, the counterpart European patent to U.S. Patent No. 8,354,437 with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmbH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthon B.V. and neuraxpharm Arzneimittel GmbH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmbH and Actavis Group PTC ehf filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines.

Civitas Acquisition; CVT-301 and ARCUS Technology

In October 2014, we completed the acquisition of Civitas Therapeutics, Inc., a Delaware corporation. As a result of the acquisition, we acquired global rights to CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease. Our acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which we believe has potential applications in multiple disease areas, and a subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Approximately 45 Civitas employees based at the Chelsea facility have joined the Acorda workforce in connection with the acquisition.

The Civitas acquisition was completed under an Agreement and Plan of Merger, dated as of September 24, 2014, by and among Acorda, Five A Acquisition Corporation, a Delaware corporation and our wholly-owned subsidiary, Civitas and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the securityholders' representative. Pursuant to the terms of the merger agreement, Five A Acquisition Corporation merged with and into Civitas, which is the surviving corporation in the merger and which is continuing as a wholly-owned subsidiary of Acorda under the Civitas name.

Pursuant to the terms of the merger agreement, all outstanding shares of Civitas common stock and Civitas preferred stock, options to purchase shares of Civitas common stock and warrants to purchase shares of Civitas preferred stock, other than shares of Civitas common stock and Civitas preferred stock held by Civitas (which were cancelled as a result of the Merger) were converted into the right to receive $525.0 million in cash in

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the aggregate, without interest, less (i) $5.3 million due and payable under Civitas' existing secured loan facility, consisting of $5.0 million in principal and $0.3 million in prepayment fees, (ii) $30.0 million due and payable to Alkermes, Inc. in connection with the exercise by Civitas of its option to purchase manufacturing facility equipment from Alkermes and (iii) a portion of Civitas' transaction expenses. Also pursuant to the merger agreement, upon consummation of the merger, $39.375 million of the aggregate consideration was deposited into escrow to secure the indemnification obligations of Civitas and Civitas's securityholders, and an additional $0.5 million of the aggregate consideration was deposited with Shareholder Representative Services for reimbursements payable to them under the terms of the merger agreement. We financed the transaction with cash on hand.

Research and Development Programs

We have one of the leading pipelines in the industry of novel neurological therapies. We are currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders, including chronic post-stroke walking deficits (PSWD), Parkinson's disease, epilepsy, heart failure, MS, and spinal cord injury. Our pipeline includes the programs described below, and includes the CVT-301 program that we recently acquired with Civitas, described above. We have evaluated and reprioritized our research and development pipeline based on our recent acquisition of Civitas. As further described below, we terminated our AC105 program in 2014, and we have no current plans to invest in further development of NP-1998 for neuropathic pain.

CVT-301 and ARCUS Technology. We acquired CVT-301 in October 2014 with our acquisition of Civitas, described above. CVT-301 is a Phase 3-ready inhaled formulation of levodopa, or L-dopa, for the treatment of OFF episodes in Parkinson's disease. Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain responsible for producing dopamine. The disease is characterized by symptoms such as impaired ability to move, muscle stiffness and tremor. The standard of care is oral L-dopa, but there are significant challenges in creating a dosing regimen that consistently maintains therapeutic effects. The unpredictable re-emergence of symptoms is referred to as an OFF episode, and current strategies for treating these OFF episodes are widely regarded as inadequate. CVT-301 is based on the proprietary ARCUS technology platform that we acquired with Civitas. The ARCUS technology is a dry-powder pulmonary delivery system that we believe has potential applications in multiple disease areas. This platform allows delivery of significantly larger doses of medication than are possible with conventional dry powder formulations. This in turn provides the potential for pulmonary delivery of a much wider variety of pharmaceutical agents. In December 2014, we announced that the first patient has been enrolled in a Phase 3 study of CVT-301 for the treatment of OFF episodes in Parkinson's disease. We expect results from this efficacy trial in 2016, and plan to file a new drug application, or NDA, in the U.S. by the end of 2016. We are projecting that, if approved, annual peak sales of CVT-301 in the U.S. alone could exceed $500 million.

In addition to CVT-301, we are exploring opportunities for other proprietary products in which inhaled delivery using our ARCUS technology can provide a significant therapeutic benefit to patients. For example, we are currently developing CVT-427, an inhaled triptan intended to provide relief from acute migraine episodes by taking advantage of the ARCUS delivery system. Triptans are the class of drug most commonly prescribed to treat acute migraine. Oral triptans, which account for approximately 98% of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in poor response rates. Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. CVT-427 is currently in pre-clinical development and we anticipate initiating a Phase 1 clinical program in 2015.

Ampyra/Dalfampridine Development Programs. We believe there may be potential for dalfampridine to be applied to neurological conditions in addition to MS. In December 2014, we announced that the first patient has been enrolled in

a Phase 3 clinical trial evaluating the use of dalfampridine administered twice daily (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke. As part of the trial design, we are planning to conduct an interim analysis of the

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trial data, and depending on the outcome of that analysis we may initiate a second pivotal trial prior to the conclusion of the first Phase 3 trial. We have been exploring a once-daily (QD) formulation of dalfampridine for use in the chronic post-stroke clinical program. Based on the results of an in-vitro alcohol dose dumping study and a subsequent fed-fasted study, we determined that the initial QD formulation that we had been developing with an external partner was not practical for further testing. We are working with different external partners to develop a new QD formulation that could be included in future post-stroke studies.

Plumiaz. We are developing Plumiaz, a proprietary nasal spray formulation of diazepam, for the treatment of people with epilepsy who experience seizure clusters, also known as acute repetitive seizures. In 2013, we submitted a New Drug Application (NDA) filing for Plumiaz to the FDA. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. We are continuing to work with the FDA to define the additional clinical work necessary for the re-submission of the NDA and approval of Plumiaz, and we are encouraged by the progress of our discussions. We anticipate that our current infrastructure can support sales and marketing of this product if it receives FDA approval. We believe this product, if approved, has the potential to generate peak annual sales significantly higher than $100 million.

Cimaglermin alfa (previously GGF2)/Neuregulins. Cimaglermin alfa (which we previously referred to as GGF2) is our lead product candidate for our neuregulin program. We have completed a cimaglermin Phase 1 clinical trial in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. Data from this trial showed a dose-related improvement in ejection fraction in addition to safety findings. A dose-limiting toxicity was also identified in the highest planned dose cohort, specifically acute liver injury meeting Hy's Law for drug induced hepatotoxicity. In October 2013, we announced that the first patient had been enrolled in a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015. 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. rHIgM22 is the lead antibody in our remyelinating antibody program, and we are developing it as a potential therapeutic for MS. We believe a therapy that could repair myelin sheaths has the potential to restore neurological function to those affected by demyelinating conditions. In April 2013, we initiated a Phase 1 clinical trial of rHIgM22 to assess the safety and tolerability of rHIgM22 in patients with MS. The study also includes several exploratory clinical, imaging and biomarker measures. We announced top-line safety and tolerability results in February 2015. The trial, which followed participants for up to six months after receiving a single dose of rHIgM22, found no dose-limiting toxicities at any of the five dose levels studied. Additional data from this trial will be presented at future medical meetings. Based on these data, we intend to advance clinical development of rHIgM22 for MS. We are currently developing the protocol for our next Phase 1 clinical trial of rHIgM22. The data from the completed trial will help inform the design of the next trial, which we expect will enroll people with MS who are experiencing an active relapse.

NP-1998. NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we have been assessing for the treatment of neuropathic pain. We acquired rights to NP-1998 from NeurogesX, Inc. in 2013 in connection with our purchase of Qutenza, an FDA-approved dermal patch containing 8% prescription strength capsaicin. We acquired development and commercialization rights in the United States, Canada, Latin America and certain other territories. Astellas Pharma Europe Ltd. has an option to develop NP-1998 in the European Economic Area (EEA) including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as

Switzerland, certain countries in Eastern Europe, the Middle East and Africa. We believe this liquid formulation of the capsaicin-based therapy has key advantages over the Qutenza patch, and we believe NP-1998 has the potential to treat multiple neuropathies. However, we have evaluated and reprioritized our

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research and development pipeline based on our recent acquisition of Civitas, and as a result we have no current plans to invest in further development of NP-1998 for neuropathic pain.

AC105. We terminated our AC105 program in 2014. We had been studying AC105 as a treatment for patients who have suffered acute spinal cord injury. In September 2013, we announced that the first patient was enrolled in a Phase 2 clinical trial evaluating the safety and tolerability of AC105 in people with traumatic spinal cord injury. Patient recruitment in this trial was challenging due to several factors, and as a result recruitment into the study has been closed and the study was terminated. We were conducting this program pursuant to a 2011 license from Medtronic, Inc. and one of its affiliates, and we have accordingly terminated this license.

Corporate Update

In May 2014, we appointed Andrew Hindman as our Chief Business Development Officer, leading our efforts to expand our pipeline through potential acquisitions and/or in-licensing of assets. In June 2014, we appointed Soon Hyouk Lee as Vice President of Business Development to support our business development efforts.

In connection with the Civitas acquisition described above, Rick Batycky, Ph.D., previously Chief Scientific Officer of Civitas, became the newest member of our senior leadership team and was appointed to the position of Chief Technology Officer and Site Head. In this position, Dr. Batycky is responsible for oversight of our Chelsea, MA manufacturing facility.

We currently lease approximately 138,000 square feet of office and laboratory space in Ardsley, NY. Our lease for this facility includes options to lease up to approximately 120,000 additional square feet of space in additional buildings at the same location. In May 2014, we notified the landlord that we were exercising our option to expand into an additional 25,405 square feet of office space. We occupied the additional space in the first quarter of 2015.

Our Strategy

Our strategy is to continue to grow as a fully-integrated biopharmaceutical company and to be a leading neurology company focused on the identification, development and commercialization of a range of nervous system therapeutics. We are using our scientific, clinical and commercial expertise in MS and spinal cord injury as strategic points of access to additional nervous system markets, including stroke, Parkinson’s disease, and epilepsy. In 2015, we are focused on the following priorities:

- Continue to make disciplined investments in growing sales of Ampyra.
- Progress our Phase 3 clinical trial of CVT-301 for the treatment of OFF episodes in Parkinson’s disease.
- Progress our Phase 3 clinical trial that is assessing the use of dalfampridine as a treatment for chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke, and continue efforts with external partners to develop a new QD formulation that could be included in future post-stroke studies.
- Complete our discussions and reach agreement with the FDA regarding the requirements for re-submission of the Plumiaz NDA, and begin the clinical work that will be necessary for re-submission.
- Complete our Phase 1 clinical trial of cimaglermin alfa (previously referred to as GGF2), our lead product candidate for our neuregulin program.
- Advance clinical development of rHIgM22 for MS by initiating a second Phase 1 trial.

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- Initiate a Phase 1 clinical trial of CVT-427, an inhaled triptan intended to provide relief from acute migraine episodes using our ARCUS pulmonary delivery technology.

- Expand our pipeline through potential in-licensing and/or acquisition of neurology and/or other specialty products and technologies, focusing on late stage/near commercial or commercial products. We will also consider earlier-stage programs based on compelling science and the potential to address significant unmet medical needs.

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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 a number of countries across Europe, Asia and the Americas	Biogen Idec (outside U.S.)
Zanaflex Capsules and an authorized generic version of the capsules	Spasticity	FDA-approved	Acorda (U.S.); authorized generic marketed by Actavis/Watson Pharma
Zanaflex tablets	Spasticity	FDA-approved	Acorda (U.S.)
Qutenza	Post Herpetic Neuralgia	FDA-approved	Acorda (U.S. Canada, Latin America and certain other countries)

Research and Development Programs	Proposed Therapeutic Area(s)	Stage of Development	Marketing Rights
CVT-301	OFF episodes of Parkinson's disease	Phase 3 clinical trial ongoing	Acorda/Worldwide
Dalfampridine	Chronic post-stroke deficits	Phase 3 clinical trial ongoing	Acorda/Worldwide (contract governs Biogen ex-U.S. option)
Plumiaz	Seizure Clusters/Acute Repetitive Seizures	NDA to be re-submitted to the FDA	Acorda/Worldwide (excluding certain Asian countries)
Neuregulin Program	Heart failure*	cimaglermin alfa (previously GGF2) Phase 1b clinical trial ongoing	Acorda/Worldwide
Remyelinating Antibodies Program	MS	Phase 1; protocol for next Phase 1 clinical trial of rHIgM22 under development	Acorda/Worldwide
CVT-427	Migraines	Pre-IND; Phase 1 clinical trial preparations underway	Acorda/Worldwide
Chondroitinase Program	Spinal cord injury	Research	Acorda/Worldwide
NP-1998	No current plans for development	Phase 3, but no current plans for development	Acorda (U.S. Canada, Latin America and certain other countries)

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

Background on Neurological and Other Conditions

We are a biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that restore neurological function and improve the lives of people with neurological disorders. 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.

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Multiple Sclerosis

Multiple Sclerosis, or MS, is a chronic, usually progressive disease in which the immune system attacks and degrades the function of nerve fibers in the brain and spinal cord. These nerve fibers consist of long, thin fibers, or axons, surrounded by a myelin sheath, which facilitates the transmission of electrical impulses, much as insulation facilitates conduction in an electrical wire. In MS, the myelin sheath is damaged by the body's own immune system, causing areas of myelin sheath loss, also known as demyelination. This damage, which can occur at multiple sites in the central nervous system, 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.

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. In a poll of more than 2,000 people with MS, 87% said they experienced some limitation to their walking ability and limited activities that involved walking. Among MS patients diagnosed within the last 5 years, 58% report experiencing mobility issues at least twice a week. Even in early stages of the disease, walking can be a significant issue; approximately 1 out of every 4 MS patients experiences walking difficulty by the time of diagnosis, according to a 2011 Harris poll sponsored by Acorda. In the European Union, over 700,000 people suffer from MS, and an additional 100,000 people in Canada are also diagnosed with this disease.

Stroke

A stroke occurs when the blood supply to part of the brain is interrupted or severely reduced, depriving brain tissue of oxygen and food, and causing the death of brain cells. Stroke may also be associated with damage to the myelin sheath of various nerve tracts in the brain. Over the first few months following a stroke, patients typically show some degree of spontaneous recovery of function, which may be enhanced by rehabilitation and physical therapy. After this initial recovery, patients may stabilize with chronic neurologic deficits. According to the American Stroke Association, or ASA, 795,000 people in the U.S. experience a stroke every year and approximately 7,000,000 people in the U.S. are living with the long term effects of stroke, or post-stroke deficits. Current treatments for post-stroke deficits include physical and occupational therapy, but there are no pharmacologic therapies indicated specifically to improve function. A majority of those living with post-stroke deficits experience walking or other lower limb disability and/or arm or other upper body deficits. Total direct annual stroke-related medical costs for 2012 were estimated to be approximately $72 billion.

Parkinson’s Disease

Parkinson’s disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons responsible for producing dopamine, which causes motor complications, including impaired ability to move, muscle stiffness and tremors. Approximately one million Americans and 1.2 million Europeans suffer from Parkinson’s disease. There is no cure or disease-modifying treatment currently available for Parkinson’s disease. Current treatment strategies are focused on the management and reduction of the major symptoms of the disease and related disabilities. These therapies either aim to supplement dopamine levels in the brain, mimic the effect of dopamine in the brain by stimulating dopamine receptors or prevent the enzymatic breakdown of dopamine. The standard of care for the treatment of Parkinson’s disease symptoms is oral levodopa (L-dopa). Approximately 70% of people with Parkinson’s disease in the United States are treated with oral L-dopa. Effective control of Parkinson’s disease symptoms is referred to as an ON state.

As Parkinson’s disease progresses, even optimized regimens of oral L-dopa are associated with increasingly wide variability in the timing and amount of absorption into the bloodstream. This results in the unreliable control of symptoms, leading to motor complications including OFF episodes, also referred to as motor fluctuations. OFF episodes, which are characterized by a re-emergence of Parkinson’s disease symptoms, increase

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in frequency and severity during the course of the disease. About half of people with Parkinson's disease experience OFF episodes within five years of initiating oral L-dopa therapy. OFF episodes are inadequately addressed by available therapies and are considered one of the greatest unmet medical needs facing people with Parkinson's disease.

Heart Failure

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

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

According to the American Heart Association, in 2013 approximately 5.1 million Americans had heart failure, and roughly 825,000 cases are newly diagnosed each year.

Epilepsy

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

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

Neuropathic Pain

There are several underserved neuropathic pain conditions that, together, represent approximately 4 million cases in the United States alone. In addition to the current indication for Qutenza, post-herpetic neuralgia, these include painful neuropathies due to diabetes, chemotherapy and HIV/AIDs.

Post-herpetic neuralgia, or PHN, also known as post-shingles nerve pain, is chronic pain resulting from shingles, a viral infection caused by the same virus that causes chickenpox. There are approximately one million new cases of shingles in the U.S. each year. Shingles is characterized by an outbreak of rash or blisters on the skin and nerve pain that typically resolves within several weeks. However, 10 to 20 percent of patients with shingles will go on to develop

PHN, which can continue for months or years after the shingles rash has healed.

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Spinal Cord Injury

A spinal cord injury, or SCI, usually refers to a traumatic blow to the spine that fractures or dislocates vertebrae and causes damage to the surrounding spinal cord tissue. SCI is caused by traumas such as a motor vehicle accident, a fall, or a sports injury. Depending on the location and severity of the injury, people with SCI can experience a number of disabilities, including partial or complete paralysis, muscle weakness, spasticity, loss or distortion of sensation, impaired bowel and/or bladder function, or sexual dysfunction. SCI often results in severe, lifelong disability, leading to long-term care and quality of life issues for the person with the injury.

Clinical research using imaging and post-mortem studies has shown that the majority of people with SCI do not have severed spinal cords and maintain some nerve fibers that cross the site of injury. However, these surviving nerve fibers are often damaged and may lose their myelin sheaths. There is no cure for SCI and no approved treatment available that is capable of significantly improving outcome from injury or improving long-term neurological function. Methylprednisolone, a steroid given in a high dose, is often used to treat acute injuries in the U.S. Methylprednisolone is administered to the patient immediately following an injury with the goal of reducing secondary tissue damage, but there is disagreement in the clinical community regarding the overall risk-benefit ratio of this treatment. The only other available medical therapies are limited treatments that target some of the symptoms of SCI, including spasticity and persistent pain, the same treatments used to address these symptoms in MS. We believe that an acute treatment that offers even an incremental improvement in outcome from injury could have a meaningful impact on the quality of life for people with SCI.

According to the National Spinal Cord Injury Statistical Center, or NSCISC, approximately 270,000 people in the U.S. live with SCI and approximately 12,000 new spinal cord injuries occur each year, the majority of which are male. SCI primarily affects young people, with nearly half occurring in those aged 16-30. Average annual medical cost for an SCI patient ranges from approximately $40,000 to $180,000 depending on the extent of the injury. NSCISC estimates that the average lifetime costs directly attributable to SCI for an individual injured at age 25 varies from approximately $1.5 million to more than $4.5 million depending on the severity of the injury.

Spasticity

Spasticity refers to the often painful involuntary tensing, stiffening or contracting of muscles. Spasticity is not a disease but a symptom of other conditions, such as MS, SCI, stroke, traumatic brain injury and cerebral palsy, where portions of the nervous system that control voluntary movement have been damaged. This damage results in the nerve cells in the spinal cord becoming disconnected from controlling centers in the brain and, as a result, transmitting unregulated impulses to the muscles. People who have spasticity may experience it intermittently – it may be triggered by a stimulus, such as pain, pressure sores, cold weather or a urinary tract infection. The majority of people with MS experience some form of spasticity, as do many people following stroke, SCI, or brain injuries. According to the American Association of Neurological Surgeons, spasticity affects more than an estimated 12 million people worldwide.

Migraine

Migraine is a neurological syndrome characterized by pain, nausea, abnormal sensitivity to sound and abnormal sensitivity to light. It is believed to affect over 10% of the global population. In the United States, the National Institutes of Health estimates 12% of the population, or approximately 37 million people, suffer from migraine, with women being nearly three times more affected than men. Triptans are the class of drug most commonly prescribed to treat acute migraine. Oral triptans, which account for approximately 98% of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in poor response rates. Patients cite the need for rapid relief from migraine symptoms as their most desired medication

attribute. Additionally, individuals with migraine suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration.

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Ampyra

Ampyra (dalfampridine) is an oral drug approved by the FDA on January 22, 2010 as a treatment to improve walking in patients with MS. This was demonstrated by an increase in walking speed. Ampyra demonstrated efficacy in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). Ampyra can be used alone or with concurrent medications, including immunomodulatory drugs. The majority of patients in our two Phase 3 clinical trials for Ampyra (63%) were taking immunomodulatory drugs (interferons, glatiramer acetate, or natalizumab). Ampyra is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), which was previously referred to as fampridine. We obtained Orphan Drug designation from the FDA for dalfampridine in MS, which will provide Ampyra with seven years of market exclusivity for this use, to January 2017. We have five issued patents listed in the Orange Book for Ampyra, which are described below in the "Intellectual Property" section of this report, providing protection up to 2027.

In 2014, we received eight Paragraph IV Certification Notice Letters from generic drug manufacturers advising that they had submitted Abbreviated New Drug Applications, or ANDAs, to the FDA requesting permission to manufacture and market a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to these filings, we filed lawsuits against all of these companies alleging multiple counts of patent infringement. This litigation is further described below in Part I, Item 3 of this report. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notice Letters. As a result, a 30 month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30 month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra. This restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date.

On February 10 and 27, 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. We will oppose the requests to institute these two IPRs, and if they are allowed to proceed, we will oppose the full proceedings. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec under a 2009 license and collaboration agreement. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen Idec anticipates making Fampyra commercially available in additional markets in 2015.

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

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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's approval letter included certain post-marketing study requirements and confirmed certain commitments made by us with respect to Ampyra, all of which we have now completed. The post-marketing requirements included additional animal toxicology studies to evaluate certain impurities, in vitro receptor binding and abuse potential studies in animals, and an evaluation of clinical adverse events related to abuse potential. We completed these studies and timely submitted the results to the FDA. Also, we committed to the FDA that we would conduct a placebo-controlled trial to evaluate a 5 mg twice-daily dosing regimen of Ampyra, as well as a pharmacokinetic evaluation of a 7.5 mg dosage strength in patients with mild or moderate renal impairment. We also committed to report all post-marketing seizure events on an expedited basis to the FDA. We completed the renal impairment study and timely submitted the results to the FDA. We are discussing with the FDA what additional steps may need to be taken. In August 2012, we announced results of the 5mg efficacy study. The study failed to confirm efficacy of the 5mg dose. We believe that this study, together with Ampyra registration studies, continue to show that 10mg twice daily is the appropriate, safe, and effective dose. The study results were provided to the FDA, which subsequently confirmed that we have satisfied this post-marketing requirement.

In our two Phase 3 clinical studies of Ampyra in spinal cord injury, which were completed in 2004, the results did not reach statistical significance on their primary endpoints.

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. In February 2012, we launched an authorized generic version of tizanidine hydrochloride capsules under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), following the launch by Apotex Inc. of its generic tizanidine hydrochloride capsules. In March 2013, Mylan Laboratories also launched 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.

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Qutenza

Qutenza is a dermal patch containing 8% prescription strength capsaicin the effects of which can last up to three months and is approved by the FDA for the management of neuropathic pain associated with post-herpetic neuralgia, also known as post-shingles pain. We acquired commercialization rights to Qutenza in July 2013 from NeurogesX, Inc. These rights include the United States, Canada, Latin America and certain other territories. Qutenza was approved by the FDA in 2010 and launched in April 2010 but NeurogesX discontinued active promotion of the product in March 2012. In January 2014, we re-launched Qutenza in the United States using our existing commercial organization, including our specialty neurology sales force as well as our medical and safety reporting infrastructure.

Astellas Pharma Europe Ltd. has exclusive commercialization rights for Qutenza in the European Economic Area (EEA) including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as Switzerland, certain countries in Eastern Europe, the Middle East and Africa.

Research and Development Programs

We have one of the leading pipelines in the industry of novel neurological therapies. We are currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders, including chronic post-stroke walking deficits (PSWD), Parkinson's disease, epilepsy, heart failure, MS, and spinal cord injury. Our pipeline includes the programs described below. We have evaluated and reprioritized our research and development pipeline based on our recent acquisition of Civitas. As further described below, we terminated our AC105 program in 2014 and have no current plans to invest in further development of NP-1998 for neuropathic pain.

Civitas Acquisition; CVT-301 and ARCUS Technology

On October 22, 2014, we completed the acquisition of Civitas Therapeutics, Inc., a Delaware corporation. As a result of the acquisition, we acquired global rights to CVT-301, a Phase 3 treatment candidate for OFF episodes of Parkinson's disease, which is further described below. Our acquisition of Civitas also included rights to Civitas's proprietary ARCUS pulmonary delivery technology, which we believe has potential applications in multiple disease areas.

CVT-301 is a Phase 3-ready inhaled formulation of levodopa, or L-dopa, for the treatment of OFF episodes in Parkinson's disease. Parkinson's disease is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain responsible for producing dopamine. The disease is characterized by symptoms such as impaired ability to move, muscle stiffness and tremor. The standard of care is oral L-dopa, but there are significant challenges in creating a dosing regimen that consistently maintains therapeutic effects. The unpredictable re-emergence of symptoms is referred to as an OFF episode, and current strategies for treating these OFF episodes are widely regarded as inadequate.

CVT-301 is based on the proprietary ARCUS technology platform that we acquired with Civitas. The ARCUS technology is a dry-powder pulmonary delivery system that we believe has potential applications in multiple disease areas. This platform allows delivery of significantly larger doses of medication than are possible with conventional dry powder formulations using a simple, patient-friendly, breath-actuated proprietary inhaler. This in turn provides the potential for pulmonary delivery of a much wider variety of pharmaceutical agents.

In December 2014, we announced that the first patient has been enrolled in a Phase 3 study of CVT-301 for the treatment of OFF episodes in Parkinson's disease. Our CVT-301 development includes this Phase 3 efficacy trial and safety extension, and two pharmacokinetic studies in specific sub-populations. We expect results from the efficacy trial in 2016, and plan to file a new drug application, or NDA, in the U.S. by the end of

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2016. We expect that the NDA will be filed under section 505(b)(2) of the Food Drug and Cosmetic Act, referencing data from the branded L-dopa product Sinemet®. Based on Civitas's interactions with the FDA, we believe a single Phase 3 efficacy study will be needed for filing an NDA, supported by existing Phase 2b data. A separate safety study will also be required, and we believe this can be completed following submission of an NDA. However, the FDA will determine the ultimate filing requirements for the NDA. We are projecting that, if approved, annual peak sales of CVT-301 in the U.S. alone could exceed $500 million.

In addition to CVT-301, we are exploring opportunities for other proprietary products in which inhaled delivery using our ARCUS technology can provide a significant therapeutic benefit to patients. Disorders of the central nervous system, or CNS, in addition to Parkinson's disease, may be addressed by ARCUS products with the delivery of active agents to the CNS with rapid onset and reduced systemic exposure.

For example, we are currently developing CVT-427, an inhaled triptan intended to provide relief from acute migraine episodes by taking advantage of the ARCUS delivery system. Triptans are the class of drug most commonly prescribed to treat acute migraine. Oral triptans, which account for approximately 98% of all triptan doses, can be associated with slow onset of action and gastrointestinal challenges. The slow onset of action, usually 30 minutes or longer, can result in poor response rates. Patients cite the need for rapid relief from migraine symptoms as their most desired medication attribute. Additionally, individuals with migraine may suffer from nausea and delayed gastric emptying which further impact the consistency and efficacy of the oral route of administration. CVT-427 is currently in pre-clinical development and we anticipate initiating a Phase 1 clinical program in 2015.

Ampyra/Dalfampridine Development Programs

We believe there may be potential for dalfampridine to be applied to neurological conditions in addition to MS. For example, we are studying the use of dalfampridine in patients who experience chronic post-stroke deficits. Chronic post-stroke deficits refer to neurological deficits, such as impaired walking, motor and/or sensory function, that persist in people who have had a stroke. There are currently no pharmacologic therapies indicated to improve function in people with chronic post-stroke deficits.

In 2013, we announced the results of a Phase 2 proof-of-concept trial of dalfampridine-ER (extended release) in people with post-stroke deficits. The primary goals of the proof-of-concept trial were to assess safety and tolerability, as well as to explore various efficacy measures. In the study, treatment with dalfampridine improved walking, as measured by the Timed 25-Foot Walk test (T25FW). The safety findings in this study were consistent with previous clinical trials and post-marketing experience of dalfampridine-ER (extended release) in MS.

Based on the results of the proof-of-concept trial, we are continuing our post-stroke development program. In December 2014, we commenced a Phase 3 clinical trial evaluating the use of dalfampridine administered twice daily (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits after experiencing an ischemic stroke. The BID formulation was used in the proof of concept study, described above. As part of the trial design, we are planning to conduct an interim analysis of the trial data, and depending on the outcome of that analysis we may initiate a second pivotal trial prior to the conclusion of the first Phase 3 trial. We have been exploring a once-daily (QD) formulation of dalfampridine for use in the chronic post-stroke clinical program. Based on the results of an in-vitro alcohol dose dumping study and a subsequent fed-fasted study, we determined that the initial QD formulation that we had been developing with an external partner was not practical for further testing. We are working with different external partners to develop a new QD formulation that could be included in future post-stroke studies.

We also are continuing to evaluate possible grants for investigator-initiated studies looking for potential benefits, including in other neurological disorders.

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Plumiaz; Neuronex Acquisition

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

Plumiaz is a proprietary nasal spray formulation of diazepam that we are developing as a treatment for the management of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who experience intermittent bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures, or ARS. Currently, the only approved outpatient treatment for people who experience this type of seizure activity is diazepam rectal gel, a rectally administered gel formulation of diazepam. Diazepam is also currently available in other formulations, such as used for intramuscular and intravenous administration, for certain indications. The nasally administered formulation potentially offers patients and caregivers a more practical and socially acceptable treatment option.

In November 2013, we announced that we submitted a New Drug Application, or NDA, filing for Plumiaz to the FDA. Plumiaz was filed under section 505(b)(2) of the Food Drug and Cosmetic Act, referencing data from a therapy previously approved by the FDA (DIASTAT® Rectal Gel) and providing pharmacokinetic data comparing the reference product to Plumiaz. We are seeking an indication for Plumiaz in people with epilepsy who experience seizure clusters, also known as acute repetitive seizures. In May 2014, the FDA issued a Complete Response Letter, or CRL, for the Plumiaz NDA. We are continuing to work with the FDA to define the additional clinical work necessary for the re-submission of the NDA and approval of Plumiaz, and we are encouraged by the progress of our discussions. We believe this product, if approved, has the potential to generate peak annual sales significantly higher than $100 million.

We have obtained orphan drug designation, which would confer seven years of market exclusivity from the date of approval for diazepam containing drug products for the same indication. We anticipate that our current infrastructure can support sales and marketing of this product if it receives FDA approval.

In June 2013 at the biennial International Congress of the International League Against Epilepsy and International Bureau for Epilepsy, we announced results of the first clinical study to assess pharmacokinetics, safety, and tolerability of Diazepam Nasal Spray in people with epilepsy. The study results showed that the Diazepam Nasal Spray pharmacokinetics are comparable whether it is administered during or immediately following a seizure.

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

Neuronex, our wholly-owned subsidiary since the acquisition, licenses patent, patent application, other intellectual property and other rights relating to Diazepam Nasal Spray products 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 Diazepam Nasal Spray products (including $1 million that was paid in 2013 upon the FDA's acceptance for review of the first NDA for Plumiaz), and up to $3 million upon the

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achievement of specified sales milestones with respect to Diazepam Nasal Spray products. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products.

Neuronex has a license from SK for two patent families comprising a granted U.S. patent and pending U.S. and foreign patent applications relating to the clinical formulation for the Diazepam Nasal Spray clinical product. The granted U.S. patent is set to expire in 2029. If granted, the pending patent applications would expire in 2029-2032. One patent family is owned by SK and one patent family is jointly owned by Neuronex and SK.

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

Cimaglermin alfa (previously GGF2)/Neuregulins

Cimaglermin alfa, which we previously referred to as GGF2, is a member of the neuregulin growth factor family, and has been shown to promote recovery after neurological injury, as well as enhance heart function in animal models of heart failure. The neuregulin growth factors are related to epidermal growth factor. These molecules bind to erbB receptors, which translate the growth factor signal and cause changes in cell growth, protein production and gene expression. Neuregulins have been shown in published studies to have a range of effects in protection and repair of cells both in the nervous system and in the heart. In 2002, we obtained from Paion AG (formerly CeNeS Pharmaceuticals plc), or Paion, an exclusive worldwide license to its neuregulin patents and related technology, including cimaglermin, our lead molecule from the neuregulin family.

Neuregulins covered in the portfolio from Paion have a number of potential applications. Neuregulins and their erbB receptors are essential for cardiac development. They have been shown to protect cardiac muscle cells from stressors that can lead to congestive heart failure, and to enhance function in heart failure induced by myocardial infarction. Additionally, neuregulins have been shown to protect the heart and brain from the toxicity of commonly used chemotherapeutic agents, such as anthracyclines. Studies in mouse, rat and dog models of congestive heart failure have shown that neuregulins significantly improve cardiac function and survival. Neuregulins have been shown to stimulate remyelination in animal models of MS and to protect the brain in animal models of stroke. Therefore, neuregulins offer the potential for multiple central nervous system and cardiac indications, including MS, stroke and heart failure as well as protection from chemotherapy-induced damage.

We have completed a Phase 1 clinical trial of cimaglermin in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. In March 2013, we presented three-month data from this clinical trial in a platform presentation at the American College of Cardiology (ACC) annual meeting. These data showed a dose-related improvement in ejection fraction in addition to safety findings. A dose-limiting toxicity was also identified in the highest planned dose cohort, specifically acute liver injury meeting Hy's Law for drug induced hepatotoxicity. In October 2013, we announced that the first patient had been enrolled in a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. 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. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015. If we are able to establish a proof of concept for treatment of heart failure through human clinical studies, we may decide to develop the product independently or we may decide to

enter into a partnership, most likely with a cardiovascular-focused company. We are also continuing with research on potential neurology indications for cimaglermin.

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Remyelinating Antibodies Program

Our remyelinating antibodies program is based on our research collaboration with Mayo Foundation for Medical Education and Research, or Mayo Clinic. Under a license agreement entered into with Mayo Clinic in September 2000, we have exclusive worldwide rights to patents and other intellectual property for these antibodies related to nervous system disorders. Studies have demonstrated the ability of this family of antibodies to stimulate repair of the myelin sheath in three different animal models of MS. In particular, these antibodies were found to react with molecules on the surface of the cells that make the myelin sheath and stimulate them, leading to increased remyelination activity. Some antibodies within this portfolio also stimulate the growth of neurons and may have applications beyond demyelinating disorders. First identified in mice, similar remyelinating antibodies were subsequently identified in human blood samples by Mayo Clinic and we have been able to produce a recombinant human antibody (rHIgM22) that may be suitable for clinical development.

We are developing the lead antibody (rHIgM22) as a potential therapeutic for MS. We believe a therapy that could repair myelin sheaths has the potential to restore neurological function to those affected by demyelinating conditions. In April 2013, we initiated a Phase 1 clinical trial of rHIgM22 to assess the safety and tolerability of rHIgM22 in patients with MS. The study also includes several exploratory clinical, imaging and biomarker measures. We announced top-line safety and tolerability results in February 2015. The trial, which followed participants for up to six months after receiving a single dose of rHIgM22, found no dose-limiting toxicities at any of the five dose levels studied. Additional data from this trial will be presented at future medical meetings. Based on these data, we intend to advance clinical development of rHIgM22 for MS. We are currently developing the protocol for our next Phase 1 clinical trial of rHIgM22. The data from the completed trial will help inform the design of the next trial, which we expect will enroll people with MS who are experiencing an active relapse.

Chondroitinase Program

This pre-clinical program is focused on developing chondroitinase as a therapeutic to break down the matrix of scar tissue that develops as a result of an injury to the central nervous system, or 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 spinal cord injury, or SCI. These studies were published in the Journal of Neurotrauma in February 2005. In these studies, rats that sustained an SCI were treated with either chondroitinase or an ineffective enzyme control and evaluated over 10 weeks of recovery. Animals treated with chondroitinase showed significant improvements both in motor function of the limbs and in bladder function, compared to those treated with the control enzyme. We have also produced and successfully tested a recombinant version of naturally occurring Chondroitinase ABC-I in these same animal models.

We are conducting a research program to develop second generation approaches to overcoming the proteoglycan matrix. Our research is currently focused on SCI but we are also looking at other neurotraumatic

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indications. The approaches we are developing include novel enzyme molecules and alternative approaches to blocking matrix formation. In 2003, we obtained an exclusive worldwide license to certain patents, patent applications, and technology from Cambridge University Technical Services Limited (now named Cambridge Enterprise Limited) and King's College London related to our chondroitinase program. We are also building our intellectual property position with respect to this technology with patent applications around uses of the known compound and new chemical structures.

NP-1998

NP-1998 is a Phase 3 ready, 20% prescription strength capsaicin topical solution that we have been assessing for the treatment of neuropathic pain. We acquired rights to NP-1998 from NeurogesX, Inc. in 2013 in connection with our purchase of Qutenza, an FDA-approved dermal patch containing 8% prescription strength capsaicin. We acquired development and commercialization rights in the United States, Canada, Latin America and certain other territories. Astellas Pharma Europe Ltd. has an option to develop NP-1998 in the European Economic Area (EEA) including the 28 countries of the European Union, Iceland, Norway, and Liechtenstein as well as Switzerland certain countries in Eastern Europe, the Middle East and Africa.

We made certain upfront payments to acquire the Qutenza and NP-1998 assets from NeurogesX, and may also make up to $5.0 million in payments contingent upon the achievement of certain regulatory and sales milestones related to NP-1998. We believe this liquid formulation of the capsaicin-based therapy has key advantages over the Qutenza patch, and we believe NP-1998 has the potential to treat multiple neuropathies. However, as described above, in connection with our recent evaluation and reprioritization of our research and development pipeline, we have no current plans to invest in further development of NP-1998 for neuropathic pain.

AC105

We terminated our AC105 program in 2014. We had been studying AC105 as a treatment for patients who have suffered acute spinal cord injury. In September 2013, we announced that the first patient was enrolled in a Phase 2 clinical trial evaluating the safety and tolerability of AC105 in people with traumatic spinal cord injury. Patient recruitment in this trial was challenging due to several factors, and as a result recruitment into the study has been closed and the study was terminated. We were conducting this program pursuant to a 2011 license Medtronic, Inc. and one of its affiliates, and we have accordingly terminated this license.

Sales, Marketing and Managed Markets

We have established our own specialty sales force and commercial infrastructure in the U.S. to market Ampyra. We currently have approximately 90 sales representatives in the field calling on a priority target list of approximately 7,000 physicians. We also have established teams of Medical Science Liaisons, Regional Reimbursement Directors, and Managed Markets Account Directors who provide information and assistance to payers and physicians on Ampyra, National Trade Account Managers who work with wholesalers and our limited network of specialty pharmacies, and Market Development Managers who work collaboratively with field teams and corporate personnel to assist in the execution of our strategic initiatives. We have a First Step program, in its fourth year, which provides eligible patients with two months of Ampyra at no cost. More than 65% of new Ampyra patients currently enroll in First Step.

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

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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 copayment costs through a copay mitigation program, where permitted by law.

We believe that, in general, people with MS are knowledgeable about their conditions, actively seek new treatments, and are directly involved with their prescriber's evaluation of treatment options. We have existing relationships with the major advocacy groups that focus on MS. As an example of our commitment, each year Acorda sponsors numerous of the National Multiple Sclerosis Society's Walk MS events around the country. These sponsorships allow us to engage thousands of people with MS, as well as their families, physicians and caregivers, in a discussion about the impact of walking impairment on their lives. In addition to these efforts, we have implemented a comprehensive series of educational and promotional programs to support Ampyra.

Ampyra is distributed in the United States exclusively through a limited network of specialty pharmacy providers that deliver the medication to patients by mail; Kaiser Permanente, which distributes Ampyra to patients through a closed network of on-site pharmacies; and ASD Specialty Healthcare, Inc. (an AmerisourceBergen affiliate), which distributes Ampyra to the U.S. Bureau of Prisons, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or VA, and other federal agencies. 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 to retail pharmacies. Our authorized generic version of tizanidine hydrochloride capsules is marketed under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.).

Qutenza is distributed in the United States by Besse Medical, Inc., a specialty distributor that furnishes the medication to physician offices, and by ASD Specialty Healthcare, Inc., a specialty distributor that furnishes the medication to hospitals and clinics. As a product that must be administered only by a health care professional in an office, clinic, or hospital setting, many commercial health plans and government insurance programs reimburse for Qutenza under the patient's medical benefit rather than the patient's pharmacy benefit. As a result of this, most utilization of Qutenza is handled on a "buy-and-bill" basis in which one of the distributors listed above (Besse Medical, Inc. or ASD Specialty Healthcare) ships the medication to a physician's office, hospital or clinic to be administered. In those limited number of cases where a payer covers the medication under a patient's pharmacy benefit, a specialty pharmacy purchases Qutenza from ASD Specialty Healthcare, and then ships the medication directly to the physician's office, rather than dispensing Qutenza to the patient.

Scientific and Medical Network

We have an established advisory team and network of well-recognized scientists, clinicians and opinion leaders in relevant fields, including for example the fields of multiple sclerosis, spinal cord injury, Parkinson's disease, epilepsy, stroke, and heart failure. 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.

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Material and Other Collaborations and License Agreements

Biogen Idec (Fampyra)

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

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

Ampyra is marketed as Fampyra outside the U.S. by Biogen Idec. Fampyra has been approved in a number of countries across Europe, Asia and the Americas. Biogen Idec anticipates making Fampyra commercially available in additional markets in 2015.

In consideration for the rights granted to Biogen Idec under the Collaboration Agreement, we were entitled to a non-refundable upfront payment of $110.0 million as of June 30, 2009, which was received in July 2009. Also, in August 2011, we received a $25 million milestone payment from Biogen for approval of Fampyra in the EU. Under our separate license and supply agreements with Alkermes, in 2009 we paid Alkermes $7.7 million of the $110 million upfront Biogen payment and in 2011 we paid Alkermes $1.8 million of the $25 million Biogen milestone payment. We are entitled to receive additional payments from Biogen of up to $10 million based on the successful achievement of future regulatory milestones and up to $365 million based on the successful achievement of future sales milestones. The next expected milestone payment from Biogen Idec would be $15 million, due when ex-U.S. net sales exceed $100 million over four consecutive quarters.

Under the Collaboration Agreement, we are also 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.

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Biogen Idec exclusively purchases all of Biogen Idec's, its affiliates' and its sublicensees' requirements of the licensed products from us. The purchase price paid by Biogen Idec for licensed products under the Collaboration Agreement and Supply Agreement reflects the prices owed to our suppliers under our supply arrangements with Alkermes or other suppliers. In addition, Biogen Idec pays 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

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Alkermes with respect to the development, supply and commercialization of the licensed products for Biogen Idec's territory. The Consent Agreement also amended our agreements with Alkermes by, among other things, permitting us to allow Biogen Idec to grant sublicenses to certain unaffiliated distributors; permitting us to allow Biogen Idec to package the licensed products and to work directly with Alkermes with respect to certain supply-related activities; and, requiring Alkermes to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

Alkermes, formerly Elan Corporation plc (Ampyra and Zanaflex)

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

Ampyra

In September 2003, we entered into an amended and restated license agreement with Elan that replaced two prior license agreements for Ampyra in oral sustained release dosage form. Under this agreement, Elan granted us exclusive worldwide rights to Ampyra for all indications, including SCI, MS and all other indications. We agreed to pay Elan milestone payments of up to $15.0 million, of which we have reached and paid $5.0 million, and royalties based on net sales of products with dalfampridine as the active ingredient. We also agreed to pay Elan 7% of any upfront and milestone payments that we receive from the sublicensing of rights to Ampyra or other aminopyridine products. As a result of our Collaboration Agreement with Biogen Idec, described above, in 2009 we paid Elan $7.7 million of a $110 million upfront payment we received from Biogen, and in 2011 we paid Elan $1.8 million of a $25 million milestone payment we received from Biogen.

Alkermes (now the licensor under this agreement due to its 2011 acquisition of Elan's Drug Technologies business) is also obligated under this agreement to supply us with our commercial requirements for Ampyra in the U.S., as well as to supply Biogen Idec under the Supply Agreement and Consent Agreement with Fampyra 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 for regulatory approvals within a commercially reasonable time after completion and receipt of positive data from all preclinical and clinical studies required for the related NDA equivalent. We could also lose our rights under the license agreement if we fail to launch a product in such countries within 180 days of NDA or equivalent approval and receipt of other needed regulatory approvals, or if we fail to fulfill our payment obligations under the license agreement. If Alkermes terminates our license in any applicable country, Alkermes is entitled to license from us our patent rights and know-how relating to the product and to market the product in the applicable country, subject to royalty payments to us.

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

Subject to the early termination provisions, the Alkermes license terminates on a country by country basis on the last to occur of fifteen years from the date of the agreement (2018), the expiration of the last to expire Alkermes patent or the existence of competition in that country.

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Zanaflex

In July 2004, we entered into an Asset Purchase Agreement with Elan pursuant to which we acquired all of Elan's research, development, distribution, sales and marketing rights to Zanaflex Capsules and Zanaflex tablets in the U.S. The assets acquired include the products' FDA registrations and FDA dossiers, proprietary product know-how, a patent and two related patent applications, certain inventory of Zanaflex tablets and certain product books and records. Elan also granted us a license allowing us to use the Zanaflex trademarks in the U.S., with the right to buy the Zanaflex trademark for a nominal sum once specified milestone and royalty payments were made. Those payments have been made, and we purchased and now own the trademarks. Elan also granted us an exclusive, perpetual and royalty-free license to certain intellectual property relating to technology contained in Zanaflex Capsules and Zanaflex tablets or used in the manufacture of Zanaflex Capsules, for use in connection with the sale and marketing of Zanaflex Capsules and Zanaflex tablets in the U.S. We also acquired the right to develop new indications, formulations, dosage forms, delivery systems and process improvements of Zanaflex. Under the agreement, Elan agreed not to directly or indirectly market, distribute or sell any products containing tizanidine as an active pharmaceutical ingredient in the U.S. until the later of the end of our obligation to pay royalties to Elan or valid termination of our supply agreement with Elan. In addition, we agreed not to directly or indirectly market, distribute or sell any products containing tizanidine as its active pharmaceutical ingredient in the United Kingdom or Ireland until July 2007.

Our agreement with Elan obligated us to pay a combination of sales-based milestone payments of up to $19.5 million, all of which have been achieved and were paid prior to our 2011 fiscal year, and royalties on sales of Zanaflex Capsules and Zanaflex tablets. We have no further Zanaflex milestone payment obligations to Elan or Alkermes (which has acquired Elan's Drug Technologies business). We also agreed to use commercially reasonable efforts to commercialize Zanaflex Capsules.

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

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

In December 2005, we entered into a financing arrangement with Paul Royalty Fund, or PRF, pursuant to which we assigned PRF the right to receive a portion of our net revenues from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. This agreement was amended in November 2006 potentially to increase the total amount of royalty payments to which PRF is entitled and to provide for additional lump-sum payments both from us to PRF and from PRF to us. The arrangement covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the arrangement is terminated earlier. In November 2014, PRF sold its Zanaflex revenue interest to another party, and in connection with our consenting to that transaction PRF released us from claims it had previously asserted regarding our alleged non-compliance with the terms of the financing arrangement. For more information on our arrangement with PRF, refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Financing Arrangements."

Rush-Presbyterian St. Luke's Medical Center (dalfampridine)

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

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its Orphan Drug Designation for dalfampridine for the relief of symptoms of MS.

We agreed to pay Rush a license fee, milestone payments of up to $850,000 and royalties based on net sales of the product for neurological indications. We have made or accrued an aggregate of $850,000 in milestone payments and $27.8 million in royalties under this agreement through December 31, 2014. In 2014, with our consent Rush sold its right to receive these royalties along with certain related rights to a third party, though this transfer did not materially change any of our obligations under the license. 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).

Alkermes (ARCUS products)

On December 27, 2010, Civitas, our wholly-owned subsidiary, entered into an Asset Purchase and License Agreement with Alkermes, Inc. pursuant to which Alkermes assigned, sold and transferred to Civitas certain of its rights in certain pulmonary delivery patents and patents applications, certain equipment and instruments relating to pulmonary drug delivery, copies of certain documents and reports relating to pulmonary delivery, certain pulmonary drug delivery inhalers and certain pulmonary drug delivery INDs filed with the FDA. Alkermes also granted to Civitas a non-exclusive sublicense to know-how for the purpose of development and commercialization of ARCUS products. Civitas is permitted to license and sublicense the pulmonary patents, patent applications and know-how, subject to certain restrictions, as necessary for our business. Without the prior written consent of Alkermes, Civitas is prohibited from assigning the intellectual property acquired from Alkermes, except to an affiliate or to a person that acquires all or substantially all of its business to which the agreement relates, whether by acquisition, sale, merger or otherwise.

Civitas is required to use commercially reasonable efforts to develop ARCUS products. Civitas is obligated to pay to Alkermes royalties for each licensed product. For licensed products sold by Civitas or an affiliate, Civitas will pay Alkermes a royalty in the mid-single digit percentages in the aggregate. For licensed products sold by a collaboration partner, Civitas will pay Alkermes the lower of either (1) a royalty in the mid-single digit percentage of net sales of licensed products in any given year, or (2) a percentage in the low-to-mid-double digits of all collaboration partner revenue received. Notwithstanding the foregoing, in no event shall the royalty paid be less than a low-single digit percentage of net sales of a licensed product in any given calendar year. Civitas must pay these royalties on a product-by-product and country-by-country basis until the later of: (1) the expiration of all patents acquired pursuant to the Alkermes agreement containing valid claims covering such licensed products in such country, or (2) a certain number of years after the launch of such licensed product in each specific country.

The Alkermes agreement remains in effect until expiration of Civitas's royalty obligations to Alkermes. Royalties are payable to Alkermes on a product-by-product and country-by-country basis until the later of (i) the expiration of the patents acquired from Alkermes containing a valid claim covering a product in a particular country and (ii) 12 years and six months after the launch of a product in a country. Either party may terminate the agreement for default of the other party. Civitas may terminate the Alkermes agreement for convenience upon 90 days' prior written notice to Alkermes.

SK Biopharmaceuticals Co., Ltd. (Plumiaz)

In December 2012, we acquired Neuronex, Inc., a privately-held pharmaceutical company developing Plumiaz (our trade name for Diazepam Nasal Spray). Plumiaz is a proprietary nasal spray formulation of diazepam that we are developing as a treatment for selected, refractory patients with epilepsy, on stable regimens

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of antiepileptic drugs, or AEDs, who experience intermittent bouts of increased seizure activity also known as seizure clusters or acute repetitive seizures, or ARS. Currently, the only approved outpatient treatment for people who experience this type of seizure activity is diazepam rectal gel, a rectally administered gel formulation of diazepam. Diazepam is also currently available in other formulations, such as used for intramuscular and intravenous administration, for certain indications. The nasally administered formulation potentially offers patients and caregivers a more practical and socially acceptable treatment option.

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

Pursuant to the SK license, Neuronex is obligated to pay SK up to $8 million upon the achievement of specified development milestones with respect to Diazepam Nasal Spray products (including a $1 million payment that was paid during the three-month period ending September 30, 2013 upon the FDA's acceptance for review of the first NDA for Plumiaz), and up to $3 million upon the achievement of specified sales milestones with respect to Diazepam Nasal Spray products. There can be no guarantee that any such milestones, other than the milestone based on the FDA's acceptance of the NDA, will in fact be met. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of Diazepam Nasal Spray products. Neuronex may offset, against a portion of the royalties payable to SK, a portion of any royalties we may pay under certain third party licenses.

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

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

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

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

Other License Agreements

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

- We have a mutual, exclusive cross license and coordination agreement with Astellas Pharma Europe Ltd., which we entered into in connection with our acquisition of Qutenza and NP-1998, pursuant to which the parties may

share certain data and may collaborate and/or share costs of future clinical trials relating to these products.

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- We have an exclusive, worldwide license from the Canadian Spinal Research Organization for specified patents and know-how relating to the use of dalfampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject.

- We have an exclusive, worldwide license from Cambridge Enterprise Limited (formerly Cambridge University Technical Services Limited) and King's College London to specified patents and patent applications for products related to enzymatic methods, including chondroitinase, of treating CNS disorders. Under the same license, we also have non-exclusive rights to these patents and patent applications for products related to small molecule inhibitors for use in treating CNS disorders.

- We have an exclusive, worldwide license from the Mayo Foundation for Education and Research, or Mayo Clinic, to specified patents, patent applications, and other intellectual property on certain antibodies relating to our research on the therapeutic use of these antibodies, specifically myelination and remyelination in MS and SCI.

- We have an exclusive, worldwide sublicense from Paion AG (formerly CeNeS Pharmaceuticals plc) to certain patents, patent applications and know-how relating to cimaglermin alfa, which we previously referred to as GGF2, or fragments thereof and non-protein products developed through the use of material covered by a valid claim in the patents. The license to these patents and the right to sub-license these patents were granted to Paion by the Ludwig Institute for Cancer Research. We also have an exclusive, worldwide sublicense from Paion to certain Paion patents, patent applications, and know-how relating to the neuregulin growth factor gene NRG-2.

- We have a license from Brigham and Women’s Hospital, Inc., or Brigham, acting on its own behalf and on behalf of Beth Israel Deaconess Medical Center, or Beth Israel, to patent rights relating to the use of cimaglermin in the treatment of congestive heart failure. Our rights in the U.S. are co-exclusive, with Brigham and Beth Israel having retained rights for internal research, clinical, and education purposes, and our rights outside the U.S are exclusive.

Manufacturing and Supply

Ampyra

We are party to a September 2003 agreement with Elan (now Alkermes, following Alkermes’s 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, we entered into a manufacturing agreement with Patheon, and 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’s 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

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supply-related activities, and requiring Alkermes to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

Regis Technologies, Inc. is the sole supplier of 4-aminopyridine, the active pharmaceutical ingredient in Ampyra. If Regis experiences any disruption in their operations, a delay or interruption in the supply of our Ampyra product could result until the Regis cures the problem or we locate an alternate source of supply. We may not be able to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements. We could experience substantial delays before we are able to qualify any new supplier.

Zanaflex

We currently rely on Alkermes to supply us under our 2004 Supply Agreement with Zanaflex Capsules (and for the supply of our authorized generic Zanaflex capsules being marketed by Watson Pharma, a subsidiary of Actavis). The initial term of the agreement expired in 2009, but is subject to two automatic two-year renewal terms. Either party may terminate the agreement by notifying the other party at least 12 months prior to the expiration of the initial term or any renewal term. In addition, either party may terminate the agreement if the other party commits a material breach that remains uncured. If a failure to supply occurs under the agreement, other than a force majeure event, or if we terminate the supply agreement for cause, Alkermes must use commercially reasonable efforts to assist us in transferring production of Zanaflex Capsules to us or a third-party manufacturer, provided that such third party is not a technological competitor of Alkermes. If we need to transfer production, Alkermes has agreed to grant us a royalty-free, fully paid-up license of its manufacturing know-how and other information and rights related to the production of Zanaflex Capsules, including a license to use its technology for specified purposes. We have the right to sublicense this know-how to a third party manufacturer, provided that this third party is not a technological competitor of Alkermes. In the event of termination of the supply agreement due to a force majeure event that continues for more than three months, Alkermes has agreed to enter into negotiations with us to preserve the continuity of supply of products, including the possibility of transferring manufacturing of Zanaflex Capsules to us or a third party manufacturer. Patheon manufactures Zanaflex tablets for us.

Farmak a.s. is our supplier of tizanidine hydrochloride, the active pharmaceutical ingredient, or API, in Zanaflex Capsules and Zanaflex tablets. If Alkermes, Patheon, or Farmak experiences any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or we locate an alternate source of supply. We may not be able to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements. We could experience substantial delays before we are able to qualify any new supplier and transfer the required manufacturing technology to that supplier.

Qutenza and NP-1998

We acquired Qutenza from NeurogesX in 2013. NeurogesX had discontinued active promotion of Qutenza by the time of our purchase, but we re-launched the product in January 2014 using our existing commercial organization, including our specialty neurology sales force. We rely on third parties to manufacture Qutenza patches, to supply the active pharmaceutical ingredient and inactive ingredients, and to package the product. We currently have a contract with the Qutenza patch manufacturer and the supplier of the gel used with the patches but not the supplier of active pharmaceutical ingredient or the packager.

We believe NP-1998 has key advantages over the Qutenza patch, and we believe NP-1998 has the potential to treat multiple neuropathies. However, as described above, in connection with our recent evaluation and reprioritization of our research and development pipeline, we have no current plans to invest in further development of NP-1998 for

neuropathic pain.

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Post-Stroke/Dalfampridine

In December 2014, we announced that the first patient has been enrolled in a Phase 3 clinical trial evaluating the use of dalfampridine administered twice daily (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke.

We have been exploring a once-daily (QD) formulation of dalfampridine for use in the chronic post-stroke clinical program. Based on the results of an in-vitro alcohol dose dumping study and a subsequent fed-fasted study, we determined that the initial QD formulation that we had been developing with an external partner was not practical for further testing. We are working with different external partners to develop a new QD formulation that could be included in future post-stroke studies.

We have granted Alkermes plc a right of first refusal to be our primary commercial supplier of the initial QD formulation. Should we complete development of and receive FDA approval for the initial QD formulation, we would owe royalties on sales of the product to the development company under our agreements with them. In such event, we will also owe royalties to Alkermes on sales of the product under our existing agreements with Alkermes.

CVT-301 and ARCUS Technology

Our acquisition of Civitas included its 90,000 square foot subleased manufacturing facility located in Chelsea, Massachusetts. The facility was built specifically for the commercial-scale manufacture of ARCUS products. Prior Civitas's acquisition of this facility from Alkermes, the facility produced more than 36 million human doses of ARCUS-based products for use in clinical trials by Alkermes's collaborator in indications other than PD. Civitas subsequently took steps to recommission the facility, which has been certified by the EU regulatory authority (known as the Qualified Person, or QP, audit). Civitas has produced GMP-quality human doses of CVT-301 for Phase 1 and Phase 2 clinical trials, is now producing GMP-quality CVT-301 powder for our ongoing Phase 3 clinical trial. As we are already at commercial scale, we believe that this will support rapid commercialization should we receive marketing approval from the FDA.

The ARCUS dry powder aerosol particles are generated by applying our proprietary and multi-step spray drying process to active pharmaceutical ingredient. The application of spray drying in the pharmaceutical industry is highly specialized, and the process of manufacturing ARCUS particles requires significant expertise in dry powder manufacture and handling and capsule filling.

We have developed mature quality systems to support commercial production. We have manufactured drug product at research scale and we believe that we have the expertise to transfer to large, commercial scale while maintaining all relevant drug product attributes. Consequently, we believe that we will be able to ensure reliable production that meets the requirements of the FDA and other regulatory agencies.

All CVT-301 dry powder inventory has been manufactured in-house using our GMP process. Current data supports CVT-301 as a room temperature stable product. We have finalized drug formulation and fill weight and have also implemented final design changes for the inhaler, for which commercial molds have been produced. All raw materials used for CVT-301 manufacture are standard in pharmaceutical production. Our manufacturing team is led by individuals who are highly experienced with manufacturing of ARCUS products and other commercial products. Many of the individuals who lead our manufacturing previously manufactured ARCUS products at this facility for Alkermes.

Our proprietary inhalers are manufactured by contract manufacturers using standard manufacturing processes. We own the molds and design history files for the inhalers. The inhalers are shipped fully-assembled to us. Final design changes for the inhaler for our Phase 3 clinical trial and anticipated commercial launch have been implemented, and the molds have been produced.

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Plumiaz

We rely on third parties for the manufacturing and packaging of this product, the nasal delivery device, and the supply of the active pharmaceutical ingredient. For commercial product, if we receive FDA approval, we have identified a potential manufacturer and potential suppliers, but we have not yet entered into any manufacturing or supply agreements with these companies and we cannot be certain that we can reach agreement with these companies on reasonable terms, if at all.

Cimaglermin alfa (previously GGF2)

We have completed a Phase 1 clinical trial of cimaglermin alfa, which we previously referred to as GGF2, in heart failure patients. This was a dose-escalating trial designed to test the maximum tolerated single dose, with follow-up assessments at one, three, and six months. In October 2013, we announced that the first patient had been enrolled in a second clinical trial of cimaglermin. This Phase 1b single-infusion trial in people with heart failure is assessing tolerability of three dose levels of cimaglermin, which were tested in the first trial, and also includes assessment of drug-drug interactions and several exploratory measures of efficacy. We voluntarily paused enrollment in this trial in December 2013 pending review of additional non-clinical data with the FDA. In April 2014, we announced that we had completed this review and recruitment was thereafter resumed. We expect to complete this trial in the second half of 2015. 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.

We contracted with CMC ICOS Biologics in 2008 to produce and purify cimaglermin bulk material under cGMPs. Acorda and CMC ICOS Biologics have jointly developed analytical and characterization assays to support the manufacture of cimaglermin. The details of the manufacturing and purification processes and data from the analytical assays were provided to FDA in an IND application in March 2010. This drug substance was generated to support Good Laboratory Practices, or GLP, safety and toxicology and to support drug product manufacturing.

The final drug product for cimaglermin for clinical studies was produced at Althea Technologies under a Product Development and Clinical Supply Agreement signed in 2009, using material produced by CMC Biologics described above. 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 a remyelinating antibodies program that we acquired under license from the Foundation for Medical Education and Research, or Mayo Clinic. Studies have demonstrated the ability of this family of antibodies to stimulate repair of the myelin sheath in three different animal models of MS. 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. Our lead recombinant human remyelinating antibody, designated rHIgM22, has been produced under GMPs, tested for safety in non-clinical studies and advanced to human trials in patients with MS.

In April 2013, we initiated a Phase 1 clinical trial of rHIgM22 to assess the safety and tolerability of rHIgM22 in patients with MS. The study also includes several exploratory clinical, imaging and biomarker measures. We announced top-line safety and tolerability results in February 2015. The trial, which followed participants for up to six months after receiving a single dose of rHIgM22, found no dose-limiting toxicities at any of the five dose levels studied. Additional data from this trial will be presented at future medical meetings. Based on these data, we intend to advance clinical development of rHIgM22 for MS. We are currently developing the protocol for our next Phase 1

clinical trial of rHIgM22. The data from the completed trial will help inform the design of the next trial, which we expect will enroll people with MS who are experiencing an active relapse. We

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believe a therapy that could repair myelin sheaths has the potential to restore neurological function to those affected by demyelinating conditions.

Other Products in Development

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

Intellectual Property

We have patent portfolios relating to: Ampyra/aminopyridines; CVT-301 and the ARCUS technology; cimaglermin alfa (previously GGF2)/neuregulins; remyelinating antibodies/antibodies relating to nervous system disorders; chondroitinase; Plumiaz/diazepam nasal spray; and Qutenza and NP-1998/topical capsaicin formulations. These portfolios are comprised of both our own and in-licensed patents and patent applications. Our intellectual property also includes copyrights, confidential and trade secret information as well as a portfolio of trademarks.

Ampyra/aminopyridines

We have five issued patents listed in the Orange Book for Ampyra, one of which issued in 2014, as follows:

- The first is U.S. Patent No. 8,007,826, with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Based on the final patent term adjustment calculation of the United States Patent and Trademark Office, or USPTO, this patent will extend into 2027.

- The second is U.S. Patent No. 5,540,938 (“the ‘938 patent”), the claims of which relate to methods for treating a neurological disease, such as MS, and cover the use of a sustained release dalfampridine formulation, such as AMPYRA (dalfampridine) Extended Release Tablets, 10 mg for improving walking in people with MS. In April 2013, the ‘938 patent received a five year patent term extension under the patent restoration provisions of the Hatch Waxman Act. With a five year patent term extension, the ‘938 patent will expire in 2018. We have an exclusive license to this patent from Alkermes (originally with Elan, but transferred to Alkermes as part of its acquisition of Elan’s Drug Technologies business).

- The third, which issued in January 2013, is U.S. Patent No. 8,354,437, which includes claims relating to methods to improve walking, increase walking speed, and treat walking disability in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2026.

- The fourth, which issued in May 2013, is U.S. Patent No. 8,440,703, which includes claims directed to methods of improving lower extremity function and walking and increasing walking speed in patients with MS by administering less than 15 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. This patent is set to expire in 2025.

- The fifth, which issued in March of 2014, is U.S. Patent No. 8,663,685 with claims relating to methods to improve walking in patients with MS by administering 10 mg of sustained release 4-aminopyridine (dalfampridine) twice daily. Absent patent term adjustment, the patent is set to expire in 2025.

In 2014, we received eight Paragraph IV Certification Notice Letters from generic drug manufacturers advising that they had submitted Abbreviated New Drug Applications, or ANDAs, to the FDA requesting permission to manufacture and market a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA

filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have

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also asserted that generic versions of their products do not infringe certain claims of these patents. In response to these filings, we filed lawsuits against all of these companies alleging multiple counts of patent infringement. This litigation is further described below in Part I, Item 3 of this report. We filed these lawsuits within 45 days from the date of receipt of each of the Paragraph IV Certification Notice Letters. As a result, a 30 month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30 month stay starts from January 22, 2015, which is the end of the new chemical entity (NCE) exclusivity period for Ampyra. This restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date.

On February 10 and 27, 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. We will oppose the requests to institute these two IPRs, and if they are allowed to proceed, we will oppose the full proceedings. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

In 2011, the European Patent Office, or EPO, granted EP 1732548, the counterpart European patent to U.S. Patent No. 8,354,437 with claims relating to, among other things, use of a sustained release aminopyridine composition, such as dalfampridine, to increase walking speed. In March 2012, Synthon B.V. and neuraxpharm Arzneimittel GmBH filed oppositions with the EPO challenging the EP 1732548 patent. We defended the patent, and in December 2013, we announced that the EPO Opposition Division upheld amended claims in this patent covering a sustained release formulation of dalfampridine for increasing walking in patients with MS through twice daily dosing at 10 mg. Both Synthon B.V. and neuraxpharm Arzneimittel GmBH have appealed the decision. In December 2013, Synthon B.V., neuraxpharm Arzneimittel GmBH and Actavis Group PTC ehf filed oppositions with the EPO challenging our EP 2377536 patent, which is a divisional of the EP 1732548 patent. Both European patents are set to expire in 2025, absent any additional exclusivity granted based on regulatory review timelines.

We have pending U.S. patent applications and corresponding foreign patent applications covering various methods of using aminopyridines, such as 4-aminopyridine (dalfampridine), including applications which if issued as patents could remain in force at least through 2030 and 2032, respectively.

CVT-301 and ARCUS Technology

The intellectual property portfolio that we acquired with Civitas has over 100 issued U.S. and foreign patents relating to CVT-301 and the ARCUS technology. This includes over 15 issued U.S. patents relating to CVT-301 directed to compositions of the drug product, the inhaler, methods of delivery of L-dopa, and manufacturing processes. The latest of the issued patents expires in 2032.

Plumiaz/Diazepam Nasal Spray

Our wholly-owned subsidiary Neuronex, Inc. has a license from SK Biopharmaceuticals Co., Ltd., or SK, for two patent families comprising a granted U.S. patent and pending U.S. and foreign patent applications relating to diazepam intranasal formulations and uses, including the clinical formulations for Plumiaz (our trade name for Diazepam Nasal Spray). The granted U.S. patent is set to expire in 2029. If granted, the pending patent applications would expire in 2029-2032. One patent family is owned by SK and one patent family is jointly owned by Neuronex and SK.

Cimaglermin alfa (previously GGF2)/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 cimaglermin alfa (which we previously referred to as GGF2). Collectively, these

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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.

Our neuregulin portfolio includes a granted U.S. patent directed to using specified neuregulin sequences to treat congestive heart failure.

Remyelinating Antibodies/Antibodies Related to Nervous System Disorders

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

Chondroitinase

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

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

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’s 2011 acquisition of Elan’s Drug Technologies business. Under this agreement, Zanaflex Capsules are manufactured for us by Alkermes using Alkermes's proprietary SODAS® technology and proprietary information. This proprietary technology is owned by Alkermes and, in the event Alkermes ceases to manufacture Zanaflex Capsules, Alkermes has agreed to grant us a royalty-free, fully paid-up license of its manufacturing know-how and other information and rights related to the production of Zanaflex Capsules, including a license to use its SODAS technology for specified purposes. We have the right to sublicense this know-how to a third-party manufacturer, so long as this third party is not a technological competitor of Alkermes.

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

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Apotex in the U.S. District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557. In September 2011, the Court ruled against us and, following our appeal, in June 2012 the U.S. Court of Appeals for the Federal Circuit affirmed the decision. We did not seek any further appeals of the decision.

Qutenza and NP-1998/Topical Capsaicin Formulations

We have commercialization and development rights for Qutenza and NP-1998 in the U.S., Canada, Latin America and certain other territories. In the U.S., we have one Orange Book-listed patent for Qutenza, which is U.S. Patent No. 6,239,180. This patent is set to expire in 2016, absent any Hatch-Waxman extension for regulatory delays. Qutenza has Orphan Drug designation which gives it marketing exclusivity in the U.S. until 2016.

There are granted U.S. patents which include claims directed to NP-1998 providing coverage until April 2027. There is also a pending U.S. patent application and pending foreign patent applications which, if granted, would expire in 2024.

Trademarks

In addition to patents, our intellectual property portfolio includes registered trademarks, along with pending trademark applications. 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,” “Zanaflex Capsules,” “Qutenza” and “ARCUS.” We also have trademark registrations for “Fampyra” and “Kampyra” and pending trademark applications therefore, in numerous foreign jurisdictions. 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, including multiple sclerosis, or MS, stroke, Parkinson’s disease, or PD, epilepsy, heart failure, and spinal cord injury. Many of our competitors have substantially greater financial, research and development, human and other resources than we do. Furthermore, many of these companies have significantly more experience than we do in preclinical testing, human clinical trials, regulatory approval procedures and sales and marketing.

Ampyra/MS

Current disease management approaches to MS are classified either as relapse management, disease course management, or symptom 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 and only 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

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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. In 2012, BioMarin outlicensed the North American rights to Catalyst Pharmaceuticals. In the EU, and the U.S., if this product is successfully developed and approved, physicians might prescribe it instead of Ampyra, even if it were not approved for MS.

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

Several companies are engaged in developing products that include novel immune system approaches and cell therapy approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete with Ampyra or our preclinical candidates in the future.

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

Ampyra could become subject to competition from generic drug manufacturers. In 2014, we received eight Paragraph IV Certification Notice Letters from generic drug manufacturers advising that they had submitted Abbreviated New Drug Applications, or ANDAs, to the FDA requesting permission to manufacture and market a generic version of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe certain claims of these patents. In response to these filings, we filed lawsuits against all of these companies alleging multiple counts of patent infringement. As a result of our filing these lawsuits, there is a statutory stay that restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of our asserted Orange Book-listed patents prior to that date. Patent litigation involves complex legal and factual questions.

On February 10 and 27, 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. We will oppose the requests to institute these two IPRs, and if they are allowed to proceed, we will oppose the full proceedings. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

We may expect to devote significant resources to thelawsuits and legal proceedings described in the preceding paragraphs, and if we are not successful our business could be materially harmed. We can provide no assurance concerning the duration or the outcome of these lawsuits and legal proceedings

Zanaflex/Spasticity

Tizanidine hydrochloride, the active pharmaceutical ingredient in Zanaflex Capsules, Zanaflex tablets and generic tizanidine hydrochloride tablets, is one of the two leading FDA-approved treatments for spasticity, a symptom suffered by, among others, both MS and SCI patients. Zanaflex tablets were approved by the FDA in 1996 and lost compound patent protection in 2002. A number of generic manufacturers of tizanidine hydrochloride are distributing their own tablet formulations.

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In 2012 Apotex Inc. launched generic tizanidine hydrochloride capsules, in 2012 we also launched an authorized generic version of Zanaflex Capsules under our agreement with Watson Pharma, Inc., a subsidiary of Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), and in 2013 Mylan Laboratories Limited launched generic tizanidine hydrochloride capsules. Other generic companies may also seek approval for their own generic tizanidine hydrochloride capsules. In addition, several companies have reported that they are working on potential new delivery formulations of tizanidine hydrochloride. Our net revenue from Zanaflex Capsules has declined significantly due to competition from existing generic versions, and we expect it will continue to decline in 2015 and beyond due to competition from existing and potentially other generic versions.

Baclofen, which is also available generically, is the other leading drug for the treatment of spasticity. The mechanism of action and associated effects of baclofen are different from those of tizanidine hydrochloride. Due to the different pharmacokinetic profile of Zanaflex Capsules, Zanaflex tablets and generic tizanidine hydrochloride tablets are not AB-rated with Zanaflex Capsules but Apotex's generic tizanidine hydrochloride capsules are.

CVT-301/Parkinson's disease

We believe that the main competitors for CVT-301 are therapies that can limit the occurrence of OFF episodes and other therapies for the on-demand treatment of OFF episodes. These therapies include both pharmacotherapies and invasive therapies for advanced patients such as deep brain stimulation that may be used in less advanced Parkinson's disease patients. Pharmacotherapies that can maintain consistent plasma concentration of L-dopa over extended durations could reduce the occurrence of motor fluctuations and thus reduce the need for on-demand treatments for OFF episodes such as CVT-301. Approaches to achieve consistent L-dopa plasma concentrations include new formulations of LD/CD, a combination of L-dopa and an inhibitor of DOPA decarboxylase (an enzyme found throughout the body) referred to as carbidopa, such as extended-release and intestinal infusions, and therapies that prolong the effect of L-dopa. Impax Laboraties has received FDA approval for RYTARY, an extended-release formulation of oral LD/CD, and extended release formulations of oral and patch LD/CD are being developed by others including Impax Depomed Inc. and NeuroDerm Ltd. Also, Abbvie Inc. has developed a continuous administration of a gel-containing L-dopa through a tube that is surgically implanted into the intestine is being developed by AbbVie Inc. This therapy, known as Duopa, has been approved by the FDA and is approved in the EU. Additionally, new formulations of dopamine agonist therapies (such as pramipexole and rotigotine) may be developed that can further prolong the effect of LD/CD regimens and reduce the frequency of motor fluctuations.

If approved for the treatment of OFF episodes, CVT-301 would compete against on-demand therapies that aim to specifically address OFF episodes. At this time, Apokyn, an injectable formulation of apomorphine, is the only therapy approved for the treatment of OFF episodes. Apokyn was approved for this use in the United States in 2004 and in Europe in 1993. A sublingual, or under the tongue, formulation of apomorphine which is being developed by Cynapsus Therapeutics, Inc. is currently in clinical development for this indication.

One or more of our competitors may utilize their expertise in pulmonary delivery of drugs to develop and obtain approval for pulmonary delivery products that may compete with CVT-301 and any other of our other ARCUS technology product candidates. These competitors may include smaller companies such as Alexza Pharmaceuticals, Inc., MannKind Corporation, Pulmatrix, Inc. and Vectura Group plc and larger companies such as Allergan, Inc., GlaxoSmithKline plc and Novartis AG. If approved, our product candidates may face competition in the target commercial areas.

Plumiaz/Seizure Clusters or Acute Repetitive Seizures

Plumiaz (Diazepam Nasal Spray) is a proprietary nasal spray formulation of diazepam that we are developing as a treatment for the management of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs,

or AEDs, who experience intermittent bouts of increased seizure activity, also known as seizure clusters or acute repetitive seizures, or ARS. Currently, the only approved outpatient treatment for people

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who experience this type of seizure activity is diazepam rectal gel, a rectally administered gel formulation of diazepam. Diazepam is also available in other formulations, such as intramuscular and intravenous formulations for use in certain indications. Our current understanding is that many patients would prefer a therapeutic product delivered intranasally rather than delivery options of rectal or intramuscular administration, but we cannot be certain that physicians would prescribe Plumiaz in preference over other available formulations of diazepam or other products. Also, if we obtain FDA approval for and launch Plumiaz for the treatment of patients who require intermittent use of diazepam to control bouts of increased seizure activity, it may be more expensive than some or all of the generic or branded versions of diazepam otherwise available. Furthermore, we are aware that Meridian Medical Technologies (a Pfizer subsidiary) is developing an intramuscular auto-injector for diazepam, Upsher Smith is developing a nasal delivery form of midazolam, and Alexza is developing an inhaled version of alprazolam for use by patients who experience ARS, each of which could have a labeled indication similar to Plumiaz. Plumiaz could be subject to substantial competition from these potential products, depending on whether and when they receive FDA approval, their cost, their labeled indications, patient acceptance, and other factors. Additionally, in May 2013, the diazepam auto-injector from Meridian Medical Technologies received orphan drug designation for the management of selected, refractory patients with epilepsy on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control bouts of increased seizure activity. The product is still in clinical development and has not been approved yet. If this product receives FDA approval before Plumiaz, Plumiaz will be excluded from the market for seven (7) years unless we are able to prove to the FDA that the nasal spray is clinically superior to the intramuscular diazepam auto-injector or offers a major contribution to patient care relative to the auto-injector for the same therapeutic indication.

In addition to these examples, there are other companies with early stage development programs for the treatment of epilepsy, including breakthrough seizures, seizure clusters or acute repetitive seizures, that could compete with Plumiaz in the future.

Qutenza/Post-Herpetic Neuralgia

Qutenza faces significant competition from various other oral and topical products that are indicated to treat PHN and/or other forms of neuropathic pain, as well as other prescription and over the counter pain medications not specifically indicated for neuropathic pain that patients may use to address their symptoms. Many of the prescription pain medications that may compete with Qutenza are available in generic forms. If we successfully develop and commercialize NP-1998, this product would similarly face significant competition from these other products.

Also, unlike our other products, Qutenza may be administered only by a health care professional in an office, clinic, or hospital setting. For this reason, it is treated as a “buy-and-bill” product by most payers, including most Medicare programs, Medicaid programs, and private payers. Buy-and-bill products must be purchased by health care providers before they can be administered to patients. Health care providers subsequently must seek reimbursement for the product from the applicable third party payer such as Medicaid or a health insurance company. Health care providers may be reluctant to administer Qutenza because they would have to fund the purchase of the product and then seek reimbursement (which may differ somewhat from their purchase price), or because they do not want the additional administrative burden required for the product.

Government Regulation

FDA Regulation of Drugs and Drug Product Approval

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the preclinical testing, clinical development, manufacture, distribution and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development

activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising, sale, promotion, import and export of our products and product candidates.

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In the U.S., Ampyra, Zanaflex Capsules, Zanaflex tablets, Qutenza, 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. Biologics are regulated under both the Federal Food, Drug, and Cosmetic Act, as amended, the Public Health Service Act, as amended, and the regulations of the FDA. Both drugs and biologics are also subject to other federal, state, and local statutes and regulations. Violations of regulatory requirements at any stage may result in various adverse consequences, including the FDA's and other health authorities' delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions, including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions and/or civil or criminal penalties. Similar civil or criminal penalties could be imposed by other government agencies or agencies of the states and localities in which our products are tested, manufactured, sold or distributed.

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

- preclinical laboratory and animal tests;
- submission to the FDA of an Investigational New Drug, or IND, application, which must become effective before human clinical trials may begin;
- completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug, or the safety, purity, and potency of the proposed biologic, for each intended use;
- FDA review of whether each facility in which the product is manufactured, processed, packed or held meets standards designed to assure the product's identity, strength, quality, and purity; and
- submission and FDA approval 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, containing preclinical and clinical data, proposed labeling, information to demonstrate that the product will be manufactured to appropriate standards, and other required information.

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. The results of the preclinical studies, together with manufacturing information, analytical data and any available clinical data or literature must be submitted to the FDA as part of an IND application. The IND sponsor may initiate clinical trials 30 days after filing the IND application, 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, or IRB, 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. The IRB(s) must continue to monitor the trial until its completion. Many studies also employ a data safety monitoring board, or DSMB, with experts who are otherwise independent of the conduct of the study and are given access to the unblinded study data periodically during the study to determine whether the study should be halted. For example, a DSMB might halt a study if an unacceptable safety issue emerges, or if the data showing the effectiveness of the study drug would make it unethical to continue giving patients placebo. Study subjects must provide informed consent before their participation in the research study.

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

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

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

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

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

Before proceeding with a Phase 3 trial, 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 to a publicly available database at www.clinicaltrials.gov. These requirements generally do not apply to Phase 1 clinical trials.

U.S. law requires that trials conducted to support approval for product marketing be "adequate and well controlled." This entails a number of requirements, including that there is a clear statement of objects and methods in the protocol, the study design permits a valid comparison with a control (e.g., a placebo, another drug already approved for the studied condition, or a non-concurrent control such as historical data), and that the statistical methods used to analyze the data are adequate to assess the effects of the drug. 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 IRBs 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 distribution 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

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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 not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug or biological product, and determines that the facility is in compliance with current Good Manufacturing Practice, or cGMP, requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products, or approval may be delayed until the manufacturing issues are resolved. The FDA may also inspect clinical trial sites and will not approve the product unless the clinical studies have been conducted in compliance with GCP.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing a BLA or NDA and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees could be significant.

Once an NDA or BLA is submitted for FDA approval, the FDA will accept the NDA or BLA for filing if deemed complete, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable. The FDA has established performance goals for the review of NDAs and BLAs: six months for priority applications and 10 months for regular applications, with two additional months added to each period for new molecular entities. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if favorable, often is not an actual approval but an “action letter” or “complete response letter” that describes additional work that must be done before the application can be approved. This additional work could include substantial additional clinical trials. The FDA's review of an application may involve review and recommendations by an independent FDA advisory committee.

The FDA may deny an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional preclinical or clinical data. Even if such data is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. If the FDA approves a product, it will limit the approved therapeutic uses for the product as described in the product labeling, may require that contraindications or warning statements be included in the product labeling, may require that additional post-approval studies or clinical trials be conducted as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk evaluation and mitigation strategy, or REMS, or may 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.

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 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, labeling changes 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.

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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 requirements relating to record-keeping, labeling, packaging, reporting of adverse experiences and other reporting, advertising and promotion, labeling, distribution, GMPs, and import/export. 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. 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, require post-approval studies or clinical trials, or impose a REMS post-approval if it becomes aware of new safety information that the agency believes impacts the drug's safety profile. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Foreign drug manufacturers must comply with similar local requirements and may be subject to inspections by FDA or local regulatory agencies. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMPs and other regulatory requirements. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In addition to inspections related to manufacturing, we are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements that apply to marketed drugs manufactured or distributed by us. The FDA also may conduct periodic inspections regarding our review and reporting of adverse events, or related to compliance with the requirements of the PDMA concerning the handling of drug samples. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations, or FDA Form 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. Failure to address the FDA's concerns may result in the issuance of a warning letter or other enforcement or administrative actions.

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, or where we may have operations. 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. Federal law and some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including requirements for the development of systems capable of tracking and tracing product as it moves through the distribution chain. Any applicable federal, state or local regulations may hinder our ability to market, or increase the cost of marketing, our products in those states or localities.

The FDA's policies may change and additional U.S. or foreign government regulations may be enacted which could impose additional burdens or limitations on our ability to market products after approval. Moreover, increased attention to the containment of healthcare costs in the U.S. and in foreign markets could result in new government regulations that could harm our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Orphan Drugs

Under the Orphan Drug Act, special incentives exist for sponsors to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the

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U.S. Requests for orphan drug designation must be submitted before the submission of an NDA, BLA, or supplemental NDA or BLA for the orphan use. We received an orphan drug designation for Ampyra for the treatment of both MS and incomplete SCI. The number of people affected by MS now exceeds 200,000. However, this does not affect Ampyra's orphan drug designation in the United States, as it was granted prior to the increase in prevalence 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 sponsor 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 demonstrates a major contribution to patient care, 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 another sponsor's application for a drug that is the same as a drug with orphan exclusivity, but for a different use, the competing drug could be prescribed by physicians outside its approved use, including 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.

Some other jurisdictions have orphan drug rules and offer similar incentives. In the EU, for example, a designated orphan drug benefits from free scientific advice and reduced application fees. Moreover, an approved orphan drug benefits from a 10-year exclusivity period, during which regulators can neither accept nor approve applications for similar medicinal products for the same indication, unless there are insufficient supplies of the approved orphan drug or the similar product is safer, more effective or otherwise clinically superior than the approved orphan drug. Under the EU system, however, the Committee for Orphan Medicinal Products, or COMP, will reassess orphan status in parallel with the European Medicines Agency's assessment of the marketing authorization application and the COMP can recommend that orphan status is removed if the product no longer meets the relevant criteria.

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. For generic versions of drugs subject to an NDA, an abbreviated new drug application, or ANDA, is filed with the FDA. The ANDA must seek approval of a product candidate that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as a so-called "reference listed drug" approved pursuant to a full NDA. Only limited exceptions exist to this ANDA sameness requirement, including certain limited variations approved by the FDA through a special suitability petition process. ANDA applicants are not required to submit clinical data to demonstrate safety and efficacy. Instead, FDA relies on its findings of safety and effectiveness of the reference listed drug to approve the ANDA. As a result, the law requires the ANDA applicant submit only 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.

Under the Federal Food, Drug, and Cosmetic Act, drugs that are new chemicals entities, or NCEs, are eligible for a five-year data exclusivity period. During this period, FDA may not accept for review an ANDA submitted by another

company that relies on any of the data submitted by the innovator company. This exclusivity period also applies to "505(b)(2)" applications, which are a hybrid application that relies in-part on pioneer data and in-part on new clinical data submitted to account for differences between the 505(b)(2) product

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and the reference listed drug. However, an ANDA (or 505(b)(2) application) may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The statute also provides three years of data exclusivity for an NDA (or NDA supplement) that is not an NCE if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed essential to approval. During this period, FDA will not approve an application filed by a third party for the protected conditions of use that relies on any of the data that was submitted by the innovator company. Neither exclusivity period blocks the approval of full applications (i.e., full NDAs) submitted to FDA that do not rely on the pioneer's data.

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 after receiving notice of the patent certification, an automatic stay bars FDA approval of the ANDA for 30 months, which period may be extended under certain circumstances. The length of the automatic stay depends on whether the FDA classifies the reference listed drug as an NCE, as follows:

- If the FDA does not classify the reference listed drug as an NCE, then the automatic stay is for 30 months from the date that the manufacturer of the reference listed drug receives the patent certification described above.

- If the reference listed drug is classified by the FDA as an NCE, then the timing of the automatic stay depends on when the ANDA is filed, as well as when the manufacturer of the reference listed drug receives the patent certification described above. No company can file an ANDA on a reference listed drug that FDA has designated as an NCE until five years after the reference listed drug's FDA approval, except that an ANDA may be submitted four years after the reference listed drug's FDA approval if the ANDA contains the patent certification described above. If the ANDA is filed five or more years after FDA approval of the NCE, then the 30 month stay is applicable. However, if an ANDA is filed in between the fourth and fifth years after FDA approval of the NCE, the automatic 30 month stay is extended by a number of months equal to the number of months remaining in the fifth year after approval of the reference listed drug, providing a total of up to a 42 month stay.

If the stay is either lifted or expires and the ANDA applicant is able otherwise meet the FDA's requirements for the approval of ANDAs, the generic manufacturer may begin selling its product even if patent litigation is pending. However, 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 copayments as an incentive to patients to ask for and accept generics.

While the question of substitutability is one of state law, most states look to the FDA to determine whether a generic is substitutable. 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 therefore are 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

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approvals, and usually requires a showing of comparable rate and extent of absorption in a small human study.

Requirements Applicable to Medical Devices in the United States

The FDA regulates, among other things, the development, testing, manufacturing, labeling, marketing, and distribution of medical devices. The level of regulation applied by the FDA generally depends on the class into which the medical device falls: Class I, II, or III. Class I medical devices present the lowest risk, and Class III medical devices present the highest risk. In general, the higher class of device, the greater the degree of regulatory control. All devices, for example, are subject to "General Controls," which include:

- Establishment registration by manufacturers, distributors, re-packagers, and re-labelers;
- Device listing with FDA;
- Good manufacturing practices;
- Labeling regulations; and
- Reporting of adverse events.

Class II medical devices are subject to General Controls, but also Special Controls, including special labeling requirements, mandatory performance standards, additional postmarket surveillance, and specific FDA guidance. Most Class III medical devices are assessed individually through an extensive Premarket Review application, or PMA. As a result, although they are subject to General Controls, they generally are not subject to Special Controls. Instead, most Class III devices have additional requirements and conditions of use imposed on them through the individualized PMA review and approval process.

Most Class I devices are exempt from the FDA premarket review or approval. With some exceptions, Class II devices may be marketed only if the FDA "clears" the medical device through the 510(k) process, which requires a company to show that the device is "substantially equivalent" to certain devices already on the market. Again with some exceptions, Class III devices are approved through a PMA, which generally requires an applicant to submit data from clinical trials that establish the safety and effectiveness of the device. Clinical data are sometimes required for a 510(k) application as well. Manufacturers conducting clinical trials with medical devices are subject to similar requirements as those conducting clinical trials with drugs or biologics. For example, a manufacturer must obtain an investigational device exemption, or IDE, to test a significant risk device in humans, must comply with GCPs, and must obtain IRB approval.

The FDA has broad post-market regulatory and enforcement powers with respect to medical devices, similar to those for drugs and biologics. For example, medical devices are subject to detailed manufacturing standards under the FDA's quality systems regulations, or QSRs, and specific rules regarding labeling and promotion. Medical device manufacturers must also register their establishments and list their products with the FDA.

States also impose regulatory requirements on medical device manufacturers and distributors, including registration and record-keeping requirements. Failure to comply with the applicable federal and state medical device requirements could result in, among other things, refusal to approve or clear pending applications, withdrawal of an approval or clearance, warning letters, product recalls, product seizures, total or partial suspension of production, fines, refusals of government contracts, restitution, disgorgement, or other civil or criminal penalties.

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Biosimilars

The Affordable Care Act amended the Public Health Service Act to authorize the FDA to approve "biosimilars" via a separate, abbreviated pathway. Under this abbreviated pathway, the biosimilar applicant must demonstrate that its product is "highly similar" to the "reference product," and that there are no "clinically meaningful differences" between the biosimilar and the reference product. Unlike ANDAs, biosimilars are not, in general, automatically substitutable for the reference product at the pharmacy. Instead, FDA must make a separate finding of "interchangeability," and the various state laws regarding pharmacy substitution of "interchangeable" and "non-interchangeable" biosimilars is as yet unsettled.

The Affordable Care Act also established a period of 12 years of data exclusivity against biosimilars for reference products in order to preserve incentives for future innovation. Under this framework, data exclusivity protects the data in the BLA-holders's regulatory application by prohibiting others, for a period of 12 years, from gaining FDA approval based in part on reliance on or reference to the reference product's data in its approved BLA. In contrast to the provisions for NDAs, the biologics data exclusivity provisions do not change the duration of patents granted on biologic products, or otherwise create an "automatic stay" of FDA approval of a biosimilar. If our product candidates are approved as biologics, they may face significant competition from biosimilars in the future.

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. Foreign marketing authorizations can be applied for at a national level, although within the European Union, or EU, registration procedures are available to companies wishing to market a product in the entire European Economic Area, or EEA (through the "centralized procedure," which is mandatory for certain products, including biotechnology and advanced therapy medicinal products, orphan medicines and new active substances for the treatment of acquired immune deficiency syndrome (AIDS), cancer, neurodegenerative disorder, diabetes, auto-immune diseases and other immune dysfunctions and viral diseases), or in more than one individual EU member state (through the "mutual recognition procedure" or "decentralized procedure"). The 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 and oversight by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act and the False Claims Act, and are affected by the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. For products to be covered by Medicaid, drug manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services on behalf of the states and must regularly submit certain pricing information to CMS. For products to be made available to authorized users of the Federal Supply Schedule administered by the Department of Veterans Affairs, 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 the Department of Defense, or DOD, the Public Health Service

and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. In

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addition, under legislative changes made in 2009, discounted prices must also be offered for certain DOD purchases for its TRICARE retail pharmacy program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

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

Under the Sunshine Act provisions of the Affordable Care Act, or ACA, pharmaceutical manufacturers are subject to federal reporting and disclosure requirements with regard to payments or other transfers of value made to physicians and teaching hospitals. Reports submitted under these requirements will be placed on a public database. Pharmaceutical manufacturers are required to submit reports to CMS annually. Similarly, pharmaceutical manufacturers are required to annually report to FDA samples of prescription drugs requested by and distributed to healthcare providers. The law does not state whether these sample disclosures will be made publicly available, and the FDA has not provided any additional guidance as to how the data will be used.

Our research and development and manufacturing activities are subject to numerous environmental, health and safety laws and regulations, including, among other matters, those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous substances; the exposure of persons to hazardous substances; the release of pollutants into the air and bodies of water; and the general health, safety and welfare of employees and members of the public. Our research and development and manufacturing activities and the activities of our third-party manufacturers involve the use of hazardous substances, and the risk of injury, contamination or noncompliance with the applicable environmental, health and safety requirements cannot be eliminated. We may incur significant costs to comply with such laws and regulations now or in the future. Although compliance with such laws and regulations has not had a material effect on our capital expenditures, earnings or competitive position, environmental, health and safety laws and regulations have tended to become increasingly stringent and, to the extent legal or regulatory changes occur in the future, they could result in, among other things, increased costs to us.

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 other programs 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.

Under the reimbursement methodology set forth in the Medicare Modernization Act, or MMA, physicians are reimbursed for drugs they administer to Medicare beneficiaries 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 ACA requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is

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in the Medicare Part D coverage gap, also known as the "donut hole."

The Deficit Reduction Act of 2005 resulted in changes to the way average manufacturer price, or AMP, and best price are reported to the government and the formula for calculating required Medicaid rebates. The ACA 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 ACA increased the additional Medicaid rebate on "line extensions" (such as extended release formulations) of solid oral dosage forms of branded products, revised the definition of AMP by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted 340B pricing.

The ACA 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 ACA also contains a number of provisions, including provisions governing the way that healthcare is financed by both governmental and private insurers, enrollment in federal healthcare programs, reimbursement changes, increased funding for comparative effectiveness research for use in the healthcare industry, and enhancements to fraud and abuse requirements and enforcement, that will affect existing government healthcare programs and will result in the development of new programs.

We are unable to predict the future course of federal or state healthcare legislation and regulations, including regulations that will be issued to implement provisions of the ACA. The ACA 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.

Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, some governments influence the price of pharmaceutical products through reference pricing approaches to pharmaceutical reimbursement for national healthcare systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits and may limit or restrict reimbursement. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Health and Care Excellence, or NICE, in the United Kingdom 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 19, 2015, we had 489 employees. Of the 489 employees, 114 perform research and development activities, including preclinical programs, clinical trials, regulatory affairs, biostatistics, and drug safety, and 375 work in sales, marketing, managed markets, business development, manufacturing, technical

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operations, medical affairs, communications, and general and administrative.

CORPORATE INFORMATION

We were incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 420 Saw Mill River Road, Ardsley, New York 10502. Our telephone number is (914) 347-4300. Our website is www.acorda.com. 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 2015 Annual Meeting of Stockholders, rather than repeating that information in this report. We intend to file our 2015 Proxy Statement within 120 days after the end of our 2014 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 2015 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 2013 and 2014, we may not be able to sustain profitability; and we expect to be substantially dependent on revenues from the sale of Ampyra for the foreseeable future.

We will be highly dependent on the commercial success of Ampyra in the U.S. for the foreseeable future. We currently derive substantially all of our revenue from the sale of Ampyra, and we believe that sales of Ampyra will continue to constitute a significant and growing portion of our total revenue 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.

As of December 31, 2014, we had an accumulated deficit of approximately $220.4 million. We had net income of $17.7 million for the year ended December 31, 2014, $16.4 million for the year ended December 31, 2013, and $155.0 million for the year ended December 31, 2012, which included a tax benefit recorded for a release of our deferred tax asset valuation allowance. However, prior to 2011 we had operating losses each year since inception. Our operating losses resulted from our significant expenses relating to clinical development, research and development, general and administrative, sales, managed markets and marketing, medical affairs and business development. We may not sustain profitability because we expect to continue investing significant amounts to market our approved products, to continue

product development and research and development activities, and, potentially, to acquire new products and product candidates.

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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 dalfampridine franchise, such as through our program evaluating the use of dalfampridine (BID) to improve walking in people who are suffering from chronic post-stroke walking deficits (PSWD) after experiencing an ischemic stroke;

- successfully advancing our late-stage clinical development programs for new product candidates, including in particular our program to develop CVT-301 for the treatment of OFF episodes in Parkinson's disease, acquired with our purchase of Civitas in 2014, and our program to develop Plumiaz as an acute treatment for selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs, or AEDs, who experience seizure clusters or acute repetitive seizures;

- continuing to advance our other clinical development programs, including our rHIgM22 and cimaglermin alfa (previously GGF2) programs;

    - continuing to develop our preclinical product candidates and advance them into clinical trials; and

- evaluating and potentially expanding our product development pipeline through the potential 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 and even if we sustain profitability we may not meet sales expectations. Also, even if we are successful in executing our business plan, our profitability may fluctuate from period to period due to our level of investments in sales and marketing, research and development, and product and product candidate acquisitions. For example, in 2015 we expect to invest a significant amount to support several clinical trial programs.

The continued commercial success of Ampyra, and the success of any future products, are highly dependent on market acceptance among physicians, patients and the medical community, adequate reimbursement by government and other third-party payers, and other factors.

In general, the success of our products is subject to numerous factors, some of which are not within our control, including the following:

- the effectiveness of our sales, managed markets and marketing efforts;

- the acceptance of Ampyra and our other products in the medical community, particularly with respect to whether physicians and patients view Ampyra and our other products as safe and effective for its labeled indication, and whether it has an acceptable benefit-to-risk profile, and the rate of adoption by healthcare providers and the target population of patients;

    - the availability of adequate reimbursement by third-party payers;

- the continued use of compounded 4-AP instead of Ampyra, available through pharmacies in the U.S. and elsewhere that engage in compounding;

- the occurrence of any side effects, adverse reactions or misuse (or any unfavorable publicity relating thereto) stemming from the use of Ampyra or our other products;

- the development of products that compete with or are an alternative to Ampyra or our other products as therapies for the treatment of underlying medical conditions or their symptoms, the timing of market entry for those competing or alternative products, the perceived advantages of competing or alternative therapies over our products, and the pricing of our products as compared to the pricing of those competing or alternative products; and

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- the loss of intellectual property protection for our products, which would enable generic competition.

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. Market acceptance also depends on the pricing of our products and the reimbursement policies of government and third-party payers, as well as on the effectiveness of our sales and marketing activities. Physicians may not prescribe our products, and patients may determine, for any reason, that our products are not useful to them. For example, physicians may not believe that the benefits of Ampyra or our other products are meaningful for patients. As described below 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 some countries 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 market acceptance of our products in the U.S., EU, or other countries does not meet expectations, our revenues or royalties from product sales would suffer and this could cause our stock price to decline or could otherwise adversely affect our stock price.

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

In general, under the Internal Revenue Code of 1986, as amended, a corporation is subject to limitations on its ability to utilize net operating losses, or NOLs, to offset future taxable income. As of December 31, 2014, we had approximately $215 million of NOLs available to reduce taxable income in future years. Losses for federal income tax purposes can generally be carried forward for a period of 20 years. We believe it is more likely than not that we will use these net operating losses. However, the ability to use net operating loss carryforwards will be dependent on our ability to generate taxable income. The net operating loss carryforwards could expire before we generate sufficient taxable income.

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

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

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

We operate in the highly-regulated pharmaceutical industry.

Our research, development, preclinical and clinical trial activities, as well as the manufacture and marketing of any products that we have developed or in the future may successfully develop, are subject to an extensive regulatory approval process by the FDA and other regulatory agencies abroad.

In order to conduct clinical trials to obtain FDA approval to commercialize any product candidate, an investigational new drug, or IND, application must first be submitted to the FDA and must become effective before clinical trials may begin. Subsequently, if the product candidate is regulated as a drug, a new drug application, or NDA, must be submitted to the FDA and approved before commercial marketing may begin. The NDA must include the results of adequate and well-controlled clinical trials demonstrating, among other things, that the product candidate is safe and effective for use in humans for each target indication. If the product candidate, such as an antibody, is regulated as a biologic, a biologic license application, or BLA, must be submitted and approved before commercial marketing may begin. 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. 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.

The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain. Any regulatory approvals may be for fewer or narrower indications than we request, may include 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 evaluation and mitigation strategy, or REMS, 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.

Any product for which we currently have or may in the future obtain marketing approval is subject to continual post-approval requirements including, among other things, record-keeping and reporting requirements, packaging and labeling requirements, requirements for reporting adverse drug experiences, import/export controls, restrictions on advertising and promotion, and cGMP requirements. All of our products and operations are subject to 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. Post-market evaluation of a product could result in marketing restrictions or withdrawal from the market.

We may fail to comply with existing legal or regulatory requirements or be slow to adapt, or be unable to adapt, to new legal or regulatory requirements. We may encounter problems with our manufacturing processes, and we may

discover previously unknown problems with our products. These circumstances could result in:

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- voluntary or mandatory recalls;
- voluntary or mandatory patient or physician notification;
- withdrawal of product approvals;
- shut-down of manufacturing facilities;
- receipt of warning letters or untitled letters;
- 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, 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 have no manufacturing capabilities for our products or product candidates other than our Chelsea, Massachusetts facility used to manufacture CVT-301 and other ARCUS inhaled therapy product candidates, and we are dependent upon Alkermes and other third-parties to supply the materials for, and to manufacture, Ampyra and our other commercial products and products in development.

We do not own or operate, and currently do not plan to own or operate, facilities for production and packaging of Ampyra or our other commercial products other than our Chelsea, Massachusetts facility used to manufacture CVT-301 and other ARCUS product candidates. We rely and expect to continue to rely on third parties for the production and packaging of our commercial products, the active pharmaceutical ingredient, or API, in those products, the inactive ingredients in those products, the finished dosage forms of our products, and for the supply of materials for our research and development activities, particularly clinical trials. In addition, due to the unique manner in which our products are manufactured, in many cases we rely on single source providers for the API or other components of, or the manufacture of, products and for materials for our research and development programs. Our dependence on others to manufacture and provide the API and finished dosage forms for our marketed products and clinical trial materials may harm our ability to develop and commercialize our products on a timely and competitive basis. Any such failure may result in decreased product sales and lower product revenue, which would harm our business.

We cannot be certain that we can reach agreement with (or renew existing agreements with) needed third party manufacturers or suppliers on reasonable terms, if at all. Manufacturers or suppliers may choose not to conduct

business with us at all, for example if they determine that our particular business requirements would be unprofitable or otherwise not appropriate for their business. Even if we have agreements with third parties, they may not perform their obligations to us and/or they may be unable or unwilling to establish or increase production

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capacity commensurate with our needs. Also, third party manufacturers and suppliers are subject to their own operational and financial risks that are outside of our control, including macro-economic conditions that may cause them to suffer liquidity or operational problems and that could interfere with their business operations.

In addition, the manufacture and distribution of our products and product candidates, including product components such as API, is highly regulated, and any failure to comply with regulatory requirements could adversely affect our supply of products or our access to materials needed for product development. The third parties we rely on are subject to regulatory review, and any regulatory compliance problems could significantly delay or disrupt commercialization of our products. U.S. and foreign governments and regulatory authorities continue to propose legislative and other measures relating to the manufacture or distribution of pharmaceutical products, including revisions to current good manufacturing practices, or cGMPs. Third party manufacturers may be unable or unwilling to comply with new legislative or regulatory measures, and/or compliance with new requirements could increase the price we must pay for our products.

The manufacturing facilities used to produce our products, including those of our third-party manfacturers and suppliers, must comply with current good manufacturing practices, or cGMPs, and will likely have to pass a pre-approval FDA inspection. Third-party manufacturers and suppliers are also subject to periodic FDA inspection for cGMP compliance. Failure by our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our products or product candidates may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters, injunctions, facility shut-downs, or the loss of operating licenses. Based on the severity of the regulatory action, our clinical or commercial supplies could be interrupted or limited, which could have a material adverse effect on our business.

If any of our third party manufacturers or suppliers fails to perform their obligations to us or otherwise have an interruption in or discontinues supply to us, we may be forced to seek supply from a different third party manufacturer or supplier. In such event, we may experience significant delays associated with finding an alternative manufacturer or supplier that is properly qualified to produce our products and product candidates or the API or other components of those products and product candidates in accordance with FDA requirements and our specifications. This could interfere with product sales or cause interruptions of or delays in our research and development programs. We may not be able to establish arrangements with an alternative manufacturer or supplier on reasonable terms, if at all. In some cases, the technical skills required to manufacture our products or product candidates or the API or other components of such products or product candidates may be unique or proprietary to the original manufacturer or supplier and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a backup or alternative supplier, or we may be unable to transfer such skills at all.

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

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

forecasts of our supply requirements are inaccurate, we may have an excess or insufficient supply of Ampyra.

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We similarly rely on Alkermes and other third parties for the manufacture of our Zanaflex and authorized tizanidine hydrochloride generic products and the supply of tizanidine hydrochloride, Qutenza, and the API in those products. Also, we intend to rely on third-party manufacturers to make the inhaler and to supply the API in CVT-301, and any failure by a third-party manufacturer or supplier may delay or impair our ability to complete clinical trials or commercialize CVT-301. We have manufactured the capsules containing formulized L-dopa for our preclinical studies, Phase 1 clinical trials and Phase 2 clinical trials of CVT-301 in our own manufacturing facility and expect to continue to do so for our Phase 3 clinical trial. We have relied, and we expect to continue to rely, on third-party plastic molding manufacturers for production of our CVT-301 inhalers and third-party suppliers of L-dopa, the API in CVT-301. Our reliance on third parties for the manufacture of inhalers increases the risk that we will not have sufficient quantities of our inhalers or will not be able to obtain such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. If our third-party plastic molding manufacturer fails to supply the inhalers and we need to enter into alternative arrangements with a different supplier, it could delay our product development activities, as we would have to revalidate the molding and assembly processes pursuant to FDA requirements. If this failure of supply were to occur after we received approval for and commenced commercialization of CVT-301, we might be unable to meet the demand for this product and our business could be adversely affected. Similarly, we do not purchase the API for CVT-301 under a supply contract and there is a risk that we will not have sufficient quantities of the API at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Similarly, if we obtain FDA approval for Plumiaz and commercialize this product, we will rely on a third party manufacturer and packager for the product and third party suppliers of the API, the nasal delivery device, and the components used in drug packaging. Although we have identified a potential manufacturer and potential suppliers for commercial supply, we have not yet entered into any manufacturing or supply agreements with these companies for commercial supply and we cannot be certain that we can reach agreement with these companies on reasonable terms, if at all. Also, these companies will be subject to FDA approval and we cannot be certain that the FDA would provide such approval.

If we are unable to use our Chelsea manufacturing facility for any reason, we would be unable to manufacture clinical supply of CVT-301 and, if this product is approved, commercial quantities of CVT-301 or other ARCUS inhaled therapeutic candidates for a substantial amount of time, which would harm our business.

We currently manufacture all clinical supply of CVT-301 at our own Chelsea, Massachusetts manufacturing facility that we have subleased under an operating lease that expires December 31, 2015, which we may extend for up to ten years. We intend to manufacture all commercial supplies of CVT-301, if approved for commercial sale, as well as supplies of all additional ARCUS inhaled therapeutic candidates that we may develop, in this manufacturing facility. However, our Chelsea manufacturing facility has not been inspected by the FDA. Prior to commercialization of CVT-301, the FDA will likely conduct a pre-approval inspection. If, during this inspection, the FDA determines that the systems or facility do not meet FDA good manufacturing practices, or GMP, requirements, the FDA may not grant marketing approval for our product.

Furthermore, if we were to lose the use of our facility or equipment, our manufacturing facility and manufacturing equipment would be difficult to replace and could require substantial replacement lead time and substantial additional funds. Our facility may be affected by natural disasters, such as floods or fire, or we may lose the use of our facility due to manufacturing issues that arise at our facility, such as contamination or regulatory concerns following a regulatory inspection of our facility. We do not currently have back-up capacity and there is only limited third-party manufacturing capacity that would be available to manufacture CVT-301 or other ARCUS inhaled therapeutic products or product candidates. In the event of a loss of the use of all or a portion of our facility or equipment for the reasons stated above or any other reason, we would be unable to manufacture CVT-301 or any other ARCUS inhaled therapeutic products or product candidates until such time as our facility could be repaired, rebuilt or we are able to

address other manufacturing issues at our facility. Any such interruptions in our ability to manufacture these products or product candidates would harm our business.

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The FDA-approved product labeling for Ampyra limits promotional opportunities for Ampyra, which may harm market acceptance of Ampyra, and we could be subject to enforcement action by the FDA if our promotional activities are not compliant with applicable laws and regulations.

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 precautions, the most common adverse events, and contraindications for risks. If potential purchasers or those influencing purchasing or prescribing 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, including civil and criminal penalties. For example, in June 2012, we received an untitled letter from the FDA stating that one of our Ampyra promotional videos did not comply with applicable law and was misleading because it overstated the efficacy of and minimized important safety information associated with Ampyra. In compliance with the untitled FDA letter, we discontinued use of the video, and in light of the FDA letter we also evaluated and discontinued the use of some other promotional materials. In July 2013, we received a warning letter from the FDA stating that one of our consumer print advertisements for a local speaker program to educate consumers about Ampyra was false or misleading because it omitted risk information associated with the use of Ampyra. The warning letter cited the prior June 2012 untitled letter and stated that this was a serious and repeat violation. The FDA instructed us to immediately discontinue using the print advertisement and submit a written response to their letter, including a plan of action to disseminate corrective messages. The print advertisement was no longer in use, and in compliance with the FDA request, we timely submitted a written response to the warning letter, committing to take appropriate corrective action, with which the FDA agreed.

We may incur significant liability if it is determined that we are promoting the “off-label” use of Ampyra or any other marketed drug or if we otherwise fail to comply with stringent FDA marketing and promotion and regulations.

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. Similar rules apply in many countries outside the U.S. Off-label uses are common across medical specialties. Although the FDA does not regulate a physician’s choice of treatments, they require the promotion of a drug to be consistent with the approved labeling. Companies may not promote drugs for off-label uses. Accordingly, for example, we may not promote Ampyra in the U.S. for any indications other than improving walking ability in people with MS. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have engaged in off-label promotion may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other applicable regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. Although we believe that all of our communications regarding our marketed products are in compliance with off-label promotion restrictions, the FDA or another regulatory or enforcement authority may disagree.

Also, 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

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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.

The identification of new Ampyra side effects, or Ampyra side effects that are more frequent or severe than in the past, would harm our business and 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 among others seizures, urinary tract infection, trouble sleeping (insomnia), dizziness, headache, nausea, weakness, back pain, and problems with balance. Since becoming commercially available in 2010, Ampyra has been used in a wider population than in clinical studies. Some patients exposed to Ampyra have reportedly experienced serious adverse side effects, including seizures. In July 2012, the FDA issued a safety communication relating to seizures based on post-marketing data from March 2010 through March 2011, which resulted in FDA safety updates and related changes to the Ampyra product labeling. We constantly monitor adverse event reports for signals regarding potential additional adverse events, which could drive further label changes such as a September 2012 label change relating to reports of anaphylactic reactions.

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:

- we may decide to, or be required to, send product warning letters or field alerts to physicians, pharmacists and hospitals; and we may be required to make further product label changes;
- healthcare practitioners, third party payers or patients may perceive or conclude that the use of Ampyra is associated with serious adverse effects, which could affect regulatory approvals for Ampyra or the availability of adequate reimbursement by third-party payers
- we may be required to reformulate the product, conduct additional preclinical or clinical studies, or make changes in labeling or changes to or reapprovals of manufacturing facilities;
- the FDA may impose a new REMS on Ampyra or otherwise restrict its distribution and use;
- our reputation in the marketplace may suffer; and
- government investigations and lawsuits, including class action suits, may be brought against us.

The above occurrences could impair our business by harming or possibly preventing sales of Ampyra, causing sales to fall below projections, and increasing our expenses.

Regulatory approval of our products could be withdrawn and our business could be harmed if we fail to comply with safety and adverse event monitoring, documentation, investigation and reporting requirements

Under FDA regulations, we are required to monitor the safety of Ampyra and inform healthcare professionals about the risks of drug-associated seizures with Ampyra. We are required to document and investigate reports of adverse events, and to report them to the FDA in accordance with regulatory timelines based on their severity and expectedness. Failure to make timely safety reports and to establish and maintain related records could result in withdrawing of marketing authorization or other regulatory action, civil actions against us, or criminal penalties, any of which could harm our business. Since 2010, we have submitted some late reports, including instances where specialty pharmacies that dispense Ampyra or a marketing partner have failed to timely report to us some of the

reports of adverse events that they received. We reported these adverse events to the FDA immediately upon receipt. However, because these adverse events were not reported to us in a timely

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manner, they were considered late reports to the FDA. Also, FDA inspections have identified issues with our adverse event reporting which have let to Form 483s and a warning letter, which are further described below. If the specialty pharmacies that we rely upon to sell Ampyra in the U.S. or our marketing partners fail timely to report adverse events and product complaints to us, or if we do not meet the requirements for safety reporting, our business may be harmed.

We 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. Failure to adequately address the FDA’s concerns could expose us to enforcement and administrative actions.

For example, the FDA conducted two inspections beginning in July 2011. The first inspection focused on our risk evaluation and mitigation strategy, or REMS (which we are no longer subject to), and the second inspection focused on our adverse event reporting system. The REMS inspection resulted in verbal comments pertaining to formalization of procedures and enhanced quality assurance responsibilities. The adverse event reporting inspection resulted in a September 2011 FDA Form 483 focused primarily on timeliness of reporting, formalization and enhancement of certain procedures and processes, communication of Ampyra post-marketing commitments, and Acorda access to source documentation. Acorda provided the FDA with formal responses to the inspectional observations as well as to the verbal comments and commenced the process of implementing specific actions to address the FDA’s concerns and enhance our overall pharmacovigilance process. However, in May 2012 the FDA issued a written warning letter based on some of the adverse event reporting issues identified in the 2011 inspection. The FDA warning letter identified some of the FDA’s observations as repeat observations from prior FDA inspections. We responded to the warning letter, advising the FDA of the corrective actions we were taking to address all of the matters covered in the warning letter.

The FDA also conducted two inspections in December 2012 through January 2013. The first inspection focused on Ampyra REMS adherence and resulted in the issuance of an FDA Form 483 with one written observation and six verbal comments. The written observation described a lack of timely distribution of REMS required letters to prescribers and pharmacists. The verbal comments pertained to verification and document control processes for REMS required letters, process control for creation and distribution of these letters and the medication guide, and the timing of prescriber surveys in relation to mailing of letters to the prescribers. The second inspection focused on adverse event reporting and was a follow-up to our responses to the 2011 FDA Form 483 and warning letter. This inspection resulted in an FDA Form 483 with six written observations and three verbal comments. The written observations noted late adverse event reporting, one late quarterly Periodic Adverse Experience Report, or PADER, and one late field alert. The FDA also noted that certain solicited adverse events were not reported in our PADERS and there was a lack of consistent adherence to procedures for timely case follow-up and investigations. The verbal comments covered the completeness and timeliness of investigations as well as need for further clarification of an existing procedure. We responded to the Form 483s and oral comments, and took corrective actions. The FDA also conducted a routine inspection in December 2013. This inspection focused on Quality Unit procedures, especially those related to handling of product complaints and field alerts as well as on adverse event reporting. An FDA Form 483 was issued with two findings. The first Form 483 finding pertained to late adverse event reporting and the second finding pertained to lack of sufficient investigation of Ampyra “lack of effect” complaint trends. We responded to the Form 483, and have taken corrective actions. We continue to monitor and enhance our adverse event and product complaint reporting systems to ensure continued adherence to regulatory requirements. However, the FDA may conclude in subsequent inspections that we have not demonstrated adequate control over our current processes or have not demonstrated adequate closure of our response commitments, and could take action against us without further notice. Action by the FDA against us could require us to take further corrective actions or even that we stop marketing

Ampyra and/or result in monetary fines, and any of such actions by the FDA could harm our business.\

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In addition, our third-party suppliers' drug product manufacturing sites are subject to inspection by the FDA. Some of these sites have been inspected by the FDA and could be inspected by the FDA in the future. If the FDA inspects the process validation efforts and manufacturing process at these sites, the FDA might find what it considers to be deficiencies in the manufacturing process or process validation efforts, which could negatively impact the availability of product supply or, in the case of a potential new product, delay or prevent commercial launch of that product. For example, although we have not yet contracted with the manufacturer of Plumiaz, we have named a potential manufacturer in the NDA that has limited experience with FDA inspections and no prior experience with commercial manufacturing. Although this manufacturer has undergone an FDA pre-approval inspection and no FDA 483 was issued, the FDA has not inspected the commercial manufacturing process. If serious concerns are identified during the manufacturing process inspection, this could delay the launch of Plumiaz, if it is approved, which could harm our business.

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 certain 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 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, shut-down of manufacturing facilities, or other civil or criminal sanctions. Non-compliance could increase our costs, cause us to lose revenue, and damage our reputation.

Even if our suppliers or manufacturing methods are in compliance with applicable requirements, we may encounter problems with the manufacture of our products. To investigate and/or resolve these problems, we may be required to withdraw or recall product and interrupt commercial supply of our products. These events could increase our costs, cause us to lose revenue, and damage our reputation. We are required to submit field alert reports to the FDA if we learn of certain reported problems with our products, and we are required to investigate the causes of the reported problems. Issues identified in field alerts could lead to product recalls and interruption of supplies, which in turn could harm our business.

Also, effective January 2015, the Federal Food, Drug & Cosmetic Act requires that trading partners such as our manufacturers, repackagers, wholesale distributors, and dispensers, take certain actions upon determining that a product in their possession or control is suspected to be: counterfeit, diverted, stolen; intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; is the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consquences to humans. The suspect product is required to be quarantined while an investigation is promptly conducted to determine whether the product meets any of the above criteria. Once a product is determined to meet any of the above-listed criteria, it will be deemed an illegitimate product. Upon such a determination, the FDA and all trading partners in the supply chain must be notified within 24 hours. The notification and quarantine of product during an investigation could impact product availability for commercial distribution and harm our business.

Our success in maintaining and increasing sales of Ampyra will depend on the continued customer support efforts of our network of specialty pharmacies.

A specialty pharmacy is a pharmacy that specializes in the dispensing of injectable, infused or certain other medications typically for complex or chronic conditions, which often require a high level of patient education and ongoing management. Specialty pharmacies are commonly used to dispense MS drugs, many of which are

injectable. The use of specialty pharmacies involves risks, including, but not limited to, risks that these specialty pharmacies will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using Ampyra, Ampyra adverse events, or Ampyra complaints;

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- not effectively dispense or support Ampyra;
- reduce their efforts or discontinue dispensing or supporting Ampyra;
- not devote the resources necessary to dispense Ampyra in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others;
- not have the required licenses to distribute drugs; or
- cease operations.

We 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, is and will subject us to a number of risks, including:

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

- collaborators may experience financial difficulties.

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While we have negotiated some terms in the Collaboration Agreement with Biogen Idec intended to assist in protecting our rights in certain of the circumstances listed above, there can be no assurance that these terms will provide us 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 and maintain regulatory approval in foreign jurisdictions where they seek to market or are currently marketing Fampyra.

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

In July 2011, Biogen Idec received conditional approval from the European Commission for Fampyra (10 mg 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 European Commission may grant a conditional marketing authorization if, at the time of the application, the marketing authorization applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, for objective, verifiable reasons based on grounds specified in EU law.

A conditional approval must be reassessed and renewed annually, and there can be no assurance that Biogen Idec will be able to satisfy the requirements for maintaining the approval. As part of its conditional approval, Biogen Idec is carrying out additional studies on the long-term effectiveness and safety of Fampyra, and the results of these studies could affect renewal of the conditional approval or granting of full approval. The requirements to conduct supplemental trials add to the cost and risks of development and approval. Additional or supplemental trials with respect to Fampyra or other product candidates could also produce findings that are inconsistent with the trial results we have previously submitted to the FDA, in which case we would be obligated to report those findings to the FDA.

Drug development programs, particularly those in early stages of development, may never be commercialized.

Our future success depends, in part, on our ability to select successful product candidates, complete preclinical development of these product candidates and advance them to and through clinical trials. We have several research and development programs that are early-stage and either have not advanced to clinical trials or are only in Phase 1 trials. These early-stage product candidates in particular will require significant development, preclinical studies and clinical trials, regulatory clearances and substantial additional investment before they can be commercialized, if at all. In addition to our research and development of new drugs, we are assessing new formulations of dalfampridine and the possible use of dalfampridine in chronic post-stroke walking deficits (PSWD). These programs, which also will require substantial additional investment, are in various stages of development and similarly may never lead to any new commercialized products or expansion of the Ampyra label for additional uses.

Our research and development programs may not lead to commercially viable products for several reasons, and are subject to the risks and uncertainties associated with drug development described elsewhere in these risk factors. For

example, we may fail to identify promising product candidates, our product candidates may

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

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

Before we can obtain regulatory approval for any product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory agencies. Clinical trials of new product candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete, and the outcome of such trials is uncertain. Clinical development of any product candidate that we determine to take into clinical trials, including our clinical trials described in this report, may be curtailed, redirected, delayed or eliminated at any time for some or all of the following reasons:

- negative or ambiguous results regarding the efficacy of the product candidate;
- undesirable side effects that delay or extend the trials, or other unforeseen or undesirable safety issues that make the product candidate not medically or commercially viable;
- inability to locate, recruit and qualify a sufficient number of patients for our trials;
- difficulty in determining meaningful end points or other measurements of success in our clinical trials;
- regulatory delays or other regulatory actions, including changes in regulatory requirements;
- difficulties in obtaining sufficient quantities of our product candidates manufactured under current good manufacturing practices;
- delays, suspension or termination of the trials imposed by us, an independent institutional review board, or a data safety monitoring board, 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.

Clinical trials are subject to oversight by institutional review boards, data safety monitoring 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

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required by regulators. If any of those standards are not complied with in a clinical trial, the resulting data from the clinical trial may not be usable or we, an institutional review board or the FDA may suspend or terminate a trial, which would severely delay our development and possibly end the development of the product candidate.

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.

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

The distribution, sale and promotion of drug and biological products are subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, the Federal Trade Commission, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, as amended, the False Claims Act, as amended, and are affected by the privacy provisions of the Health Insurance Portability and Accountability Act, as amended and similar state laws. Because of the breadth of these laws and the narrowness of safe harbors under these laws, it is possible that some of our business activities could be subject to challenge under one or more of these laws. All of these activities are also subject to federal and state consumer protection and unfair competition laws.

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Numerous pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; and engaging in off-label promotion that

caused claims to be submitted to Medicaid for non-covered, off-label uses. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply

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regardless of the payer.

Sanctions under these federal and state laws may include requirements to make payments to government-funded health plans to correct for insufficient rebates paid by us or overpayments made to us, civil monetary penalties, exclusion of our products from reimbursement under government programs, criminal fines and imprisonment.

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Service Act pharmaceutical pricing program, which requires us to sell our products to certain customers at prices lower than we otherwise might be able to charge. For products to be made available to authorized users of the Federal Supply Schedule, additional pricing laws and requirements apply, as do certain obligations imposed by the Federal Acquisition Regulations. Under the Veterans Health Care Act of 1992, as amended (VHCA), we are required to offer certain drugs at a reduced price to a number of federal agencies, including the Veterans Administration, the Department of Defense (DOD), the Public Health Service and certain private Public Health Service designated entities, in order to participate in other federal funding programs including Medicare and Medicaid. Also, legislative changes enacted in 2009 require that discounted prices be offered for certain DOD purchases for its TRICARE retail program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

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 laws and regulations governing 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 and penalties, 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.

Also, Qutenza (which we re-launched in January 2014) differs from our other products because it may be administered only by a healthcare professional. For this reason, it is treated as a “buy-and-bill” product by most payers, including most Medicare programs, Medicaid programs, and private payers. Buy-and-bill products must be purchased by healthcare providers before they can be administered to patients. Under the buy-and-bill model, healthcare providers subsequently bill the product to the patient’s insurer, which may be a government healthcare program or private health plan. Purchasers of buy-and-bill products that are administered to Medicare patients are reimbursed under that program’s Average Sales Price, or ASP, payment model. Because reimbursement for these patients is based on ASP and not the healthcare provider’s actual purchase price for the prescription drug, the reimbursement often differs somewhat from the actual price paid by the healthcare provider. Acorda does not sell Qutenza directly to healthcare providers, but rather, healthcare providers purchase this drug from a specialty distributor, who in turn acquires the

product from us.

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Historically, some pharmaceutical manufacturers have been accused by the government of "marketing the spread" between the healthcare provider's purchase price and the reimbursement price, by allegedly promoting the potential to earn profit on each administration of the drug. Alternatively, other manufacturers have been alleged to have "manipulated" that spread by manipulating the determination of reimbursement rates by artificially inflating reported prices. We have adopted policies and training programs for our employees intended to prevent marketing or manipulating the spread between the price at which Qutenza is purchased and the price reimbursed by federal healthcare programs. However, if our actions are viewed by government regulators or qui tam relators as inappropriately marketing or manipulating that spread, we could be investigated and, potentially, charged with violations of the anti-kickback and fraud and abuse provisions of the Social Security Act, as amended, the False Claims Act, as amended, the Medicaid drug rebate statute, and similar state laws.

In addition, if the actions we take by providing background educational material and other information to healthcare providers concerning billing for Qutenza are viewed as encouraging healthcare providers to misrepresent the professional services provided to beneficiaries of federal healthcare programs or to otherwise submit claims to federal healthcare programs that are designed to maximize reimbursement inappropriately, this could result in investigations, and possible charges of violating, these same laws.

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

The Patient Protection and Affordable Care Act,or Affordable Care Act, enacted in 2010, substantially changes the way that healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. This law contains a number of provisions, including provisions governing enrollment in federal healthcare programs, reimbursement changes, the increased development of comparative effectiveness research for use in healthcare decision-making, and enhancements to fraud and abuse requirements and enforcement, that will affect existing government healthcare programs. A key provision of the Affordable Care Act, which provides federal premium tax credits to individuals purchasing coverage through Health Benefit Exchanges, is currently being challenged in a case before the Supreme Court, King v. Burwell. An adverse decision in that case could severely curtail the number of individuals who have become or are expected to become newly insured. A decision in the case is expected by June 2015. In addition, changes to the Affordable Care Act, or other federal legislation regarding healthcare access, financing, or delivery and other actions taken by individual states concerning the possible expansion of Medicaid could impact our financial position or results of operations.

A number of provisions contained in the Affordable Care Act may harm our net revenue for our marketed products and any future products. The law, among other things, increased the minimum basic Medicaid rebate for branded prescription drugs from 15.1% to 23.1% and requires pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, the Affordable Care Act increased the additional Medicaid rebate on "line extensions" (such as extended release formulations) of solid oral dosage forms of branded products, revised the definition of average manufacturer price by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted 340B pricing. Government efforts to reduce Medicaid expenses may also lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

The law also requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." In addition, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) is based on the manufacturer's market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U.S. government programs.

The Affordable Care Act also includes substantial provisions affecting compliance. For example, under a section of the Act known as the Sunshine Act, pharmaceutical manufacturers are required to collect information

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on payments or other transfers of value made to “covered recipients,” which are defined as physicians and teaching hospitals. The collected information has to be disclosed in annual reports that are placed on a public database. Similarly, pharmaceutical manufacturers are also required to annually report samples of prescription drugs requested by and distributed to healthcare providers. The law does not state whether these disclosures regarding samples will be made publicly available, and the FDA has not provided any guidance. If we fail to provide these reports, or if the reports we provide are not accurate, we could be subject to significant penalties.

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

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

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

Our ability to maintain and increase sales and profitability will depend in part on third-party payers, such as government or government-sponsored health administrative authorities, including Medicaid and Medicare Part D, private health insurers and other such organizations, agreeing to reimburse patients for the cost of our products. Significant uncertainty exists as to the reimbursement status of newly approved drug products. Third-party payers are increasingly challenging the pricing of medical products and services and their reimbursement practices may affect the price levels for Ampyra and our other marketed products, or potential products. Our business could be materially harmed if the Medicaid program, Medicare program or other third-party payers were to deny reimbursement for our products or provide reimbursement only on unfavorable terms. Our business could also be harmed if the Medicaid program, Medicare program or other reimbursing bodies or payers limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate or limit the circumstances under which our products will be reimbursed to a smaller set of circumstances than we believe is appropriate.

Third-party payers frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. We have agreed to provide such discounts and rebates to some third-party payers in relation to Ampyra. We expect increasing pressure to offer larger discounts or discounts to a greater number of third-party payers to maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary. There is no guarantee that we would be able to negotiate agreements with third-party payers at price levels that are profitable to us, or at all. A number of third-party payers also require prior authorization for, or even refuse to provide, reimbursement for Ampyra, and others may do so in the future. Patients who cannot meet the conditions of prior authorizations are often prevented from obtaining the prescribed medication, because they cannot afford to pay for the medication without reimbursement. If we are unsuccessful in maintaining reimbursement for our products at acceptable levels, or if reimbursement for our products by third-party payers is subject to overly restrictive prior authorizations, our business will be harmed. In addition, if our competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce our sales and harm our results of operations.

The Medicare Part D outpatient prescription drug benefit is provided primarily through private entities, which attempt to negotiate price concessions from pharmaceutical manufacturers. These negotiations increase pressure to lower prescription drug prices or increase rebate payments to offset price. While the law specifically prohibits the U.S. government from interfering in price negotiations between manufacturers and Medicare drug

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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 Affordable Care Act contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include limitations on prescription drug prices. The Affordable Care Act requires drug manufacturers to provide a 50% discount on prescriptions for branded products filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." Legislative or regulatory revisions to the Medicare Part D outpatient prescription drug benefit, as well as additional healthcare legislation that may be enacted at a future date, could reduce our sales and harm our results of operations.

The success of our existing and potential products in the EU substantially depends on achieving adequate government reimbursement.

The commercial success in the EU of products approved there, including Fampyra, will depend largely on obtaining and maintaining government reimbursement because, in many European countries, patients may not have access to prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with government authorities can delay commercialization. Even if reimbursement is available, reimbursement policies may negatively impact revenue from sales of our products and therefore our ability or that of our partners, such as Biogen Idec, to sell our products on a profitable basis. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of products by us or our partners, such as Biogen Idec, and exert commercial pressure on pricing within a country.

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

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 conditions, including multiple sclerosis, or MS, stroke, Parkinson's disease, or PD, epilepsy, heart failure, and spinal cord injury, or SCI.

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

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

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Ampyra. We are aware that Catalyst Pharmaceuticals is developing a 3,4-diaminopyridine product, licensed from Biomarin, that may compete with Ampyra. Also, 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 it is possible that some people will want to continue to use compounded formulations even though Ampyra is commercially available. Several companies are engaged in developing products that include novel immune system approaches and cell therapy approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete in the future with Ampyra or some of our product candidates.

CVT-301. We believe that the main competitors for CVT-301 are therapies that can limit the occurrence of OFF episodes and other therapies for the on-demand treatment of OFF episodes. These therapies include both pharmacotherapies and invasive therapies for advanced patients such as deep brain stimulation that may be used in less advanced Parkinson's disease patients. Pharmacotherapies that can maintain consistent plasma concentration of L-dopa over extended durations could reduce the occurrence of motor fluctuations and thus reduce the need for on-demand treatments for OFF episodes such as CVT-301. Approaches to achieve consistent L-dopa plasma concentrations include new formulations of LD/CD, a combination of L-dopa and an inhibitor of DOPA decarboxylase (an enzyme found throughout the body) referred to as carbidopa, such as extended-release and intestinal infusions, and therapies that prolong the effect of L-dopa. Extended-release formulations of oral and patch LD/CD are being developed by groups including Impax Laboratories, Inc., Depomed Inc. and NeuroDerm Ltd. A continuous administration of a gel-containing L-dopa through a tube that is surgically implanted into the intestine is being developed by AbbVie Inc. This therapy, known as Duopa, is approved in the EU and AbbVie may gain approval in the United States and other countries. Additionally, new formulations of dopamine agonist therapies (such as pramipexole and rotigotine) may be developed that can further prolong the effect of LD/CD regimens and reduce the frequency of motor fluctuations.

If approved for the treatment of OFF episodes, CVT-301 would compete against on-demand therapies that aim to specifically address OFF episodes. At this time, Apokyn, an injectable formulation of apomorphine, is the only therapy approved for the treatment of OFF episodes. Apokyn was approved for this use in the United States in 2004 and in Europe in 1993. A sublingual, or under the tongue, formulation of apomorphine which is being developed by Cynapsus Therapeutics, Inc. is currently in clinical development for this indication.

One or more of our competitors may utilize their expertise in pulmonary delivery of drugs to develop and obtain approval for pulmonary delivery products that may compete with CVT-301 and any other of our other ARCUS technology product candidates. These competitors may include smaller companies such as Alexza Pharmaceuticals, Inc., MannKind Corporation, Pulmatrix, Inc. and Vectura Group plc and larger companies such as Allergan, Inc., GlaxoSmithKline plc and Novartis AG. If approved, our product candidates may face competition in the target commercial areas.

Plumiaz. Plumiaz is a proprietary nasal spray formulation of diazepam, which is currently available as an FDA approved rectal gel and in other formulations, such as intramuscular and intravenous formulations used in certain indications. Our current understanding is that many patients would prefer a therapeutic product delivered intranasally rather than delivery options of rectal or intramuscular administration, but we cannot be certain that physicians would prescribe Plumiaz in preference over the other available formulations of diazepam or other products. Also, if we obtain FDA approval for and launch Plumiaz for the treatment of patients who require intermittent use of diazepam to control bouts of increased seizure activity, it may be more expensive than some or all of the generic or branded versions of diazepam otherwise available. Furthermore, we are aware that Meridian Medical Technologies (a Pfizer subsidiary) is developing an intramuscular auto-injector for diazepam, Upsher Smith is developing a nasal delivery form of midazolam, and Alexza is developing an inhaled version of alprazolam for use by patients who experience ARS, each of which could have a labeled indication similar to Plumiaz. Plumiaz could be subject to substantial

competition from these potential products, depending on whether and when they receive FDA approval, their cost, their labeled indications, patient acceptance, and other factors. Additionally, in May 2013, the diazepam auto-injector from Meridian Medical Technologies received

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orphan drug designation for the management of selected, refractory patients with epilepsy on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control bouts of increased seizure activity. The product is still in clinical development and has not been approved yet. If this product receives FDA approval before Plumiaz, Plumiaz will be excluded from the market for seven (7) years unless we are able to prove to the FDA that the nasal spray is clinically superior to the intramuscular diazepam auto-injector or offers a major contribution to patient care relative to the auto-injector for the same therapeutic indication.

In addition to these examples, there are other companies with early stage development programs for the treatment of epilepsy, including breakthrough seizures, seizure clusters or acute repetitive seizures, that could compete with Plumiaz in the future.

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

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

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

We cannot assure you that any acquisition or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed products or product candidates, for example by overestimating approvability by the FDA or the market potential of acquired or in-licensed products or product candidates. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions and in-licenses. Any acquisition might distract resources from and otherwise harm sales of Ampyra or our other marketed products. 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 products or product candidates work or be successful. Furthermore, the development or expansion of our business or any acquired business or company or in-licensed product or 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.

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

If the use or misuse of Ampyra, Zanaflex Capsules, Zanaflex tablets, Qutenza, 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 indemnification obligations.

The approval of Zanaflex Capsules is subject to certain post-approval regulatory requirements that we have not completed, and we may be subject to penalties if we fail to comply with these requirements and our Zanaflex products could be subject to enforcement actions or withdrawal from the market.

We have an outstanding FDA commitment, inherited from Alkermes (formerly Elan), to provide an assessment of the safety and effectiveness of Zanaflex Capsules in pediatric patients. This commitment, which is included in the NDA approval for Zanaflex Capsules, was to be satisfied by February 2007. We provided retrospective pediatric safety data to the FDA in April 2007. However, we were not able to complete the pediatric pharmacokinetic study by the February 2007 deadline due to delays in investigator recruitment and obtaining Institutional Review Board approvals. The study was completed and the final report submitted to the FDA in April 2008. The FDA reviewed our report against new standards set out in the Pediatric Research Equity Act (PREA) and reauthorized by both the 2007 FDA Amendments Act (FDAAA) and the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) and concluded that the report did not satisfy the commitment. The FDA has informed us that a series of studies designed to further characterize the pharmacokinetics and demonstrate the efficacy and long-term safety of Zanaflex Capsules in children are required to fulfill the pediatric commitment for Zanaflex Capsules. In June 2011, the FDA informally advised us that it would be amending the pediatric commitment for Zanaflex Capsules to require a non-clinical juvenile toxicology study, as well as formalize the timeline for the required pediatric studies. In December 2012, the FDA issued a formal written request that confirmed the information in its informal June 2011 request, and set forth specific deadlines for the required pediatric nonclinical and clinical studies. In January 2013, we submitted a written request to extend the deadlines for these studies and in September 2014 we received a “Denial of Deferral Request” letter from the FDA. We responded to this denial letter in October 2014, requesting the FDA to reconsider the denial, and we are awaiting a response from the FDA on this additional request. Additionally, and separate from the pediatric commitment, the FDA asked for, and we have completed, a clinical electrocardiogram study in adult humans to investigate potential QT prolongation (heart rhythm measure). The clinical study report has been submitted to the FDA and remains subject to FDA review and potential FDA action based on its review of the data. The remaining studies could be more extensive and more costly than our prior studies and might result in new data that are not consistent with the current safety and efficacy profile of the drug, which might require us to change our product labeling and could harm product sales. We also may be subject to penalties for not meeting our pediatric study commitments, including a court-imposed injunction to conduct studies.

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

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

Several states have also enacted legislation regarding promotional and other activities conducted by pharmaceutical companies. The specifics of these laws vary, but in general they require companies to establish marketing compliance programs; disclose various sales and 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. Similarly, some states, including California, Massachusetts, Minnesota, Vermont and West Virginia, and the District of Columbia have passed laws of varying scope that ban or limit the provision of gifts, meals and certain other payments to healthcare providers and/or impose reporting and disclosure requirements upon pharmaceutical companies pertaining to drug pricing, payments and/or costs associated with pharmaceutical marketing, advertising and other promotional activities. Other states also have laws that regulate, directly or indirectly, various pharmaceutical sales and marketing activities, and new legislation is being considered in many states.

Many of the state requirements continue to evolve, and the manner in which they will be enforced going forward is uncertain. In some cases, the penalties for failure to comply with these requirements are unclear. We are continually updating our compliance infrastructure and standard operating procedures to comply with such laws, but we cannot eliminate the risk created by these uncertainties. Unless we are in full compliance with these laws, we could face enforcement action, fines and other penalties, including government orders to stop selling drugs into a state until properly licensed, and could receive adverse publicity.

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

As of December 31, 2014, we had approximately $307.6 million in cash, cash equivalents, short-term and long-term investments. We have several product candidates in various stages of development, and all will require significant further investment to develop, test and obtain regulatory approval prior to commercialization. We may need to seek additional equity or debt financing or strategic collaborations to complete our product development activities, and could require substantial funding to commercialize any products that we successfully develop. We may not be able to raise additional capital on favorable terms or at all. To the extent that we are able to raise additional capital through the sale of equity securities, the issuance of those securities would result in dilution to our stockholders. Holders of such new equity securities may also have rights, preference or privileges that are senior to yours. If additional capital is raised through the incurrence of indebtedness, we may become subject to various restrictions and covenants that could limit our ability to respond to market conditions, provide for unanticipated capital investments or take advantage of business opportunities. To the extent funding is raised through collaborations or intellectual property-based financings, we may be required to give up some or all of the rights and related intellectual property to one or more of our products, product candidates or preclinical programs. If we are unable to obtain sufficient financing on favorable terms when and if needed, we may be required to reduce, defer or discontinue one or more of our product development programs or devote fewer resources to marketing Ampyra or our other commercial products.

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Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including our convertible senior notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of our convertible senior notes or to repurchase the notes upon a fundamental change.

Holders of our convertible senior notes will have the right to require us to repurchase their notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered therefor or notes being converted. In addition, our ability to repurchase the notes or to pay cash upon conversion of the notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the indenture pursuant to which the notes were issued, or to pay any cash payable on future conversions of the notes as required by the indenture, would constitute a default under the indenture.

The conditional conversion feature of our convertible senior notes, if triggered, may adversely affect our financial condition and operating results. In addition, if our notes are converted into common stock, you may experience significant dilution.

Our convertible senior notes are only convertible, prior to December 15, 2020, in certain limited circumstances. This conditional conversion feature may not be effective in delaying conversion of our notes. In the event that the conditional conversion feature of our convertible senior notes is triggered, holders of notes will be entitled to convert the notes at any time during specified periods at their option. If one or more holders elect to convert their notes, we may elect to satisfy our conversion obligation by delivering solely shares of our common stock, solely cash, or a combination of cash and common stock. If we elect to settle a portion or all of our conversion obligation through the payment of cash, our liquidity and financial position could be adversely affected. If we elect to settle all or a portion of our conversion obligation in common stock, our stockholders could experience significant dilution. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

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. 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

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personnel, could substantially impair our ability to implement our business plan.

We and our third-party contract manufacturers must comply with environmental, health and safety laws and regulations, and failure to comply with these laws and regulations could expose us to significant costs or liabilities.

Our research and development activities are subject to numerous and increasingly stringent environmental, health and safety laws and regulations, including those which govern laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous substances. With our recent acquisition of Civitas Therapeutics, which operates a manufacturing facility, we are subject to further environmental, health and safety laws and regulations, including those laws and regulations which govern the exposure of persons to hazardous substances, the emission of pollutants into the air, the discharge of pollutants into bodies of water, and the general health, safety and welfare of employees and members of the public. We may incur substantial costs in order to comply with current or future such laws and regulations, which may also impair our research, development and/or manufacturing efforts.

In connection with our R&D and manufacturing activities, we cannot completely avoid the risk of contamination or injury, and in such cases of contamination or injury, or in cases of failure to comply with environmental, health and safety laws and regulations, we could be held liable, and in some cases strictly liable, for any resulting damages. Moreover, the existence, investigation and/or remediation of contamination at properties currently or formerly owned, leased or operated by us may result in costs, fines or other penalties. Furthermore, our third-party manufacturers are subject to the same or similar environmental, health and safety laws and regulations as those to which we are subject. It is possible that if our third-party manufacturers fail to operate in compliance with the applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages and/or experience a disruption in the manufacture and supply of our product candidates or products. Any such liability may result in substantial civil or criminal fines, penalties or other sanctions, which could exceed our assets and resources, as well as reputational harm.

We depend on sophisticated information technology systems to operate our business and a cyber attack or other breach of these systems could have a material adverse effect on our results of operations.

Similar to other large companies, the size and complexity of our information technology systems makes them vulnerable to a cyber attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our systems have been and are expected to continue to be the target of malware and other cyber attacks. We have invested in its systems and the protection of our data to reduce the risk of an invasion or interruption and we monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance that these measures and efforts will prevent interruptions or breakdowns that could have a significant effect on our business.

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.

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We have patent portfolios relating to Ampyra/aminopyridines, CVT-301 and our ARCUS inhaled therapeutic technology, cimaglermin alfa (previously GGF2)/neuregulins, remyelinating antibodies/antibodies relating to nervous system disorders, chondroitinase, Plumiaz/diazepam nasal spray, Qutenza and NP-1998/topical capsaicin formulations, comprised of both our own and in-licensed patents and patent applications. For some of our proprietary technologies, for example our ARCUS technology, we rely on a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property rights. Our intellectual property also includes copyrights 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. For example, eight generic drug manufacturers have already filed Abbreviated New Drug Applications, or ANDAs, for generic versions of Ampyra with the FDA. In filing these ANDAs for Ampyra, the generic drug manufacturers have challenged all of the Orange Book-listed patents that protect the Ampyra franchise. As such, to protect our intellectual property rights we have initiated legal proceedings asserting the challenged Orange Book-listed patents against these generic drug manufacturers. Also, the validity of our patents can be challenged by third parties pursuant to procedures introduced by American Invents Act, specifically inter partes review and/or post grant review before the U.S. Patent and Trademark Office. For example, in February 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging two of the five Ampyra Orange Book-listed patents. Patent litigation, IPR, and other legal proceedings involve complex legal and factual questions. We may need to devote significant resources to such legal proceedings, and if we are not successful our business could be materially harmed. We can provide no assurance concerning the duration or the outcome of any such lawsuits and legal proceeddings.

We may initiate actions to protect our intellectual property (including, for example, in connection with the filing of an ANDA as described above) 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.

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We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, collaborators, advisors and others. Nonetheless, those agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, collaborators, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, joint ownership may result, which could undermine the value of the intellectual property to us or disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements or that our trade secrets become known or independently discovered by competitors, could harm us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.

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

Third parties may claim that we or our licensors or suppliers are infringing their patents or are misappropriating their proprietary information. In the event of a successful claim against us or our licensors or suppliers for infringement of the patents or proprietary rights of others relating to any of our marketed products or product candidates, we may be required to:

- pay substantial damages;
- stop using our technologies;
- withdraw a product from the market;
- stop certain research and development efforts;
- significantly delay product commercialization activities;
- develop non-infringing products or methods, which may not be feasible; and
- obtain one or more licenses from third parties.

In addition, from time to time, we may become aware of third parties who have, or claim to have, intellectual property rights covering matters such as methods for doing business, conducting research, diagnosing diseases or prescribing medications that are alleged to be broadly applicable across sectors of the industry, and we may receive assertions that these rights apply to us. The existence of such intellectual property rights could present a risk to our business.

A license required under any patents or proprietary rights held by a third party may not be available to us, or may not be available on acceptable terms. If we or our licensors or suppliers are sued for infringement we could encounter substantial delays in, or be prohibited from developing, manufacturing and commercializing our product candidates and advancing our preclinical or clinical programs. In addition, any such litigation would be costly, time consuming, and might distract management from other important tasks.

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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, Qutenza, and all of our research and development programs such as our program evaluating the use of dalfampridine as a treatment for chronic post-stroke deficits and our CVT-301 and Plumiaz 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, or continue commercializing, 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 for regulatory approvals within a commercially reasonable time after completion and receipt of positive data from all preclinical and clinical studies required for the NDA-equivalent. We could also lose our rights under our license agreement with Alkermes in markets outside the U.S. if we fail to launch a product within 180 days of NDA-equivalent approvals and receipt of other needed regulatory approvals in those countries. Alkermes could also terminate our license agreement if we fail to make payments due under the license agreement. If we lose our rights to dalfampridine, our prospects for generating revenue would be materially harmed as we currently derive substantially all of our revenue from Ampyra.

Risks relating to our common stock

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

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

- achievement or rejection of regulatory approvals by us or our collaborators or by our competitors;
- publicity regarding actual or potential clinical trial results or updates relating to products under development by us, our collaborators, or our competitors;
- announcements of new corporate partnerships, alliances, financings or other transactions, or of technological innovations or new commercial products by our competitors or by us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- economic or other crises or other external factors;
- conditions or trends in the pharmaceutical or biotechnology industries;
- litigation and other developments relating to our patents or other proprietary rights or those of our collaborators or competitors;
- governmental regulation and legislation in the U.S. and foreign countries;

- changes in securities analysts' estimates of our performance or our failure to meet analysts' expectations;

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- 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 in recent years. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock, regardless of our actual operating performance.

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

If our existing stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. Sales of substantial amounts of shares of our common stock in the public market by our executive officers, directors, 5% or greater stockholders or other stockholders, or the prospect of such sales, could adversely affect the market price of our common stock. As of February 17, 2015, we had outstanding 42,575,393 shares of voting common stock. Also, options to acquire 7,679,975 shares of common stock were outstanding as of February 17, 2015, exercisable at an average exercise price of $29.27 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, 2014, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 53% of our common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval or mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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

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

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- 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.

Ardsley, New York

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

location. Our extension, early termination, and expansion rights are subject to specified terms and conditions, including specified time periods when they must be exercised, and are also subject to limitations including that we not be in default under the lease. In 2014, we exercised our option to expand into an additional 25,405 square feet of office space, which we occupied in January 2015.

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The Ardsley lease provides for monthly payments of rent during the term. These payments consist of base rent, which takes into account the costs of the facility improvements being funded by the facility owner prior to our occupancy, and additional rent covering customary items such as charges for utilities, taxes, operating expenses, and other facility fees and charges. Our base rent is currently $4.1 million per year, which reflects an annual 2.5% escalation factor as well as our recent expansion, described above.

Chelsea, Massachusetts

Our 2014 acquisition of Civitas Therapeutics, Inc. included subleased manufacturing facility in Chelsea, Massachusetts with commercial-scale capabilities. The approximately 90,000 square foot facility also includes office and laboratory space. Civitas subleases the Chelsea, Massachusetts facility from Alkermes, Inc., which leases the facility from H&N Associates, LLC. The sublease is an operating lease that expires December 31, 2015, which Civitas may extend for up to ten years. The base rent is currently $722,000 per year. The economic terms during an extension will be determined by a process set forth in the sublease, and Civitas will be required to provide a letter of credit for the obligations during the extension. Alkermes leases the building from H&N Associates, LLC pursuant to an overlease dated December 6, 2000, as amended. Civitas assumed all of Alkermes's rights and obligations under the overlease.

Item 3. Legal Proceedings.

Apotex

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc., advising that it had submitted an Abbreviated New Drug Application, or ANDA, to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. In response to the filing of the ANDA, in October 2007, we filed a lawsuit against Apotex in the U.S. District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557. In September 2011, the Court ruled against us and, following our appeal, in June 2012 the U.S. Court of Appeals for the Federal Circuit affirmed the decision. We did not seek any further appeal of the decision. On September 6, 2011, we filed a citizen petition with the FDA requesting that the FDA not approve Apotex's ANDA because of public-safety concerns about Apotex's proposed drug. On December 2, 2011, Apotex filed suit against us in the U.S. District Court for the Southern District of New York. In that suit, Apotex alleged, among other claims, that we engaged in anticompetitive behavior and false advertising in connection with the development and marketing of Zanaflex Capsules, including that the citizen petition we filed with the FDA delayed FDA approval of Apotex's generic tizanidine capsules. On January 26, 2012, we moved to dismiss or stay Apotex's suit. On February 3, 2012, the FDA denied the citizen petition that we filed and approved Apotex's ANDA for a generic version of Zanaflex Capsules. On February 21, 2012, Apotex filed an amended complaint that incorporated the FDA action, but otherwise made allegations similar to the original complaint. Requested judicial remedies include monetary damages, disgorgement of profits, recovery of litigation costs, and injunctive relief. Following our filing of a motion to dismiss the amended complaint, in 2013 the Court dismissed five of the six counts in the amended complaint, including all of the antitrust claims, leaving only a claim under the Lanham Act relating to alleged product promotional activities. In October 2014, the Court granted our motion for summary judgment against Apotex's remaining claim. On November 20, 2014, Apotex filed a Notice of Appeal to the Second Circuit Court of Appeals seeking an appeal of both the motion to dismiss and summary judgment decisions. The Company will defend itself vigorously throughout the appeal process.

Ampyra Patents

In June and July of 2014, we received eight separate Paragraph IV Certification Notices from Accord Healthcare, Inc., Actavis FL, Inc., Alkem Laboratories Ltd., Apotex, Inc., Aurobindo Pharma Ltd., Mylan Pharmaceuticals, Inc.,

Roxane Laboratories, Inc., and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of our Orange Book-listed patents for Ampyra, and they have also asserted that generic versions of their products do not infringe

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certain claims of these patents. In response to the filing of these ANDAs, in July 2014, we filed lawsuits against these generic pharmaceutical manufacturing companies in the U.S. District Court for the District of Delaware asserting infringement of our U.S. Patent Nos. 5,540,938, 8,007,826, 8,354,437, 8,440,703, and 8,663,685. Requested judicial remedies include recovery of litigation costs and injunctive relief, including a request that the effective date of any FDA approval for these generic companies to make, use, offer for sale, sell, market, distribute, or import the proposed generic products be no earlier than the dates on which the Ampyra Orange-book listed patents expire, or any later expiration of exclusivity to which we are or become entitled.

In August 2014, Mylan Pharmaceuticals, Inc. and its parent, Mylan, Inc. (collectively, “Mylan”), filed a motion challenging the jurisdiction of the U.S. District Court for the District of Delaware. On January 14, 2015, the Court denied Mylan’s motion to dismiss with respect to the ANDA filer, Mylan Pharmaceuticals, Inc. On January 30, 2015, the Court granted Mylan’s request for an interlocutory appeal of its jurisdictional decision to the Federal Circuit Court of Appeals. Due to Mylan’s motion to dismiss, we also filed another patent infringement suit against Mylan in the U.S. District Court for the Northern District of West Virginia asserting the same U.S. Patents and requesting the same judicial relief as in the Delaware action. On December 17, 2014, we filed a motion in the Northern District of West Virginia to stay that action in deference to the Delaware proceeding and until the issue of jurisdiction has been decided. On February 11, 2014, the District Court for the Northern District of West Virginia granted Acorda’s motion to stay the proceeding in that district until the Federal Circuit Court of Appeals decides Mylan’s appeal of Delaware’s jurisdictional decision. The patent infringement case against Mylan, however, is still proceeding in Delaware with the other seven generics at the present time.

On February 10 and 27, 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) filed two two separate inter partes review (IPR) petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,663,685, and 8,007,826, which are two of the five Ampyra Orange Book-listed patents. We will oppose the requests to institute these two IPRs, and if they are allowed to proceed, we will oppose the full proceedings. The 30-month statutory stay period based on patent infringement suits filed by Acorda against ANDA filers is not impacted by these filings, and remains in effect.

Item 4. Mine Safety Disclosures.

Not applicable.

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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, 2014		
Fourth Quarter	$41.65	$30.22
Third Quarter	$37.85	$28.26
Second Quarter	$39.48	$29.32
First Quarter	$39.95	$27.51

	High	Low
Fiscal Year Ended December 31, 2013		
Fourth Quarter	$36.75	$28.67
Third Quarter	$38.62	$33.19
Second Quarter	$40.87	$30.79
First Quarter	$32.21	$24.48

Computershare is the transfer agent and registrar for our common stock. As of February 17, 2015, we had approximately 20 registered holders of record of our common stock.

Stock Price Performance Graph

The following graph compares the cumulative five-year total return attained by stockholders on Acorda Therapeutics, Inc.'s common stock relative to the cumulative total returns of the NASDAQ Composite index and the NASDAQ Biotechnology index. An investment of $100 is assumed to have been made in our common stock and in each of the indexes on December 31, 2009 and its relative performance is tracked through December 31, 2014.

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	12/09	12/10	12/11	12/12	12/13	12/14
Acorda Therapeutics, Inc.	100.00	108.17	94.60	98.65	115.87	162.18
NASDAQ Composite	100.00	117.61	118.70	139.00	196.83	223.74
NASDAQ Biotechnology	100.00	106.73	122.40	166.72	286.55	379.71

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

Dividend Policy

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

Issuer Purchases of Equity Securities

Acorda did not repurchase any shares of its Common Stock during the fiscal year ended December 31, 2014. Acorda has not announced any plans or programs for the repurchase of its Common Stock.

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Item 6. Selected Financial Data.

The following unaudited selected consolidated financial data for each of the five years in the period ended December 31, 2014 are derived from our audited consolidated financial statements. These data should be read in conjunction with our audited consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 below.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(in thousands, except per share data)				
Statement of Operations Data:					
Total net revenues	$401,480	$336,430	$305,814	$292,237	$191,005
Costs and expenses:					
Cost of sales	79,981	66,009	57,007	64,183	35,518
Cost of milestone and license revenue	634	634	634	2,384	660
Research and development	73,470	53,877	53,881	42,108	30,600
Selling, general and administrative	201,813	185,545	168,690	148,508	132,657
Asset impairment	6,991	—	—	—	—
Changes in fair value of acquired contingent consideration	2,200	—	—	—	—
Total operating expenses	365,089	306,065	280,212	257,183	199,435
Operating income (loss)	36,391	30,365	25,602	35,054	(8,430)
Other expense:					
Interest and amortization of debt discount expense	(9,288)	(2,170)	(1,880)	(3,570)	(3,922)
Interest income	674	668	552	552	575
Other income (expense)	232	—	(6)	(18)	8
Total other expense	(8,382)	(1,502)	(1,334)	(3,036)	(3,339)
Income (loss) before income taxes	28,009	28,863	24,268	32,018	(11,769)
(Provision) benefit for income taxes	(10,337)	(12,422)	130,690	(1,413)	—
Net income (loss)	$17,672	$16,441	$154,958	$30,605	$(11,769)
Net income (loss) per share —basic	$0.43	$0.41	$3.93	$0.78	$(0.31)
Net income (loss) per share —diluted	$0.42	$0.39	$3.84	$0.76	$(0.31)
Weighted average shares of common stock outstanding used in computing net income (loss) per share —basic	41,150	40,208	39,459	39,000	38,355
Weighted average shares of common stock outstanding used in computing net income (loss) per share —diluted	42,544	41,682	40,332	40,064	38,355

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	As of December 31,				
	2014	2013	2012	2011	2010
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents and investments	$307,618	$367,227	$333,188	$295,907	$240,030
Working capital	294,754	270,690	234,192	273,599	217,274
Total assets	1,080,679	607,127	565,332	379,488	342,101
Long-term liabilities	426,040	70,131	80,540	86,936	96,944
Accumulated def					